

A cross sectional study on the current status of retail pharmacy in Dhaka city

A project submitted

by

Afrin Akhter Nun

ID:13346059

Session: Summer 2013

to

The Department of Pharmacy

in partial fulfillment of the requirement for the degree of

Bachelor of Pharmacy (Hons.)



Inspiring Excellence

Department of Pharmacy

Dhaka, Bangladesh

September 2018

Certification Statement

This is to certify that this project titled “A cross sectional study on the current status of retail pharmacy shops in Dhaka city” 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. Md Jasim Uddin, Assistant Professor, Department of Pharmacy, BRAC University.

Signed,

Countersigned by,

Acknowledgement

I am truly indebted and thankful to be my supervisor Dr. Md Jasim Uddin, Assistant Professor of the Department of Pharmacy, BRAC University, who has constantly supported and guided me and encouraged me to do my work accurately. He also helped me to resolve any kind of inaccuracy and was always responsive with my queries.

I would also like to thank Professor Dr. Eva Rahman Kabir, Chairperson of the Department of Pharmacy, BRAC University, who has been a continuous inspiration to me and has guided me to develop and grow as a better student.

I am also very thankful to BRAC University for providing me all kinds of facilities such as modernized Computer Lab, Pharmaceutical Lab, and Ayesha Abed Library from where most of the research journals and articles were extracted.

I am also thankful to all the faculty members of the Pharmacy Department of BRAC University, without whom I would not be the improved student that I am.

Finally, I would like to express my profound gratitude to my family and friends for being the greatest support that anyone can ever be.

Sincerely

Afrin Akhter Nun

Abstract

Drug manufacturing industry has significantly improved in Bangladesh with the advancement of new technologies. However irrational drug usage, insufficient access to essential drugs, wrong prescribing are major hitches affecting the overall health care scheme of Bangladesh. The National Drug Policy (NDP) 2016 has been constructed to ensure better health care by ensuring affordability, availability and rational use of medicine. However, lacks of knowledge and awareness among the dispensers and general people have suppressed the effective implementation of the NDP 2016. After doing a questionnaire survey we found that 75% of dispensers of the country know that selling, dispensing and distribution of drugs should be conducted under the supervision of a registered pharmacist but only 5% of A grade pharmacist, 4% of B grade pharmacists and 15% of C grade pharmacists were found in the medicines shops to dispense drugs. Although all the participants responded positively when they were asked if they know selling expired drug is a punishable offense. When the participants were asked whether they are interested in participating training programs in future or not 71% gave positive answer where as 29% said they would not attend in any program .These conditions may lead to irrational and in appropriate use of drugs for instance over prescribing of drugs, inappropriate antibiotics selling, multidrug prescribing etc. However, the effective solutions to overcome this situation can be effective regulation and monitoring. Considering the fact that the dispensers have no other way of gaining knowledge except the formal way that is opened to them, they get into the aggressive marketing strategies easily. More opportunities should be created for the dispensers so that they can acquire knowledge in their convenient way. Initially the study was run only in Dhaka city but in near future similar kind of study can be run in the other parts of Bangladesh. Subsequently relevant projects can be designed for the development of this sectors for example educating dispensers, arranging private workshops or training programs etc. A cross sectional study on the medicine buyers might be done to understand their perspectives and to aware them about the appropriate use of medicines.

Table of Contents

Contents	Page No
Certification Statement	I
Acknowledgement	II
Abstract	III
Table of Contents	IV-V
List of Tables	VI
List of Figures	VII
List of Acronyms	VIII
Chapter 1: Introduction	1
1.1 Drug Police	1
1.2 The National Drug Policy (NDP)	1
1.3 Objectives of National Drug Policy	2
1.3.1 Key components of a National Drug Policy	2
1.4 Formation of National Drug Policy for Bangladesh	3
1.5 International Drug Regulation	4
1.5.1 Drug Regulation in Australia	4
1.5.2 Drug Regulation in Canada	5
1.5.3 Drug Regulation in United Kingdom	5
1.5.4 Drug regulation in United States of America	6
1.6 Drug policy advocacy organizations	6
1.6.1 Drug Regulatory Organization of United States of America	7
1.6.2 Drug Regulatory Organizations of Australia	7
1.6.3 Drug Regulatory Organizations of United Kingdom	7
1.6.4 Drug Regulatory Organization of Bangladesh	8

