A Survey on the Knowledge and Attitude on Pharmacovigilance among the Pharmacy Students of Different Universities of Dhaka, Bangladesh

A project submitted
by
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Dedicated to my parents, who inspire me in every steps of my life.

Certification Statement

This is to certify that this project titled “A Survey on the Knowledge and Attitude on Pharmacovigilance among the Pharmacy Students of Different Universities of Dhaka, Bangladesh” submitted for the partial fulfillment of the requirements for the degree of Bachelor of Pharmacy from the Department of Pharmacy, BRAC University constitutes my own work under the supervision of Dr. Sharmind Neelotpol, Assistant Professor, Department of Pharmacy, BRAC University and that appropriate credit is given where I have used the language, ideas or writings of another.

Signed,

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Countersigned by

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Abstract

Pharmacovigilance, an important tool for the monitoring of post market surveillance of drugs through evaluation of reported adverse drug reaction after its release in the market This study has been focused on students‟ knowledge on pharmacovigilance conducted through a questionnaires survey involving a sample size of 504 (Public university students, n=196; Private University students, n =308). Data analysis was carried out using SPSS Findings obtained from the study showed correct definition of Pharmacovigilance and ADRs were written by 35.7% and 52% respectively, among the participants showing signs of limited knowledge on the issue. Highly significant differences was found in the knowledge related to duration of ADR reporting time ($p<0.000$), participants‟ view to report pharmacovigilance ($p<0.000$), even in students satisfaction on pharmacovigilance in their academic syllabus when segmented through comparison analysis of public and private university students as well. From the study, it can suggested to develop the educational system than present to a state-of-the art level as the results suggest a higher degree of knowledge on pharmacovigilance. Study findings suggested that the educational system has to be developed far more than now to get to a state-of-the art level.

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List of abbreviations

PV: Pharmacovigilance

ADRs: Adverse Drug Reactions

USA: United States of America

UK: United Kingdom

FDA: Food and Drug Administration

SPSS: Statistical Package for Social Sciences

Chapter 1: Introduction

1.1 Pharmacovigilance

The science and exercises involved in the identification of discovery, appraisal, comprehension and avoidance of antagonistic impacts or related issues of medication is characterized through pharmacovigilance. Obtained from two Greek words: „pharmaco" meaning medicine and vigilance meaning to watch, pharmacovigilance is the branch of pharmacology concentrated on identifying, surveying, understanding and counteracting long and transient unwanted effects of drugs. In other words, pharmacovigilance is also called post marketing observation or post market surveillance.

Medications have a universal acceptance as restorative intercessions in the healthcare infrastructure. One of the major risk factors of patient well-beings and personal satisfaction, adverse drug reaction (ADRs) has been perceived as a major contributor to patient-related bleakness and mortality. The events of ADRs have resulted as one of the major real issues concerned with healthcare alleviation and perceived risk of medication treatment (Sivadasan et al, 2015). ADRs have contributed in the significant rise of the effective cost of the treatment regimens. Studies has shown the cost of treatment with ADRs were around 4 billion USD and report from FDA published in 1989 has shown around 12000 instances of deaths has been caused by ADRs. Thus, procedures related to the appropriate monitoring and surveillance for the aversion and administration of ADRs has raised a need of pivotal importance (Jagminder et al, 2013).

ADR has been termed in basic definition as undesirable impacts of medication beyond its therapeutics action amid clinical use. As indicated by the World Health Organization (WHO), Adverse Drug Reaction (ADR) has been termed as "any toxic, unintended and undesired impact of a medication which happens at measurements utilized as a part of people for prophylaxis, analysis or treatment of sickness, or for the alteration of physiologic capacity." (Shepherd et al, 2011).

Classification of ADRs can done in five distinct categories, however, most common categorization of ADRs involves the criteria of impacts of ADRs. Enlarged ADRs (Type A) has been defined as impacts related to measurement degrees while Odd ADRS (Type B) has been

defined through identification of unusual connection of patient and medications. On the Contrary, ADRs can be organized in the perspective of onset of action as intense, sub-intense and inert while criteria of degree of response segments into gentle, direct and separate (Sivasadan et al, 2015)

Pharmacovigilance constitutes a fundamental instrument in ADR reduction through which viable and safe clinical practices has been investigated. It deals with spontaneous system of ADR reporting thus providing less costly, easy to operate post-marketing surveillance of drug induced risk. Identification new and rare ADRs with the additional opportunity of monitoring new drug adverse reaction can be implemented through these system (Suyagh et al, 2015)

Healthcare facilities having the provision of utilization of pharmaceutical drug product should have the opportunity of monitoring and reporting undesirable incidents. This should involve the hospital general experts, medical caretakers, retail dispensaries and drug specialists. Drug specialists, notably can act as valuable source for reporting ADRs (Suyagh et al, 2015). Successful monitoring of ADRs have culminated in making pharmacovigilance an emerging sector minimizing the risks of medication use as well as ensuring proper implementation of drugs and medicine for the appropriate treatment or prevention of ADRs. Recent studies has shown, in developed nations health care professionals encounter of an incidence rate is 1.6-41.4% of adverse drug reactions. Drug specialist and nurses are playing effective roles in reporting adverse effects (Shephered et al, 2011).

Every nation in the world has been recommended to develop its own tailored program of ADRs monitoring due to the presence of variance in accessibility of medication, system of control and monitoring of drug administration, prescribing patterns as well as degree of ADRs among people (Sivadasan et al, 2015).

An approval from the drug regulatory body before the release of the medicaments in the market requires the investigation of its pharmacological properties in addition to the analysis of its viability, followed by a comprehensive detailed study on safety and toxicological aspect. Pharmacovigilance allows the post-market surveillance to ensure expansion of scientific knowledge as well as patients safety in alleviation from diseases during treatment through a particular medication (Akilci et al, 2005). Voluntary reporting of adverse drug reaction (ADR) of a medication is a critical source of data to the health care experts. It can be used as accessible

medications effectively and decreases the medication related risks in patients. Knowledge of health care providers about ADR reporting can improve their patient care attitude and issues on patient health care service. Drug specialists are essential providers of medications to the general population. They play significant role in administering and advising to promote effective use of medications and patient security.

In depth knowledge related to the pharmacological aspects of the drugs and medicament can empower the healthcare professional in the development of significant commitment towards successful ADR reporting. It is an important part of any new implementations in healthcare education. The commitment and responsibilities of pharmacist as a stakeholder of healthcare has been elevated due to emerging complication of adverse reaction of medicament having the concern of high degree towards patient wellbeing as the day. It will go after the reasons of unawareness (M Suyagh et al, 2015). Gross under-reporting of ADRs is a reason for concern. The reason behind under-reporting of ADRs might be insufficient assets, lack of prepared staff and absence of awareness about recognition, communication and spontaneous checking of ADRs. The capability and achievement of any pharmacovigilance system depends on all health care experts like physician, pharmacist and nurses‟ significant stakeholders of healthcare responsible for in charge of pharmacovigilance activities and ADR reporting (Sivadasan et al, 2015). As many doctors don't know about significance of observing and reporting of ADRs, they might be under reported. Involvement of healthcare professional as well as in-depth knowledge pertain to the success and achievement of pharmacovigilance program.

The ultimate focus for ADRs reporting by health care experts, because of improving the reporting rates (Patil et al, 2014). In low and middle income countries show no efforts to enhance access to medicines use and advancement in pharmacovigilance practices. Somewhat in view of the various difficulties in checking the wellbeing of medicines, including-

- Use of more up to date medicines for which there is just limited experience from pre-marketing clinical trials and restricted information of utilization;

- Overburdened healthcare systems, poor medication control, casual medication markets (at which fake and sub-standard pharmaceuticals are regularly sold);

- Poor record keeping of prescription exposures and results, including recording of any adverse events;

Addressing of these complication should be done through a complete global system of pharmacovigilance conducted by the WHO Program for International Drug Monitoring (here after alluded to as the WHO pharmacovigilance system). The concerns should be addressed pertaining to the requirement of healthcare settings of low and middle income during planning activities of pharmacovigilance and development of ADRs reporting system in these nations (Olsson et al, 2010)

The major responsibility of the prescriber of the medicine is not only to prescribe the medicaments appropriate for the disease as well to take into consideration of the development of adverse impacts due to medicaments as efficacy and adverse reaction are two sides of medicine similar to two sides of a coin.Adverse drug reactions are risk to the patient's safety and the personal satisfaction. ADRs increase the health care cost significantly (Karelia et al, 2014). A new medication approval depends on regulated clinical trials. This approval procedure has imperative challenges with respect to safety in post-marketing period. Despite the fact that in stage IV studies require extra data including a few risks of the medication, they don't promise totally about medication safety. Once a licensed medicine is available, it leaves the controlled experimental environment of clinical trials. In, most medication that have been tried for short-term safety and efficacy on a predetermined number of precisely chose people. Additionally, quite often the patients are chosen from particular groups of relatively homogeneous individuals on the basis of that they have only one disease which is being utilized with restricted medicines in clinical trials. This authorized medicine is not utilized only for selected patients but also for those whose are treated by different agents for the related disease. Consequently, it is important that the utilization of these prescriptions is observed for their continuous effectiveness and safety (Karelia et al, 2014).

Effective and safe pharmacological treatment process requires a cooperation of the patient and healthcare experts. Pharmaceutical care incorporates considering these dangers on a patient-oriented premise by "distinguishing and solving (or staying away from)" medication treatment issues. Despite the fact that the prescription is composed by physician in many countries, pharmacists and nurses have a vital part in checking the treatment and determining the medication related issues and maintaining the safety of prescriptions. Pharmacovigilance is the science committed to the safety of medications as utilized as a part of the clinical practice. Experiences from clinical practices and knowledge on the harmful effects of medications will

lead to a more secure utilization of medications. The usage of pharmacovigilance needs enough significant learning about safety of medications. Satisfactory reporting of suspected adverse drug reactions (ADR) reported by healthcare experts is extremely important in this issue. The quantity of reports, and evaluation of these reports should be conducted in order to alert drug safety professionals (Toklu et al, 2016). As renowned citations state “Safety is not a device but rather a perspective" and “Safety first is safety always” (Prakasam et al, 2012). These citations also apply for safety of medications that we use in everyday life to treat different disease and sicknesses. The Thalidomide disaster in 1961 attracted attention for the area of adverse drug reaction observing and following further resolutions in 1966, 1967 and 1970. In 2005, the Berlin announcement on pharmacovigilance presumed that 'the systems for pharmacovigilance are not well organized and supported to serve patients and public ideally. The significance of Pharmacovigilance has increased with expanded number of drug molecules entering the market. In a few high risks profile incidents including marketed pharmaceuticals have pushed that issues of patient safety and the adverse occasions to the administrative consideration (Prakasam et al, 2012).

ADRs are connected with prolonged length of hospital stay, increased financial burden and increased death. Numerous studies have reported that ADRs were responsible for large quantities of hospital admissions. In the United States, more than 100,000 deaths are attributed every year to serious adverse drug reactions. In the UK, around 6.5% of all admissions to clinics are expected to an ADR, and the overall fatality was 0.15% (Latif et al, 2014). Reporting of adverse drug reaction (ADR) of a medication is an essential source of data to the health care experts. It helps to use the medications in a unique manner and prevent the medication related issues in patients. Physician and pharmacist can implicate their attitude towards patient care and issues on patient safety by learning ADR reporting. In Malaysia their pharmacovigilance center is known as Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) which is monitor ADR and also which promotes ADR reporting information furthermore flows drug related data to all the healthcare experts. The healthcare experts can report an ADR straightforwardly to MADRAC through email, Fax and on the web. The World Health Organization prescribes that 200 or more reports are to be submitted per million of Malaysia's population for every year, which sets an objective of around 6000 reports of 28.9 million. In any case, contrasted with different countries,

which utilize the continuous reporting systems, the reporting rate in Malaysia is low (Rajiah et al, 2015).

Pharmacovigilance plays an important part in ensuring that the specialists together with the patients are given sufficient safety data to make on a good choice while picking a medication for treatment. The procedure of collection of such safety data about a medication normally starts in phase-I of the clinical trial before endorsement of the medication and proceeds after the endorsement. Moreover, a few post-market safety studies are conducted, with numerous compulsory prerequisites by medication administrative offices around the world. Out of a few strategies for identifying ADRs, continuous reporting is the one that essentially added to the enhanced levels of pharmacovigilance in numerous countries. Pharmacovigilance is especially concerned with, or ADRs, which are officially term as: "A response to a medication which is harmful and unintended but which occurs at doses that are normally utilized for the prophylaxis, diagnosis or treatment of disease or for modification of physiological capacity". ADRs are 4th to 6th driving reason for death among the hospitalized patients and occur in each 0.3 percent to 7 percent of hospital admissions. Contribution of Pharmacists‟ will remain an essential component in compelling pharmacovigilance. Pharmacists have an important part in medication wellbeing by contributing to the avoidance, assessment, documentation and reporting of ADRs. All healthcare providers have key parts to play in keeping up a balance between drugs' advantages and risks (Rajiah et al, 2015).

National medication monitoring programs throughout the world vary in their sources of involving in the reporting of ADRs by healthcare experts. In Canada or the US, where most of the reports originate from pharmacists but a few nations like France, Ireland, Malaysia, New Zealand, the Nordic nations, and in the UK, have the biggest contribution of ADR reports originating from doctors. In numerous developed nations like the Netherlands, community pharmacists play an important part in ADR reporting. There are some factors for under reporting which is under reporting of ADRs is a normal fact in continuous post marketing observation programs. Contribution of community pharmacists in ADR reporting is lowest in the world. This might be Pertaining to imperfect level of learning about the medications, lack of confidence and weak proficient methodology. For dispensing of marketed preparation community pharmacists keep themselves restrict. In a developing and over populated nation like Bangladesh, access to medications is simple. The greater part of the general population purchases the medicines from

nearby stores without counseling a doctor for e diseases as it is simple, less time consuming and monetary. There are a huge number of community pharmacies which work on private standards or as a part of corporate chains (Prakasam et al, 2012). It is expected that involvement of purchasers can be an important approach towards ensuring medicine safety. Consumers are important players in medication safety and key stakeholders with connection to pharmacovigilance. They can actively contribute through a coordinated and efficient reporting system. In addition, direct reporting is an essential tool to enable buyers and enhance their involvement in the management of their own wellbeing. With consumer reporting, ADRs can be identified earlier. Similarly, purchaser reporting can serve as a useful method to overcome under reporting. It can also be a decent answer for mitigate the limitations of the current healthcare system. However, it is important that customer reporting can't displace the current system but it can strengthen this system. Moreover numerous studies are led in both developed and developing nations and indicated poor information among healthcare experts about ADRs reporting. This is because of the way that medication safety has not been considered seriously and is not one of the top priorities in healthcare programs around the world (Aisakkha et al, 2015).

Toward the start of 1900s German researcher Paul Elrich characterized the perfect medication as "a magic bullet" which specifically achieves the area of the sickness, and does not create any harm to healthy tissues." Drugs apply their impacts on infected region and harm healthy tissues also. Firstly in the year 1848, chloroform utilized during operation performed for the extraction of an ingrown toe nail in a pediatric patient named Hannah Greener. After that it brought development of atrial fibrillation resulting in death of the patient. From that time, potential deadly adverse impacts of the medications attracted widespread consideration. However, in 1893 Lancet began to record antagonistic impacts of the medications. Again in 1906, FDA set out the rule which was, medications ought to be formulated in pure forms that‟s mean it should be free from other chemical substances. In 1936 sulphanilamide dissolved in ethylene glycol brought about the death of 107 patients. This heartbreaking event led the best approach to sanction pharmacovigilance laws. Toward the end of 1950s, emergence cases with phocomelia optional to thalidomide prescribed as a narcotic in pregnant ladies which was shocked the entire world. Particularly in Germany where the medication initially marketed was affected from adverse impacts by it. Almost 10.000 embryos worldwide were presented to teratogenic impacts of the medication. For this reason about 10,000 fetuses were exposed to teratogenic effects of the drug

in worldwide. In 1961 the cases with phocomelia brought about by thalidomide were issued in Lancet which prompted the safety security law. Legal controls known as Kefauer-Harris amendments, which banned the utilization of dangerous medications whatever was their adequacy would be. These tragic occasions experienced identified drug safety and emphasized the significance of systems and Phase IV studies. After that started the foundation of pharmacovigilance systems in the entire world. From 2000s on, morbidity and mortality identified related to utilization of medication has turned into the most essential health problem in developed nations. Other than in some developed countries death rates increase because of undesirable medication responses have taken the fourth and sixth place among all cause deaths which constituted 15-20% of health care uses and required formation of pharmacovigilance systems(Vural et al, 2014). Consistently about ten thousand individuals lost their lives because of antagonistic impacts of the medications and even with the utilization of registered medications which shows undesirable, and unexpected impacts. Differences in diseases seen, and prescription routines among those nations has been pointed out to by World Health Organization. These differences include a wide range of genetic, dietary, and sociocultural varieties. In view of contrasts in the dispension, production, and utilization of medications and furthermore herbal therapeutic items which can prompt different toxicological issues among nations. For this reason every nation ought to set up its novel national pharmacovigilance system. Before marketing a medication for the first time, pharmacological properties, and efficacy of the medication are analyzed and the medication goes through some process like detailed toxicological, and safety tests. However data about Adverse drug reaction can be obtained after post marketing experience, sophisticated clinical trials and reports of health care experts about adverse responses are gone into national and universal databases. As reported in the study, health care experts experience Adverse drug reaction rate of 1.6-41.4%, and in developed nations, Pharmacist and attendants have been assuming effective parts in reporting adverse reaction (Vural et al, 2014).

Pharmacist are essential suppliers of prescriptions to the public and also their important part in administering and counselling to the patients about utilization of medication and health safety. Their pharmacological learning and exposure to patient pharmaceutical records enable them to make an important commitment towards pharmacovigilance and ADR reporting. To implement any new regular practice in health care education students‟ spontaneous participation and training can create a significant change in health care system. As medication related issues are

developing as a potential risk for patient safety and the commitment of a pharmacist in the health care facility set up and community practice to report ADR is developing more important. A lack of information about ADR reporting process has been connected with negative attitudes towards the pharmacovigilance (Rajiah et al, 2015). Since Pharmacist and attendants are the principle appliers of human therapeutic items in hospital, they are in a position to recognize undesirable impacts which may develop during treatment procedure (Vural et al, 2014).

1.2 Importance of pharmacovigilance

Pharmacovigilance is required in each nation, in light of the fact that there are contrasts in the middle of nations (and even locales inside of nations) in the event of adverse medication responses and other medication concerned issues. This might be a direct result of contrasts in:

• Drug creation

• Use and distribution (e.g. signs, dosage, accessibility)

• Hereditary qualities, diet, conventions of the general population

• Pharmaceutical quality and arrangement (excipients) of privately delivered pharmaceutical items

• The utilization of non-standard medications (e.g. herbal remedies) which might posture extraordinary toxicological issues, when utilized alone or as a part of blend with different medications.

• Identification of expansions of known adverse responses

• Distinguishing proof of dangerous components which have hidden toxic responses

• Estimation of quantitative parts of advantage/risk investigation and dispersal of data expected to enhance drug recommending and regulation.

1.3 Ultimate goals of pharmacovigilance

• The sound and safe utilization of restorative medications

• The appraisal and correspondence of the dangers and advantages of medications available

• Teaching and advising of patients.

1.4 Pharmacovigilance scenario in Bangladesh

Drug safety information must serve the strength of the state funded education in the suitable utilization of medications, including translation of wellbeing data. It is fundamental for the general population everywhere, and additionally for health care provider. All the proof expected to survey and understand risk and advantages must be transparently accessible. Bangladesh needs a system with autonomous expertise to ensure that safety information on all available drugs is adequately collected, impartially appreciated and made available to all. Advancement in medication observing and conveying data about the safety and viability of prescriptions can make pharmacovigilance system more effective. Health care provider and the public in the core debate about the risks and benefits of medicines. Also the choice of treatment is also mentioned in this case. The development of new ways for collection and investigation and transference of data can serve for the betterment of the system overall. The quest for gaining from different orders about how pharmacovigilance techniques can be improved, close by boundless expert, official and public collaboration. (Muntansir et al, 2013).

1.5 Necessity of pharmacovigilance study in Bangladesh

Patient faces numerous huge health hazards over his normal life expectancy e.g. kidney damage, liver disorders etc. Over these reasons pharmacovigilance study is important for the safety of the general mass. We are exporting wide range of products like all major therapeutic class & dosage forms along with high -tech products like inhalers, nasal sprays, suppositories, IV fluids, Injectable etc. We ought to begin reporting adverse occasions effectively and participate in the National pharmacovigilance project to help that people in Bangladesh get safe medications. This project will require the ability to perform survey and investigate information from adverse occasions reporting system in conjunction with other internal organization information or external information. These information must be accurate enough to answer to any special health safety queries or issues from the regulators. In order to do so, and compact approach to a data system and pharmacovigilance along with appropriate business processes need to be developed

and put in place. Pharmaceutical industries and Drug manufacturers should indicate both customers and regulators that they are doing everything conceivable to assure drug safety, while discovering more effective ways to deal with drug security information. NGOs, medicinal services experts, customer and hospital ought to ensure that there is currently a system set up to gather and analyze adverse reaction information. With the assistance of all partners, let us promise to get this going in Bangladesh and fabricate a world-class pharmacovigilance system. This will help medical services experts to comprehend the subject furthermore to raise awareness by giving sufficient learning to patients toward the beginning of any treatment about the potential benefits and risks of the treatment (D Saha et al, 2014).

1.6 AIM

The aim of this study is to find out the depth of knowledge of the Pharmacy students of Dhaka, Bangladesh.

1.7 Objectives

- To analyse the pharmacovigilance knowledge in Bangladeshi public and private universities students.
- To know the importance of pharmacovigilance study
- To try to let the students know about their knowledge on pharmacovigilance.