1.7 WHO's role on making National Drug Policy	8
1.8 Bangladesh National Drug Policy 2016	8
1.9 Insufficient Regulation and Irrational Drug use in Bangladesh	9
1.10 Pharmacovigilance Practice for Safety of Medication System in Bangladesh	10
1.11 Essentiality of Pharmacovigilance learning in Bangladesh	10
Chapter 2: Methodology	11
2.1 Research goals and objectives	11
2.2 Research design	12
2.3 Determination of sample size	12
2.4 Ethical permission	12
2.5 Questionnaire: Pre-testing, validity testing and finalizing	13
2.6 Data collection and completion of the survey	13
2.7 Specific methods used for data analysis	15
Chapter 3: Results and Discussion	16-32
Chapter 4: Conclusion	33
Chapter 5: Recommendations	34
Chapter 6: References	35-39

List of Figures

Figure 2.1 Flow Chart on Research Design

Figure 3.1 Gender of the participants

Figure 3.2 Age of the Participants

Figure 3.3 Job Category of the participants

Figure 3.4 Educational Qualification of Participants

Figure 3.5 Experience of participants in the concerned field

Figure 3.6 Training participation ratio of the participants

Figure 3.7 Interest of the participants for attending training program in future

Figure 3.8.1 knowledge of participants on NDP

Figure 3.8.2 Participants' source of knowledge

Figure 3.9: Knowledge about pharmacists' mandatory involvement in dispensing.

Figure 3.10 Opinion on the involvement of professional pharmacists' in dispensing

Figure 3.11 Participant's opinion on Increase of cost

Figure 3.12.1 Participants' awareness level about selling drug without

Figure 3.12.2 Participants' opinion on the improvement of health sector

Figure 3.13 Participants' response to the patient who wants buy drug without prescription

Figure 3.14.1 Participants' knowledge about OTC

Figure 3.14.2 Presence of OTC drug list in the investigating medicine shop

Figure 3.15 Participants' knowledge on Essential Drug list

Figure 3.16 Participant's knowledge about fixation the price essential Drugs

Figure 3.17 Participants' knowledge on selling Drug at higher price as a punishable offense

Figure 3.18 Participants knowledge on expiry date

Figure 3.19 Participants' knowledge on expired Drug

Figure 3.20 Selling of expired drug as punishable offense

List of Acronyms

ADEC = Australian Drug Evaluation Committee
ADR = Adverse Drug Reaction
ADRM = Adverse drug reaction monitoring
CDER. = Center for Drug Evaluation and Research
CPRD = Clinical Practice Research Data
DGDA = Directorate General of Drug Administration
MCA = Medicines Control Agency
MDA = Medical Devices Agency
MHRA = Medicines and Healthcare Products Regulatory Agency
NDP = National Drug Policy
NDS = National Drug Strategy
NIBSC = National Institute for Biological Standards and Control
OTC = Over The Counter
STG = Standard Treatment. Guidelines
SIAPS = Systems for Improved Access to Pharmaceuticals and Services
TGA = Therapeutic Goods Administration
WHO = World Health Organization
WHA = World Health Assembly

Chapter 1: Introduction

1.1 Drug Policy

Policy can be recognized as an arrangement of laws, disciplinary measures, action framework, and funding priorities highlighting a specific topic promoted by a governmental entity or the representative of government (Dean G. Kilpatrick, 2000). Medications can explain numerous compelling answers for some medical issues, for example, sicknesses, wellbeing wounds and wellbeing disorders if available, manufactured in good quality and appropriately utilized. WHO has recognized the importance of NDP years ago, in ensuring availability, appropriate use and quality of medicines. In 1975 the WHA has asked WHO to help countries to formulate NDP and building strategies so that people can get access to quality medicine and learn the appropriate utilization of standard quality medicines. Since then WHO has been supporting countries to establish and use NDP and till now there are 150 countries worldwide, who have developed NDPs (tylor, 2012). Bangladesh has developed its first NDP in 1982. Altogether there are 150 essential drugs by NDP in accordance to the WHO Essential Medicine (Ahmed, 2012.).