Chapter 2: Methodology

2.1 Research design

This study was planned to develop a reflection of the knowledge and awareness of pharmacovigilance among the B. Pharm and M. Pharm students through the questionnaire. The purpose of this review outline examination was picked by assessing various investigation papers from prestigious journals in various regions including PubMed, Elsevier, Oxford Journals, and Cambridge Journals and so forth. The rationale for selecting this issue was to discover the level of knowledge and awareness about pharmacovigilance among the B. Pharm and M. Pharm students. Thereby it helps to establish a comparison between Public and private universities students regarding their knowledge about pharmacovigilance and their merits. Articles published regarding the knowledge of pharmacovigilance systems among students of pharmacy in different country has found out to recognize and advocate the field. So far, no work has been carried out to judge the level of knowledge and awareness about pharmacovigilance among the B. Pharm and M. Pharm students. The participants for this survey were selected normally from different public and private universities (Dhaka University, Jahangirnagar University, Jagannath University, East West University, Gono University, Daffodil University, Stamford University, PrimeAsia University, UODA, and State University) in Dhaka city. The essential point and motivation behind the survey and the significance of the study to the participants were explained. The range of the age s of participants was 22 to 30 years. Total participant are 504 from here 128 participants were from M. Pharm background and rest 376 participants were from B. Pharm background. This has been done for the purpose of comparing the knowledge about B. Pharm and M. Pharm students and also public and private universities participants.

At first, we included those participants who satisfied the criteria of this study and every one gave their consent to contribute to this research study.

2.2 Determination of sample size

The study was employed with a sample size of five hundred and four representing the fact that appropriate sample size can contribute to the development of genuine picture of the population concerned. However, there was no data for the sample size regarding the assessment of the depth

of knowledge on pharmacovigilance. In the medical field, Julious (2005) obtained that at least 10-12 subjects for each variable be considered for pilot study. It can be said that a total number of 504 participants for 26 variables is satisfactory for this pilot study.

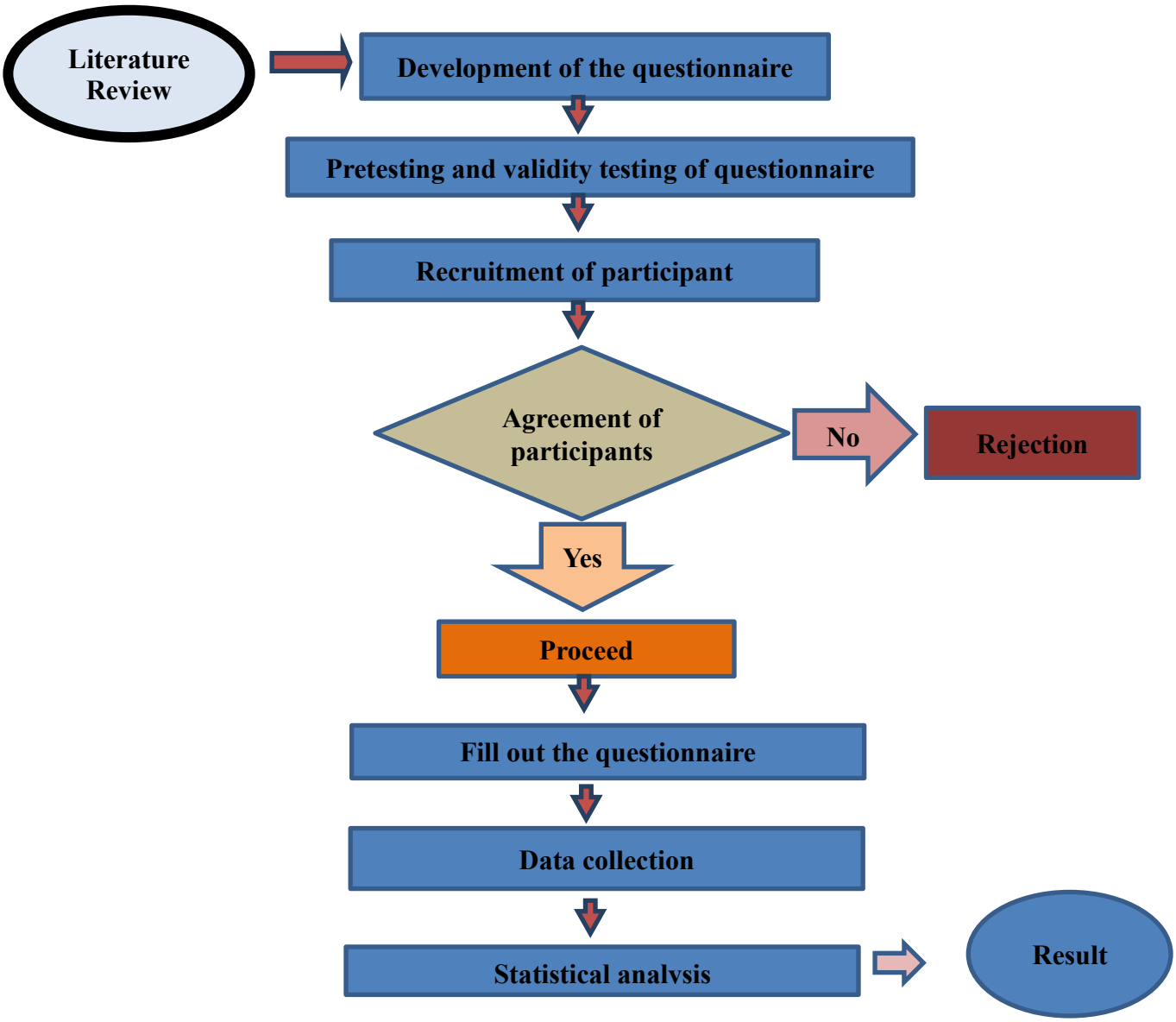


Figure 2.1: Flow Chart of Research Design

2.3 Ethical permission

This survey includes human support and gathering information. Along these lines in this study, ethical permission was an important matter for ensure the safety and rights of the participants. For fulfillment of moral requirement of survey was reviewed by the Research Ethics advisory group, Department of Pharmacy, BRAC University. Subsequent to assessing the material and the way of the study, moral endorsement was allowed furthermore moral authorization was affirmed from applicable Universities from where participants were selected.

2.4 Development of the questionnaire

The questionnaire was set up by surveying distinctive literary works to satisfy the goal of this survey. The survey was set up in a manner that it would be sufficiently powerful to concentrate information from the participants with respect to the learning about recognize the field in Bangladesh. The study would likewise give data if the members were at that issue were already familiar with the information about pharmacovigilance. The authenticity a likeness of the survey were ensured before starting the study. Before starting the last review, discussion was done with an expert as to the overview. The survey included inquiries concerning the member's age, Educational level, University, information about pharmacovigilance learning about ADR. The questionnaire was effortlessly understandable and the inquiries were straightforward and significant to the theme the survey likewise contained some box where they answer some inquiry from their knowledge.

2.4.1 Questionnaire: Pre-testing, validity testing and finalizing

A reliable, justifiable advancement of questionnaire, in a word, pre-testing of survey is required in order to filling out the answer of the question easily. Validity testing of questionnaire is important to avoid analytical error. The more straightforward questionnaire will less hard for the member to reply in this study. Five participants were chosen for pre-test, of the questionnaire. The inquiries found hard to comprehend to the individuals were stamped and cured honest to goodness as showed by the expert's comments. Authenticity testing of the review was furthermore done to ensure that the substance of the study are adequately careful to accumulate

all information and adequately appropriate to finish the targets of the study. Before starting the study, guidance was done with an examiner and the overview was settled in like way.

2.4.2 Data collection and completion of the survey

Information were gathered just from the participants the individuals who satisfied the prerequisites of this study, such as gender, age and education. Survey completed with normally selected five hundred and four participants.

2.5 Specific statistical methods used for data analysis

The statistical analysis of the survey data was finished by programming SPSS (Statistical Package for Social Sciences). SPSS form 20.0 was utilized as a part of this study for examining the information. in the beginning , all information were gone into the SPSS information sheet and afterward information cleaning was performed.

The statistical package was utilized to calculate descriptive statistics. For constant metric variables, mean and standard deviation were utilized as enlightening measures, while the autonomous t-test was utilized for correlations when the information could be appeared to be ordinarily dispersed (e.g. participant age). The Pearson's Chi-square ($\chi 2$) test and probability Ratio Chi-square test was utilized with ostensible information (e.g. counts/frequencies).

Chapter 3: Results & Discussion

3.1 Results

The demographic details of the respondents participated in the study are presented in Table 3.1. By the end of the 5-month study period, 504 final-year B. Pharm and M. Pharm students had responded to this survey from different university. In this survey about 334 (66.3) student where B. Pharm (4^{th} year), 42 (8.3) were B. Pharm students (5^{th} year) and 128 (25.4) students were M. pharm. Most of them from private university about 308 students from private university and 196 students from public university. The number of male respondents was comparatively higher than the female respondents. In this survey females accounted for 238 (47.2%) of students and males accounted for 266 (52.8%) of students. The mean age value obtained was 23.26 years. Most of them are students. The survey was conducted on different classes of people of which about 96.4% were students and 3.6% were both student and job holders.

Table 3.1 Demographic information of the study: sample (N = 504)

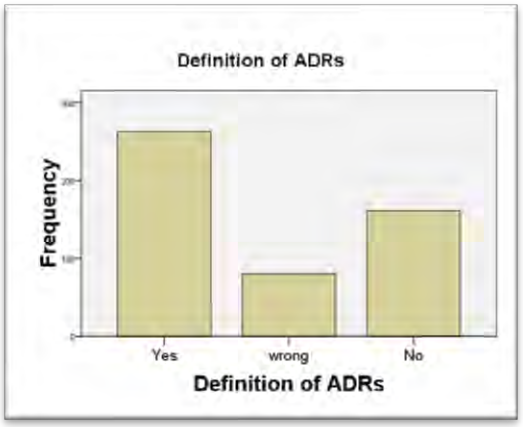
Variable	N (%)
Age	23.26
Gender	
Female	238(47.2)
Male	266(52.8)
University	
public	196(38.9)
private	308(61.1)
Year	
B. Pharm(4th)	334(66.3)
B. Pharm(5th)	42(8.3)
M. Pharm	128(25.4)
Occupation	
Student	486(96.4)
Student and Job	18(3.6)

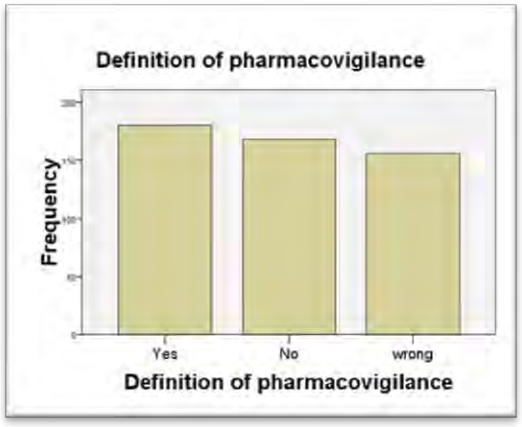
In Table 3.2 this questionnaire contained two close-ended questions in which the students were asked to define the terms „Pharmacovigilance" and „adverse drug reaction". Of the responding pharmacists, only 35.7% defined „Pharmacovigilance" correctly while 52.2% defined ADR correctly. About 31% students had no clear idea and 33.3% had no idea about

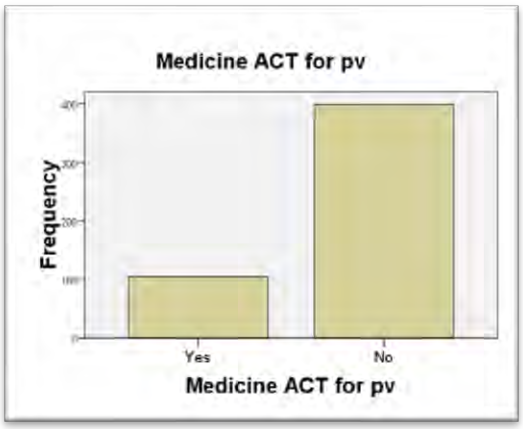
„Pharmacovigilance". Again 31.9% students had no clue about ADRs, 15.8% had no clear idea about ADRs. Most of the students were not aware of the presence of legal provisions in the Medicines Act that provide for pharmacovigilance activities (76.6%), and most of them (87.7%) did not know that there is a pharmacovigilance center in Bangladesh and an official standardized form for reporting adverse drug reactions (58.7% and 76.4%, respectively).

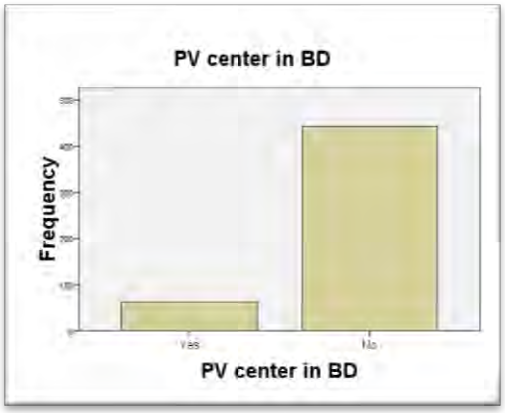
Table 3.2 Assessment of students' knowledge of Pharmacovigilance (PV) concept and policy

Variable	N (%)
Have you ever heard about the concept of PV?	
Yes	180(35.7)
No	168(33.3)
wrong	156(31)
What is the definition of adverse drug reaction?	
Yes	263(52.2)
No	161(31.9)
wrong	80(15.8)
In Bangladesh, are there legal provisions in the Medicine Act that provide for Pharmacovigilance activities?	
Yes	105(20.8)
No	399(76.6)
In Bangladesh, is there a PV center?	
Yes	62(12.3)
No	442(87.7)
Have you ever seen an official standardized form for reporting adverse drug reactions?	
Yes	119(23.6)
No	385(76.4)









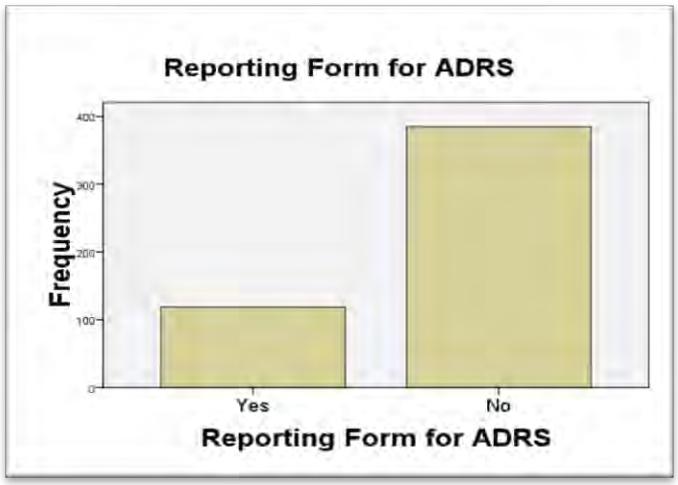


Figure 3.1: Assessment of students‟ knowledge of Pharmacovigilance concept and policy

In Table 3.3most of the students didn‟t know where to get the ADR reporting form. When students were asked about what they must do if they want to report an ADR, approximately 74.1% of students admitted that they did not know from where they could collect the ADRs reporting forms, and almost all of them (72.6%) did not know the period within which they should report serious ADRs experienced by a patient. The survey revealed that 58.7% of the students don‟t know whom should report ADRs to. Different student had ambiguous opinions about whom should report ADRs. They gave different answer about to the following question in the manner as to Pharmacist, Doctor, Pharmacist and Doctor, PV department and Drug administration (12.9%, 14.9%, 5%, 2.6% and 6% respectively). About 364(72.2%) agreed that, before reporting on ADRs, it should be confirm that the adverse reaction has been developed for a particular drug. Most of the students (60.7%) agreed on the point that, the topic "Pharmacovigilance" should be included in the syllabus as a chapter rather than as a core subject which was supported by a population size of 39.7%.

Table 3.3 Assessment of students' knowledge of Pharmacovigilance (PV) concept and policy

Variable	N (%)
Do you know from where can you get the ADR reporting form?	
Yes	129(25.6)
No	375(74.1)
Within how many hours you should report a serious ADR experienced by a patient?	
Don‟t know	366(72.6)
To whom should you report the ADRs?	
Pharmacist	65(12.9)
Doctor	75(14.9)
Pharmacist and Doctor	25(5)
Don‟t know	296(58.7)
Pharmacovigilance department	13(2.6)
Drug Administration	30(6)
Before reporting on ADRs, it should be confirm that the adverse reaction has developed for a particular drug.	
Yes	364(72.2)
No	140(27.8)

Do you think the topic "Pharmacovigilance" should be included in the syllabus:	
As a core Subject	198(39.3)
As a chapter	306(60.7)

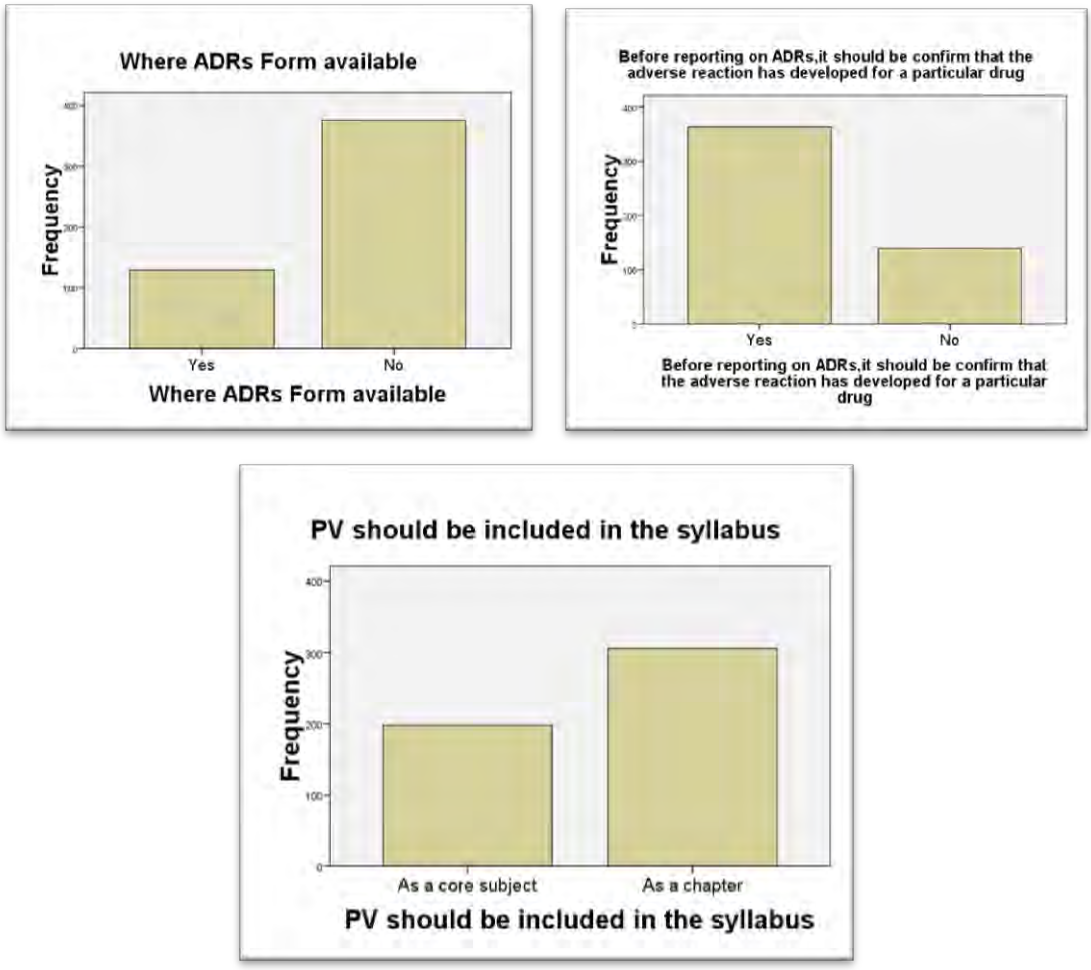


Figure 3.2: Assessment of students" knowledge of Pharmacovigilance concept and policy

In Table 3.4 approximately two third of the students 370 (73.4%) agreed that the reporting on adverse drug reaction is a professional obligation and 134 (26.6%) didn"t agree with this statement. Approximately quarter portion of the student population 326 (64.7%) were not well prepared to report any ADRs occurring in their work place but about 173(35.3%) confident that they were well prepared for report ADRs. Most of the students comprising of more than two-third students 442(87.7%) agreed that adverse drug reaction should be reported officially. InTable 3.4,we received positive attitude in students indicating that they believe ADRs should be

reported only for new medicines. About two-third students 367(72.5%) agreed that ADR reporting is not only for new medicine. Hereby, we can see another positive response from students that Pharmacovigilance reporting should be made compulsory. More than two-third of the students (80.2%) agreed that pharmacovigilance report should be compulsory and about 100(19.8%) pointed out that pharmacovigilance report should be voluntary.