1.2 The National Drug Policy (NDP)

The NDP can be defined as a guide to achieve a predefined goal (Islam, 1984). It explores and analyzes the medium to ultimate dreams set by the administration for the pharmaceutical area. In addition to that it directs to the most attainable ways to accomplish them by giving a framework within which all the activities of the pharmaceutical sectors can be controlled (WHO, 2003). Moreover it emerges private sectors along with public areas, and involves every important members in the field of pharmaceuticals (WHO, 2003). In this way it would be an error to feel that NDP is a record just identified with pharmaceuticals and alternate partners require not acting into it. In fact it's a crying need to have consultation, discussion and negotiations with all interested folks and stakeholders throughout the policy development and implementation process including other ministries such as education, trade, and industry (Ahmed, 2012.). The construction implementation of a NDP needs to take several political measures, as it requires gaining access to the essential medicinal services, basically by making the pharmaceutical division increasingly proficient, financially savvy and receptive to wellbeing needs (Tylor, 2012). Vivid and moral guidance in politics and real deals are very important for the successful execution of the Drug Policy that has been proposed. It will

recirculate the power for sure in the pharmaceutical sector and a group of people will be affected. Antagonism to the new policy and efforts to bring a change in it during implementation can occur because of the diverse interests and the financial importance of the issues. Therefore, identifying the concerned classes of people, and ensure their simultaneous help in running the overall process is very important, efficient protocols to control the protestors must be propagated and system of dealing with them should be predefined. In addition to that settlement of most important areas must be done and keeping the demands of these stakeholders in consideration should be managed side by side based on accomplishments and failures.

1.3 Objectives of National Drug Policy

NDP needs to uphold its effectiveness in the pharmaceutical sector. After all the common objectives of NDP are very similar between many countries of the universe (Tushar, 2016). There are three very important words that have been used to summarize NDP. Access (to the health care), quality (of the health care product), and rational use (of drug) are those three very important words. (Islam, 1984). To elaborate more we can judge the word „Access“ as availability also affordability of essential and traditional medicine. This indicates all the people of that particular nation have to get an easiest way of access to the health care necessities at the most convenient place in a very reasonable price so that their struggle gets reduced. The word “Quality”, can be unfolded by the scenario where medicines are of standard quality and totally harmless. Finally, the word “Rational Use” which is a self-explainable word and clearly says medicines should not be used unnecessarily or should not be used without correct direction. Moreover, using medicines for genuine purpose in the right doses form is what it says. The precise goals of NDP are different from country to country based on the national policy of health and political conditions ruled by the government of that particular country (Tylor, 2012).

1.3.1 Key components of a National Drug Policy

The NDP can be contemplated as a elucidatory skeleton in which all the module take part in immensely important part in fetching up one or more of the prevailing objectives of the policy (access, quality and rational use)(Islam, 1984). The policy has to be compelled to amalgamate the miscellaneous goals and objectives by making a whole and unwavering unit. For an instance, getting ingress to essential drugs is doable only if there is a unit coherent choice, cheap costs; property finance and authentic healthcare provide systems. The four

components of the “access framework” are equally essential but not self-sufficient to ensure access. The rational use of Drugs depends upon many other factors, such as rational selection, educational strategies, regulatory measures and financial incentives. The key components of NDP are to select essential medicines, make medicines affordable, to make it economic, to regulate and ensure the quality, to confirm the rational use, to do more research, to maintain human resources, to monitor and evaluate. The record unveils how the elements are empathic to the three main objectives of the policy and no elements can be interrelating to any one of the objectives only.