Table 3.4 Assessment of students' knowledge of Pharmacovigilance (PV) concept and policy

Variable	N (%)
Do you think reporting on adverse drug reaction is a professional obligation?	+
Yes	370(73.4)
No	134(26.6)
With my present knowledge, I am very well prepared to report any ADRs occurred in my work place.	
Yes	178(35.3)
No	326(64.7)
I believe that adverse reaction should be reported officially.	
Yes	442(87.7)
No	62(12.3)
I believe that ADRs should be reported only on new medicines.	
Yes	89(17.7)
No	367(72.5)
Don't know	48(9.5)
Do you think Pharmacovigilance reporting should be:	
Voluntary	100(19.8)
Compulsory	404(80.2)

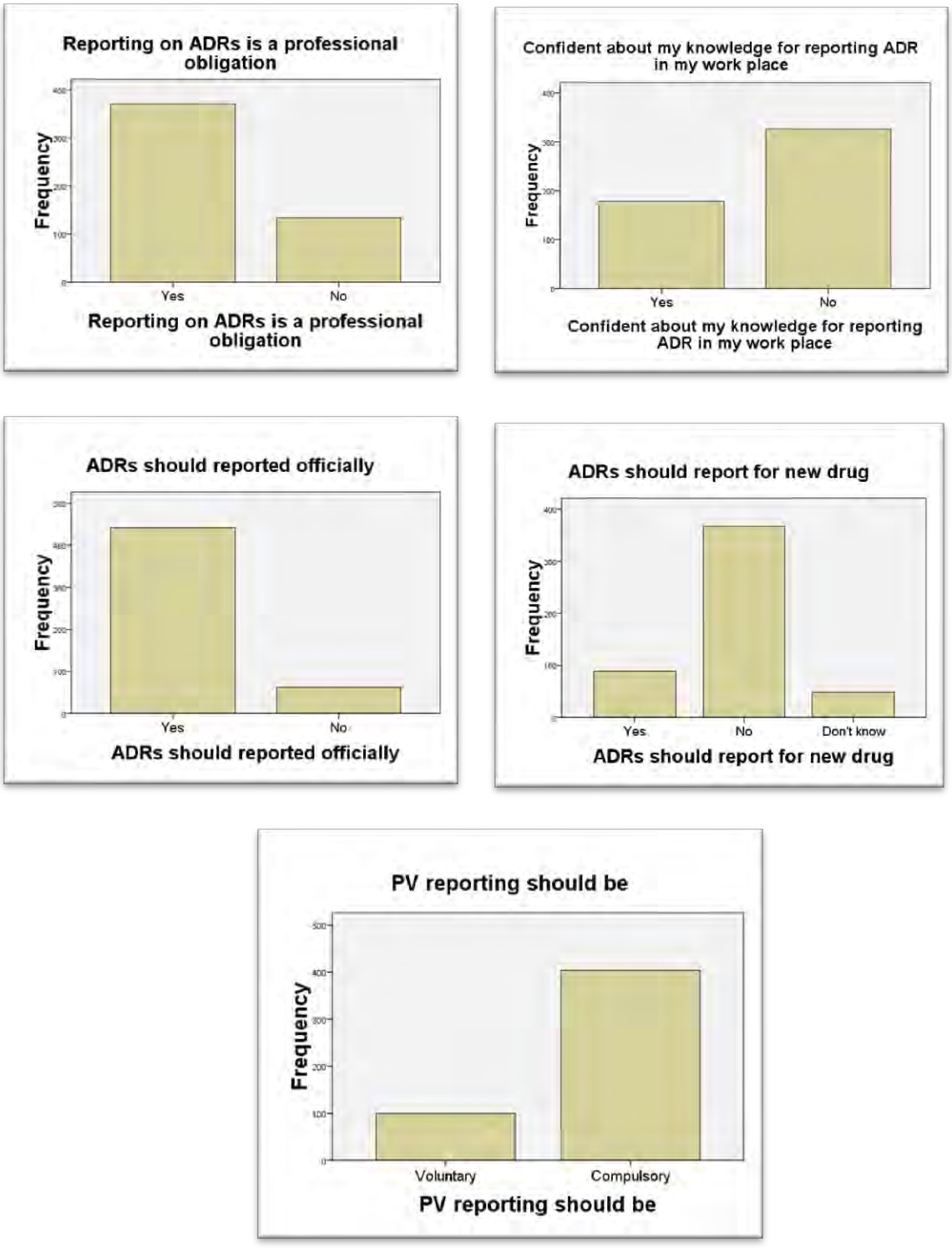


Figure 3.3: Assessment of students‟ knowledge of Pharmacovigilance concept and policy

In Table 3.5 approximately half of the students 236 (46%) agreed that the topic of Pharmacovigilance is well-covered in their pharmacy academic course curriculum but here about

half of the students 268 respondents(54%) opined opposite with this statement .We can see in this table that students have different perspective about where ADRs should be better learnt. In here different results were found. Those results were Class, Internship, Clinical Posting, Class and Clinical posting (33.3%, 32.3%, 20.6% and 13.7% respectively). Most of the students, 454 respondent (90.1%) agreed that pharmacist is one of the most important health care professionals to report ADRs. However, about half of the students 352 respondents (69.9%) disagreed that reporting of ADRs to appropriate authority will make no significant difference to the reporting system, and around 152(30.2%) agreed.

Table 3.5 Assessment of students' knowledge of Pharmacovigilance (PV) concept and policy

Variable	N (%)
I believe that the topic of Pharmacovigilance is well covered in my academic course curriculum.	
Yes	236(46.6)
No	268(53)
I believe that Information on reporting ADRs shall be better learnt during the (Trick as many as apply)	
Class	168(33.3)
Internship	163(32.3)
Clinical Posting	104(20.6)
Class and Clinical posting	69(13.7)
A pharmacist is one of the most important health care professionals to report ADRs.	
Yes	454(90.1)
No	50(9.9)
In my opinion, reporting of ADRs to appropriate authority will make no significant difference.	
Yes	152(30.2)
No	352(69.9)

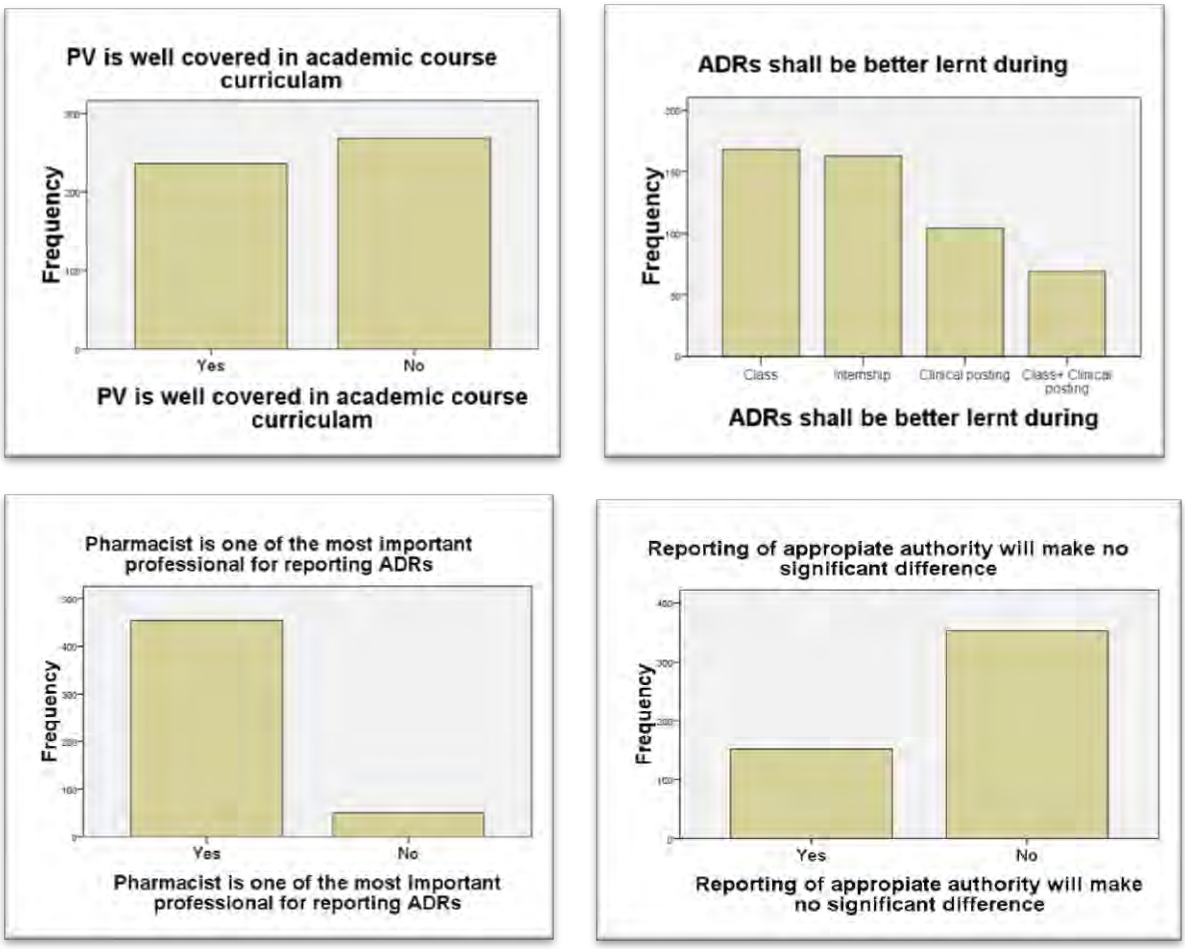


Figure 3.4: Assessment of students‟ knowledge of Pharmacovigilance concept and policy

In Table 3.6, we can see that, when students were asked about the importance of ADRs reporting is to enable safe drugs to be identified to which most of the participants of sum total of 487 (96.6%) agreed. Again 92.7% students agreed with the importance of ADRs reporting is to measure the incidence of ADRs. About two third students, a total of 417 respondents (82.7%) agreed that ADRs reporting is to identify factors that might lead to an ADR. Approximately 83.7% students agreed that ADRs reporting is to identify previously unrecognized ADRs. More than two third students 82.9% students agreed that ADRs reporting is to compare ADRs of the same drug from different drug companies.

Table 3.6 Assessment of students' knowledge of Pharmacovigilance (PV) concept and policy

Variable	N (%)
Importance of ADRs reporting is to enable safe drugs to be identified.	
Agree	487(96.6)
Uncertain	11(2.2)
Disagree	6(1.2)
Importance of ADRs reporting is to measure the incidence of ADRs.	
Agree	467(92.7)
Uncertain	36(7.1)
Disagree	1(.2)
Importance of ADRs reporting is to identify factors that might predispose to an ADR.	
Agree	417(82.7)
Uncertain	67(13.2)
Disagree	20(4)
Importance of ADRs reporting is to identify previously unrecognized ADRs.	
Agree	422(83.7)
Uncertain	66(13.1)
Disagree	16(3.2)
Importance of ADRs reporting is to ADRs for drugs in similar therapeutic classes.	
Agree	438(86.9)
Uncertain	48(9.5)
Disagree	18(3.6)

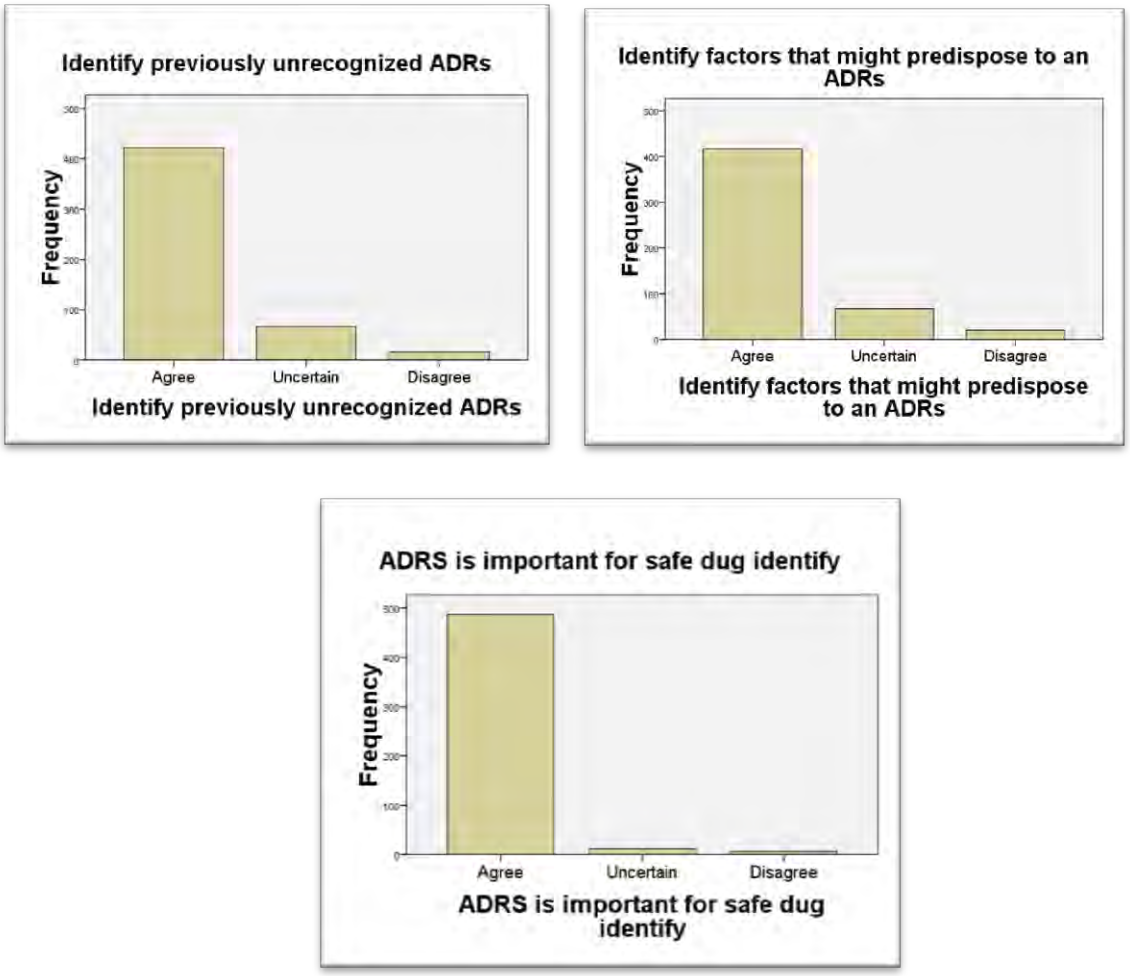


Figure 3.5: Assessment of students‟ knowledge of Pharmacovigilance concept and policy

As listed in the table 3.7, the students of both the Public and Private Universities were given a questionnaire to test the common concept of the students about the overall knowledge level of Pharmacovigilance. The table lists about 5 questions which were formulated on common notions such as- concept of pharmacovigilance, adverse drug reactions and provisions of the Medicine Act, situation of the PV center and the form for reporting ADRs. All of the studies revealed a p-value of less than 0.000 which proves the significance of the survey.

Table 3.7 Comparison between Public and Private University Students

Variable	section	Variable	N (%)	P value
Have you ever heard about the concept of PV?	Public	Yes No No clear idea	94(47.9) 34(17.3) 68(34.7)	χ2=39.651 P<.000
	Private	Yes No No clear idea	86(27.9) 134(43.5) 88(28.5)	
What is the definition of adverse drug reaction?	Public	Yes No No clear idea	137(69.8) 33(16.8) 26(13.3)	χ2=45.344 P<.000
	Private	Yes No No clear idea	126(40.9) 128(41.5) 54(17.6)	
In Bangladesh, are there legal provisions in the Medicine Act that provide for Pharmacovigilance activities?	Public	Yes No	30(15.3) 166(84.7)	χ2=11.841 P<.000
	Private	Yes No	75(24.3) 233(75.7)	
In Bangladesh, is there a PV center?	Public	Yes No	9(4.6) 187(95.4)	χ2=24.109 P<.000
	Private	Yes No	53(17.2) 255(82.8)	
Have you ever seen an official standardized form for reporting adverse drug reactions?	Public	Yes No	43(21.9) 153(78.1)	χ2=.497 P<.481
	Private	Yes No	76(24.6) 232(75.4)	

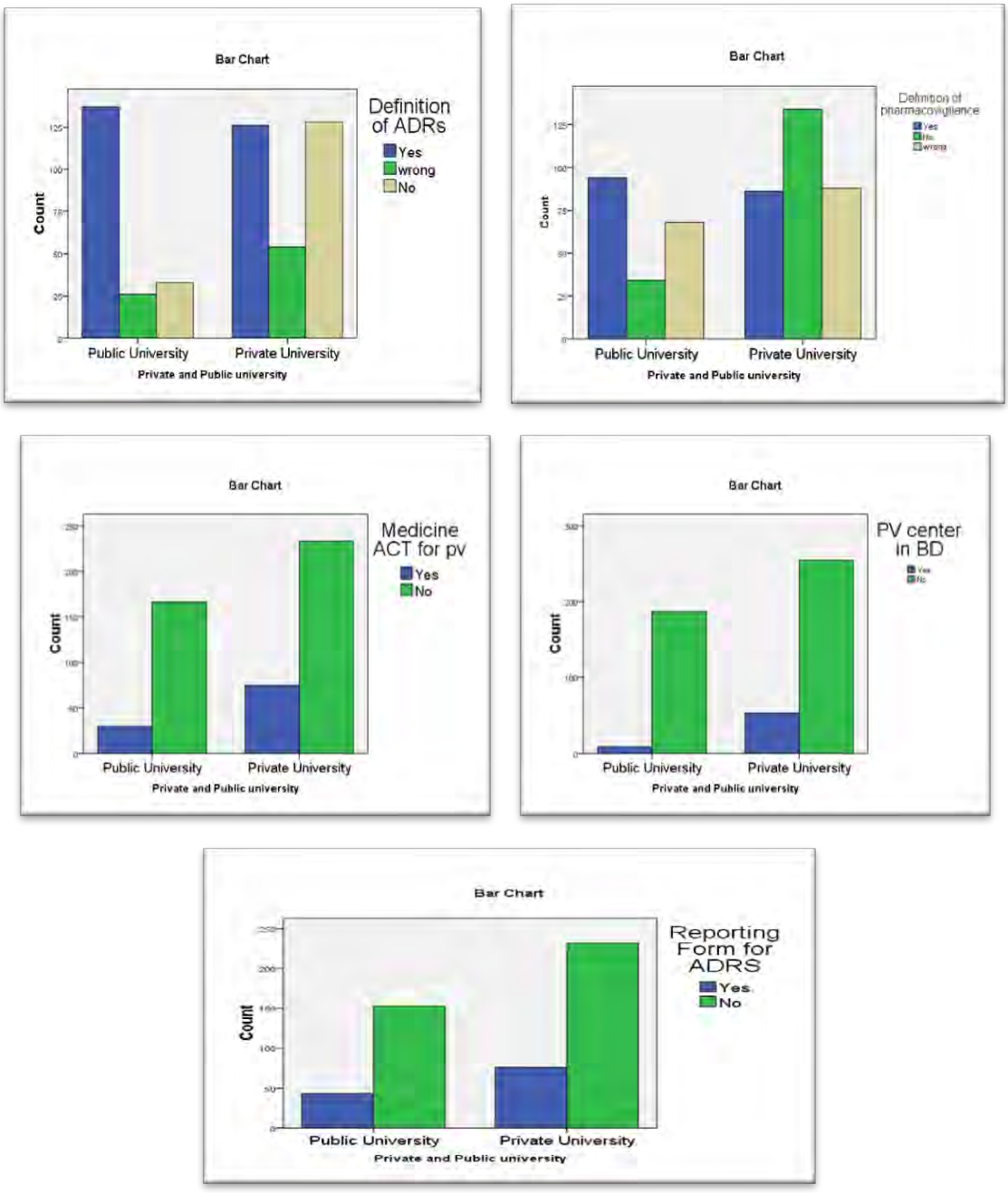


Figure 3.6: Graphical representation on comparison between Public and Private University Students

In case of the table 3.8, the list of questions are based on the knowledge of reporting process for the incidence of adverse drug reactions associated with Pharmacovigilance study. In the context

of the question about acquiring reporting form, the chi-square value $\chi 2=2.256$ and the value of P<.324 which indicates poor significance value which shows that 21.9% of the public university students knew about the process while an increasing 27.9% students of the private university students are aware of the fact. On a primary question regarding the confirmation of the incidence of ADRs before filing a report, a p-value of <.024 was obtained. This dictates a positive sign to the hypothesis.

Table 3.8 Comparison between Public and Private University Students

Variable	section	Variable	N (%)	P value
Do you know from where can you get the ADR reporting form?	Public	Yes Don‟t know	43(21.9) 153(78.1)	$\chi 2=2.256$ P<.324
	Private	Yes Don‟t know	86(27.9) 222(72.1)	
Before reporting on ADRs, it should be confirm that the adverse reaction has developed for a particular drug.	Public	Yes Don‟t know	154(78.6) 42(21.4)	$\chi 2=.122$ P<.024
	Private	Yes Don‟t know	210(68.2) 98(31.8)	
Do you think the topic “Pharmacovigilance” should be included in the syllabus:	Public	As a core Subject As a chapter	78(39.8) 119(60.2)	$\chi 2=.035$ P<.852
	Private	As a core Subject As a chapter	120(38.9) 188(61.1)	