1.4 Formation of National Drug Policy for Bangladesh

In 16 December of 1971 Bangladesh got independence. The ill-fated situation of Bangladesh was described in the first five-year plan of 1973(Chowdhury, 1995). It got an unprivileged, equivalent economy along with an underdeveloped constitution; perish agriculture and speedily expanding population. The country had gone through the colonial domination for hundred years and failed to catch opportunities with weakening effects on persuasive splurge. This heart-breaking factor was hugely distinguishable to the insufficient and miserably allotted health facilities. Fundamental drugs were overpriced and rarely found. In accordance with the first five-year plan many alleged manufactures were associated with in producing drugs imported in mass. Drossy drugs were easily found whereas authentic drugs were insufficient. To dig up this loophole various activities were taken throughout 1970 (Chowdhury, 1995). In 1982, The Health Minister of Bangladesh government formed an active committee consisting of 8 members to examine all the registered pharmacological goods which were available at that time and also to make a draft of NDP (Islam, 1984). The aim of consisting this committee are given as follows.

1. To assure the quality and availability of drugs by providing support.
2. In order to sort out void, dispensable and defective drugs deprecating the price of the drugs from the selling area.
3. To uplift vicinal manufacturing of complete drugs assuring consistency between government units.
4. Encouraging the scientific growth and use of Unani, Ayurveda and homeopathic medicines in order to enlarge a drug monitoring and information system as well as enhance

the grade of hospital and community pharmacies and assuring quality full manufacturing system.

1.5 International Drug Regulation:

The significance of drug regulation is growing every day to confirm the safe and effective utilization of drug (Daemmrch, 2009). The proclamation of medicines by administration in countries like United States, the manufacturing, circulating and distributing of medicine are controlled at the federal level by one bureau. At the same time in alternative countries these are controlled at the state height or at every state and national heights by various bodies. The most important goal of controlling is guaranteeing the protection, standard, and usefulness of Drugs. Virtually in each jurisdiction, Drugs have to be enrolled before they are placed in the market for selling. Some restrictions on the provision of sure medicine are obligatory reckoning on their risk to shoppers. Once there are numerous similarities among the countries of the globe in concern with drug safety and availableness, variations in regulative systems and drug markets are perceptibly impacting the essential panning and therefore the relevant performance of pharmaceutical firms from totally different countries (Daemmrch, 2009).

1.5.1 Drug Regulation in Australia

During 1990s, the Australian government did many activities. For example, equitable access for the citizens regarding health care by means of a delicate designed system of pharmaceutical advantages, upholding the proper use of drugs by treatment guidelines (e.g. antibiotic guidelines), prescribing trainings, education the general mass, building up a usable national pharmaceutical industry (World, 2003). These activities could be counted as the elements of NDP. In 2000, Australia became one of the top developing nations with official comprehensive NDP when all the efforts were combined into the national medicines policy in Australia (WHO, 2003). The present NDP outline in Australia is known as the (NDS). It is a symbiotic venture between Commonwealth and State/Territory governments along with the non-government sector (Cathy, 2002).

1.5.2 Drug Regulation in Canada

Health Canada, which is acknowledged as the Federal department of drug regulation in Canada, is at the helm of helping the citizen of Canada by supporting and enhancing their health condition without any disrespect of their choices and state of affairs. Since the inauguration of Health Canada in 1996, it has been overseeing by many pharmaceutical companies and advertisers (Katers, 2017). An act was passed in 1909, which is known as “Patient medication Act 1909” was the initial step toward federal drug regulation in North American nation (Katers, 2017). The Food & Drugs act of 1920 was the root of Canada’s contemporary system of drug regulation, which systematizes all the aspects of local pharmaceutical industries (Katers, 2017). The food & Drugs act was ameliorated in 1951 by announcing that before advertising and distributing of all the pharmaceutical products, the developers must have the approval from the federal government. Since the news of thalidomide scandal came into the limelight, which was used as a sleeping pill but later recognized responsible for aggregating birth defects, pharmaceutical companies have to go through the Notice of Compliance from Canadian government (Katers, 2017). When an organization in doubts satisfies the four important specifications then the goal is to achieving a Notice of Compliance given by Health Canada which is a prerequisite for selling prescription or over the counter in Canadian store (Katers, 2017). These benchmarks are notifying Health Canada management of ADR from clinical traits, noticing advertising constraints to the letter, expending a manufacture process that keep up the drug standard and will be applicable for every change after the primary NOC has been confirmed (Katers, 2017).