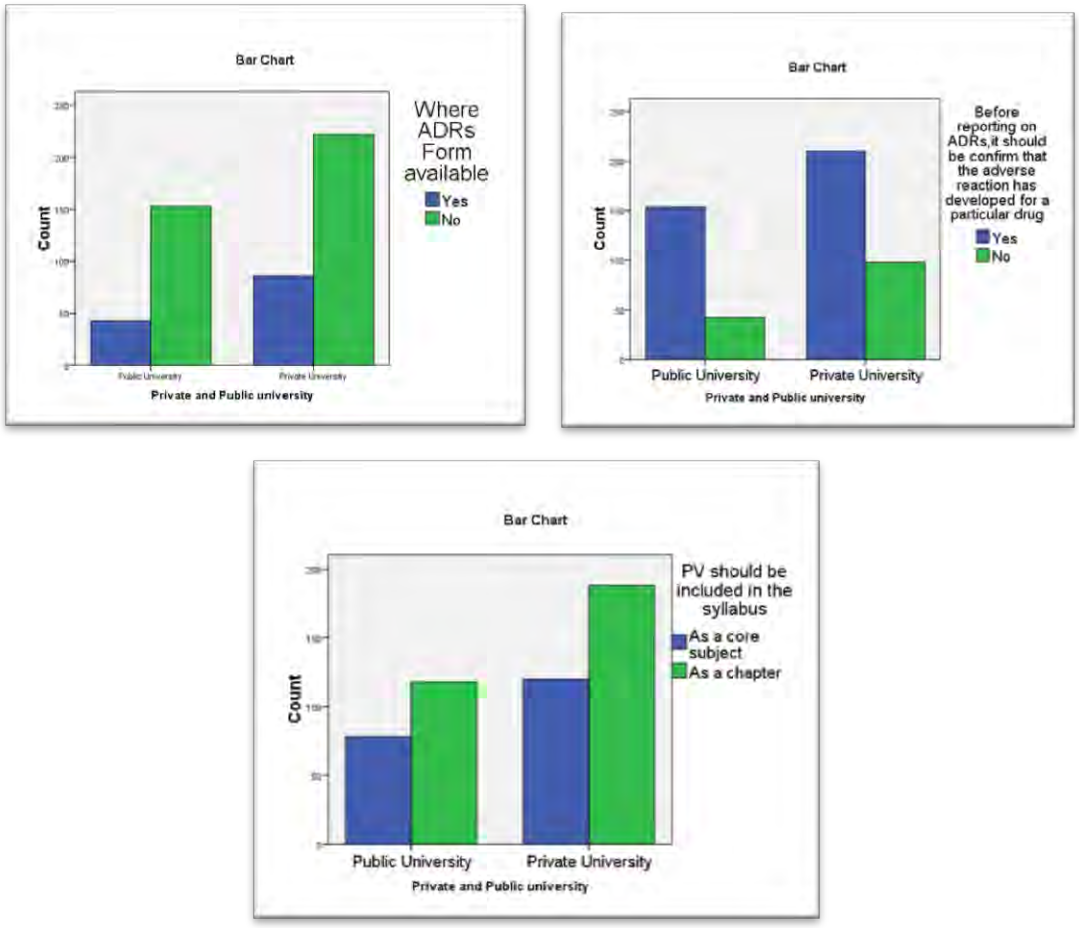


Figure 3.7: Graphical representation on comparison between Public and Private University Students

From table 3.9, we get the following p-values P<.004, P<.005, P<.003, P<.000, P<.000 from questions in relation to the knowledge of duties and responsibilities a pharmacist must discharge of associated with pharmacovigilance report. The p-values clearly assign the fact that the public university students are more aware about their part in medical or pharmaceutical services than the private ones.

Table 3.9 Comparison between Public and Private University Students

Variable	Section	Variable	N (%)	P value
Do you think reporting on adverse drug reaction is a professional obligation?	Public	Yes No	159(81.1) 37(18.9)	$\chi 2$=11.147 P<.004
	Private	Yes No	211(68.5) 97(31.5)	
With my present knowledge, I am very well prepared to report any ADRs occurred in my work place.	Public	Yes No	66(17.6) 130(82.4)	$\chi 2$=10.622 P<.005
	Private	Yes No	112(36.4) 147(63.6)	
I believe that adverse reaction should be reported officially.	Public	Yes No	184(93.9) 12(6.1)	$\chi 2$=11.747 P<.003
	Private	Yes No	258(83.7) 50(16.3)	
I believe that ADRs should be reported only on new medicines.	Public	Yes No	19(9.6) 177(90.4)	$\chi 2$=19.528 P<.000
	Private	Yes No	70(22.7) 238(77.2)	
Do you think Pharmacovigilance reporting should be:	Public	Voluntary Compulsory	22(11.2) 174(88.7)	$\chi 2$=14.973 P<.000
	Private	Voluntary Compulsory	78(39.7) 230(60.3)	

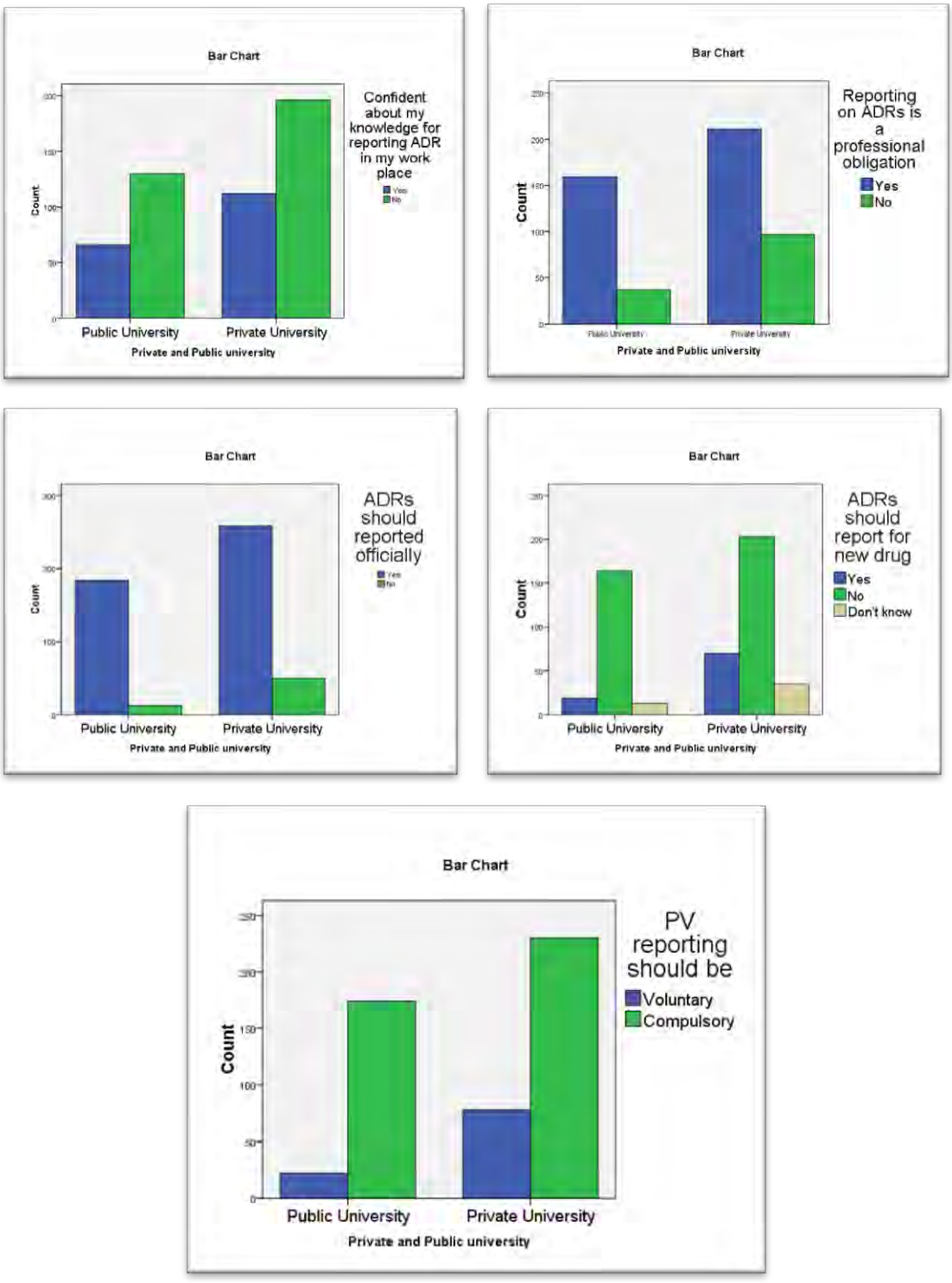


Figure 3.8: Graphical representation on comparison between Public and Private University Students

By taking into account the results from the table 3.10, we can assume that the results are highly significant and in parallel with the hypothesis. The calculated p-values are P<.000, P<.012, P<.000 which indicates that the results are significant.

Table 3.10 Comparison between Public and Private University Students

Variable	section	Variable	N (%)	P value
I believe that the topic of Pharmacovigilance is well covered in my academic course curriculum.	Public	Yes No	61(31.1) 135(68.9)	$\chi 2$=32.452 P<.000
	Private	Yes No	175(56.8) 133(43.2)	
A pharmacist is one of the most important health care professionals to report ADRs.	Public	Yes No	186(94.3) 10(5.7)	$\chi 2$=8.831 P<.012
	Private	Yes No	268(87) 22(13)	
In my opinion, reporting of ADRs to appropriate authority will make no significant difference.	Public	Yes No	41(20.9) 155(79.1)	$\chi 2$=29.882 P<.000
	Private	Yes No	111(56.6) 197(43.4)	

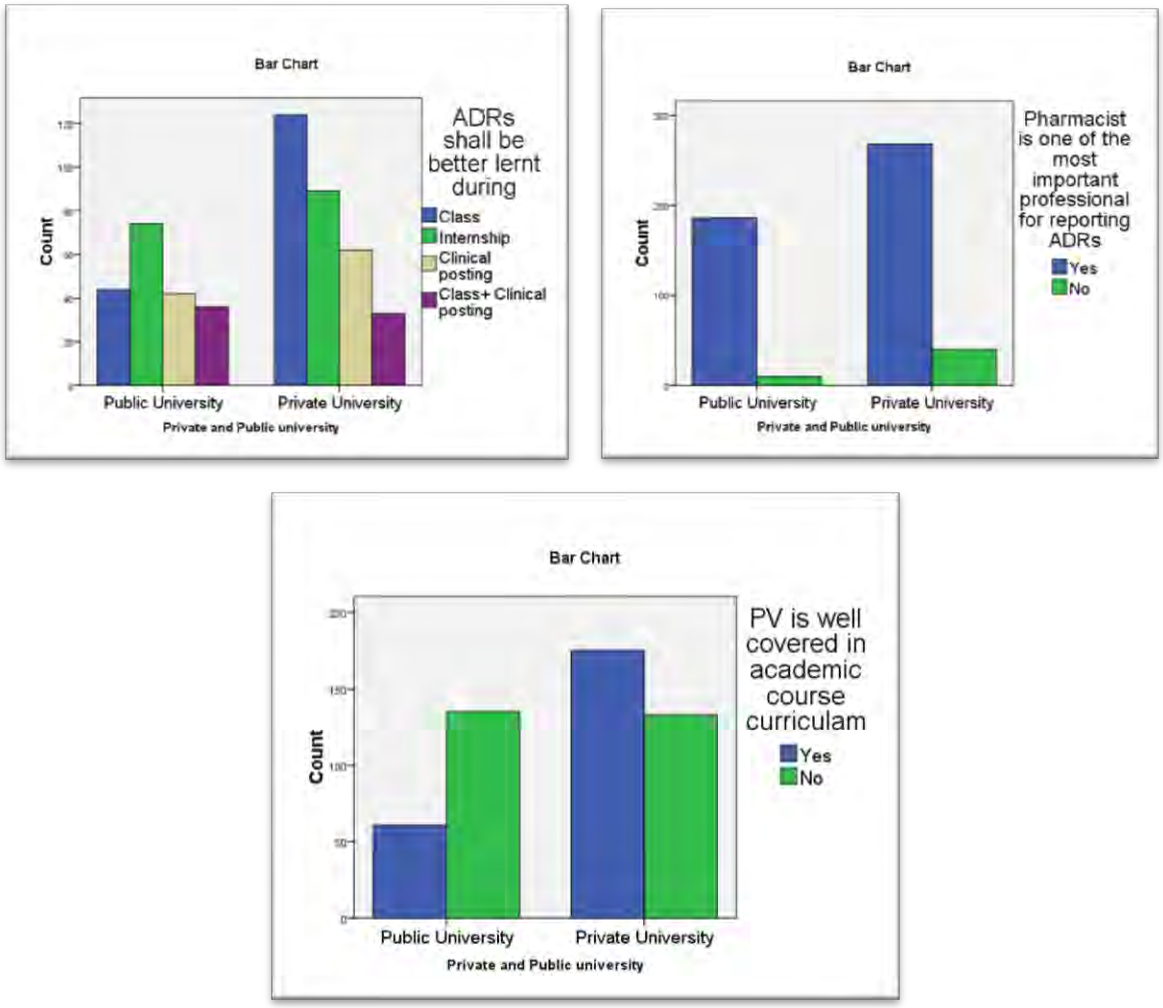


Figure 3.9: Graphical representation on comparison between Public and Private University Students

3.2 Discussion

The aim of this questionnaire survey was to evaluate the knowledge and mindset of the students of the private and public university students studying in the department of Pharmacy Dhaka, Bangladesh. This study showed that the public university students had more ground to hold in case of knowledge about adverse drug reaction associated Pharmacovigilance studies as well as the reporting process of incidence of adverse drug reactions in relation to the private university students. It should be noted that the private university students are more up-to-date on reporting process than the public university. Nevertheless, an additional list of data tables (table 3.1-3.6) developed by taking a population of 504 with variables in occupation, year, university, gender and age. Surveys were done to judge the knowledge level of these students. A surprising fact became evident from the data table that most of the populations of the study were aware of their duties and responsibilities, but they are defiant of the basic concept of pharmacovigilance and adverse drug reactions. This set of data is consistent with another study which showed a high percentage of (about 82.5%) pharmacists were not familiar with the notion of „Phamacovigilance" (Toklu and Uysal, 2008). From the result (table 3.3), 72.6% of the sample population did not know about the time limit within which any incident has to be reported to the authority. They were also ignorant about the proper authority that they are supposed to send a report to and the number is astounding, a cumulative of 296 persons, providing a population percentage of 58.7%.Among of them Maximum did not know about the existence of a pharmacovigilance center or an official form for reporting adverse medication effects (87.7% and 76.4%). So, it can be presumed that there is a huge gap in concept in the basic section in the knowledge regarding pharmacovigilance which is a risk indeed. Moreover, the students are not aware of the basics of existing educational system and a little bit change is required. It is seen from the query the necessity of inclusion of core course solely devoted to pharmacovigilance. About 60.7% of the population consented on placing pharmacovigilance as a chapter rather than a core subject. This indicates the disinterest of the population towards the issue at hand which in turn can lead to certain demise. It is known that drugs have both effects and side-effects. However this result shows that they are only concentrating on one part of the coin, leaving the other merely as an escape route, let alone a major part to focus on. The same population is providing different opinions in a set of questions in respect of multiple drug side effect reporting issues. When they were asked on the context of whether the adverse drug effect reporting should

be ruled out as mandatory or voluntary action for the public, a large portion of the subjects agreed to the fact that it should be acted as an compulsory action by the public (table 3.4). This data is in agreement with the reference of Hardeep et al., 2013. Knowledge, Attitude and the Practice of pharmacovigilance, where the variable was different as doctors are used as subjects instead where 71% of the doctors felt that the pharmacovigilance study should be compulsory. Hence, it shows there is concern to change the current practice, but too little effort is given to actually make any form of modification. The table 3.6 is hardly reliable as the subjects were given a set of hard bound questions concerning their duties and responsibilities as a pharmacist towards filing a report in occurrence of any such incidence of adverse drug reaction. Without having proper information, they all answered affirmatively to the duties they were to perform as a pharmacist, which is actually inconsistent with the results determined in the previous data tables that exposed their current level of knowledge about their future roles as medical service holders or above all, as pharmacists. The table 3.6 is mainly provided mentioning the importance of ADRs reporting. Another set of tables were prepared (table 3.7-3.10) by taking the same sample population of 504 students where the variable was set to students between public and private universities. The public university students comprise a population of 196 whereas private university consists of 308. This population was used to evaluate the working knowledge of adverse drug reaction as well as to topics related to pharmacovigilance. The primary hypothesis was based on the idea that the public university students are more diligent about their duties and responsibilities than the students in private universities. The results were somewhat inconclusive. On the basis of query on the basic concept of pharmacovigilance and adverse drug reactions, the public university students came up with a good response (47.9% and 69.8%) as from the data table 3.7. On the contrary, the private university students had less base to hold on to (27.9% and 40.9%). The next questions on the table were formulated to measure the knowledge of the students about the state of pharmacovigilance in their own country. Surprisingly, the percentage of public university students in this section plummeted (15.3%) whereas the private university students came up with an increase in numbers (24.3%). This may be due to the advanced age of modern web whereby the private university students are well accustomed to. This table may indicate the lack of effort of public university students as they are not used to the use of modern technology as much as the private institutions. None of the two sections saw an official form of report of ADRs. This may dictate towards a disinterest of the subjects in taking any form of

action regarding ADRs, which in turn gives a signal to weak consciousness towards their duties as a pharmacist. The previous statement is further strengthened by the data provided by the results of query in data table3.8. A set of basic questions were stated to determine if the students knew about the primary process of reporting an incidence. A Significantly low percentage was observed in percentage was seen from the results. In relation to questions of collection of reporting form, the students were unaware of the place whereby they can get the form to complaint about a drug reaction (public-78.1%and private-72.1%). Since, the base concept of adverse drug incidence report is impaired; it is fathomable about the state of mind of the subjects about the issue at hand. The fact is justified by the answers in the subsequent question regarding the time limit of reporting, which covers a percentage of 62.7% from public and about 78.9% from private university. The next question on the table 3.8 was on confirmation of the incidence of drug reaction to which all of the subjects gave answers out of cognitive judgment (public-78.6% and private 68.2%).This question was not efficient to judge the actions of the subject. There was another question regarding the change in syllabus which is merely similar with the question in table 3.3 and the results has been found from the variable. From the study it has been obtained that students take the shortcut rather than taking the hard ridden knowledge gained from the core course. Then, the next table 3.9 resembles the table 3.6, with the mere distinction in the variables- public and private university. This table also is designed to investigate the knowledge level of students as a pharmacist in sectors of pharmacovigilance and in addition the confidence of the students in their future role to play. The results were conceivable beforehand as they match the data gained previously with different set of variable of the same group of students. Finally, the table 3.10 enlists a series of questions in respect of the involvement of academic curriculum in this aspect. Most of the private university scholars (56.8%) said that the approach from the institution was enough to comply with the current situation but the public university students differed in opinion (31.1%).Rest of the questions produced average results. From these studies performed on different aspects of pharmacovigilance, we can assume that the syllabus is not consistent with the requirement of real working knowledge required for the current situation and patient safety. So, there is an increasing need for updating the education system to better comply with the real-time situation.

Chapter 4: Conclusion

4.1 Conclusion

To ensure the reporting of ADRs, it is highly recommended to create consciousness among the students of private and public universities. The results ensure that Pharmacy students do not have up-to-date knowledge on ADR reporting and pharmacovigilance. In order to optimize patient care, safety improvement should be needed in educational programs. ADR reporting can be elevated by providing more workshops and training during their educational period. They will get eligibility to play an important role in future practices and decrease the incidence of ADR related problem. To reduce the lack of knowledge and behavior of the healthcare professionals concerning both under-reporting of ADRs and other drug safety issues they need to be enlightened with a particular pharmacovigilance education. Training ensures ascension of quality rather than the quantity of the reports. Though the development of a pharmacovigilance system can prove to be effective to curtail the confusion and faced difficulties in real-time, an all-out effort needs to be raised to reach maximum acceptance. To create a positive impact on patient caring process, educational programs are necessary to improve pharmacists‟ role and their knowledge about the reporting process and its needs.

4.2 Recommendation

- The syllabus of Pharmacy Department should be modernize.
- Universities should organize more seminars and training for improvement of knowledge

4.3 Future research plan

Further research would be planned by questionnaire survey with physician and nurse to find out their knowledge about pharmacovigilance.

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Appendix

Perticepient no:

DEPARTMENT OF PHARMACY

A Survey on the Knowledge and Attitude of Pharmacovigilance among the Pharmacy Students of Different Universities of Dhaka, Bangladesh

1. Demographic Information

Name: Gender :

Age: Occupation:

University: Semester/Year:

Phone: (Optional) Email: (Optional)

2. What do you mean by adverse drug reaction (ADR).

3. Have you ever heard about Pharmacovigilance (PV)? Yes ☐ No ☐ don't know ☐

If yes, what do you mean by Pharmacovigilance?

4. In Bangladesh, are there legal provisions in the Medicine Act that provide for Pharmacovigilance activities? Yes ☐ No ☐ don't know ☐

5. In Bangladesh, is there a PV center? Yes ☐ No ☐ don't know ☐

6. Have you ever seen an official standardized form for reporting adverse drug reactions? Yes ☐ No ☐

7. Do you know from where can you get the ADR reporting form? Yes ☐ No ☐ don't know ☐

8. Within how many hours you should report a serious ADR experienced by a patient?

don't know ☐

9. To whom should you report the ADRs?

don‟t know ☐

10. Before reporting on ADRs, it should be confirm that the adverse reaction has developed for a particular drug. Yes☐ No☐ don‟t know ☐

11.Do you think the topic “Pharmacovigilance” should be included in the syllabus:

As a core Subject ☐ As a chapter ☐

12. Do you think reporting on adverse drug reaction is a professional obligation?

Yes ☐ No☐ don‟t know☐

13. With my present knowledge, I am very well prepared to report any ADRs occurred in my work place.

Yes☐ No☐ don‟t know ☐

14. I believe that adverse reaction should be reported officially. Yes☐ No ☐ don‟t know ☐

15. I believe that ADRs should be reported only on new medicines. Yes ☐ No☐ don‟t know☐

16. Do you think Pharmacovigilance reporting should be: Voluntary ☐ Compulsory ☐

17. I believe that the topic of Pharmacovigilance is well covered in my academic course curriculum.

Yes ☐ No ☐ don‟t know☐

18. I believe that Information on reporting ADRs shall be better learnt during the (Trick as many as apply)

Class ☐ Internship ☐ Training ☐ Clinical posting ☐

19. A pharmacist is one of the most important health care professionals to report ADRs.

Yes ☐ No☐ don‟t know ☐

20. In my opinion, reporting of ADRs to appropriate authority will make no significant difference.

Yes☐ No ☐ don‟t know☐

Do you agree with the following statement?

Importance of ADRs reporting is to

21. to enable safe drugs to be identified. Agree☐ Uncertain☐ Disagree ☐

22. to measure the incidence of ADRs. Agree ☐ Uncertain ☐ Disagree ☐

23. to identify factors that might predispose to an ADR. Agree ☐ Uncertain ☐ Disagree ☐

24. to identify previously unrecognized ADRs. Agree ☐ Uncertain ☐ Disagree ☐

25. to compare ADRs for drugs in similar therapeutic classes. Agree ☐ Uncertain ☐ Disagree ☐

26. to compare ADRs of the same drug from different drug companies. Agree ☐ Uncertain ☐ Disagree ☐