1.5.3 Drug Regulation in United Kingdom

United Kingdom published its first nationwide drug policy back in 1995. The drug problem was identified as a complex issue. For this reason, the strategy is based on partnership between government departments, groups and agencies involved planning and executing activities that are most commonly corresponded at the local level. The approach comprised of four targets namely young people, treatment, availability and communities. The first Annual Report and National Plan of Anti-Drug Coordinator set out to have determined goals regarding the drug strategy. The most current one was the “2017 Drug Strategy” published on July 14, 2017. Reducing the use of all illegal and other detrimental drugs, and increasing the rate of persons improving from their dependence is the goal of the strategy of 2017(HM

Government 2017a, Page 7). This goal is expected to be accomplished by following four branches which are- Reducing Demand, Containing Supply, Supporting Recovery and lastly Global Action, which is a new addition to this strategy. This contains a detailed and greatly accurate list of illegal drug practice in United Kingdom. The approach takes a slow turn into a righteous plan as it is organized to be faced as a government back practice, where the goals are presumed around a stereotyped drug abuser, not what a drug abuser is (Stothard, 2017).

1.5.4 Drug regulation in United States of America

The aim of NDP in the United States is related with the prevention, cure, mitigation, and education regarding drugs, treatment of diseases and research activities along with programs which are accompanied by “supply reduction”. Disposal of opium, morphine, cocaine and other psychoactive drugs was lawful from the time of United States civil war and lasts to the end of 19th century. Prescription filling was not mandatory for opium though but it was an important ingredient for the patients who are taking medicines. For example, painkillers, cough syrup etc. for infants. Cocaine has also therapeutic effect. In 1898, opium replaced by heroin but it resembles the same benefits of them. Drug addiction did not cause any problem in case of heroin. Societies of alcohol temperance and some religious groups play vital role as they took actions of forbidding the laws. Some statements with strong opposition from the patent medication history appeared. In 1906, congress established the food and drugs act. This codification input and lists "over the counter" drugs hoping that use of these medicines will be minimized. Finally, congress prohibited to bring drugs from abroad into the United States that is non-medicinal.

1.6 Drug policy advocacy organizations

Advocacy associations are imperative regarding satisfying the mission which is saving lives through recuperation (Owen, 2017). These associations consistently chip away at enhancing the approaches that can work for the improvement of the social insurance framework, as of late, the significance of promotion associations in the medications zone has expanded. A more extensive scope of people and associations are currently engaged with battling on medicine related matters (Owen, 2017). They are currently captivating with policymakers to recognize regions where a requirement for modification has been recognized, running from the extension and substance of drug arrangements and procedures, to the accessibility of

particular measures and administrations. In numerous nations, backing associations partake in medicate arrangement talks and the advancement of NDP.

1.6.1 Drug Regulatory Organization of United States of America

American shoppers' have the supremacy of the most unshakeable and most progressive pharmaceutical work skeleton on the universe (FDA). The fundamental customer watchdog in this framework is FDA's CDER. CDER's assessment avoids misrepresentation, as well as gives specialists and patients the data they have to utilize medicines carefully. The organization guarantees that medications, both brand-name and non-specific, work effectively and that their medical advantages exceed their known risks. The agency was enabled by the U. S. Congress to authorize the Federal Food, Drug, and Cosmetic Act, that fills in because the essential concentration for the Agency; the agency to boot upholds totally different laws, conspicuously Section 361 of the general public Health Service Act and connected controls, large numbers of that don't seem to be four square connected with nourishment or medications. These incorporate guiding lasers, mobile phones, condoms and management of malady on things extending from bound family pets to spermatozoon gift for helped multiplication (FDA).

1.6.2 Drug Regulatory Organizations of Australia

TGA is the regulatory authority of medicines in Australia. After recognizing TGA following the Baume report of 1991, it has been evaluating the quality, safety, efficacy of prescription and over the counter drugs, medical devices in Australia considering their availability. TGA has the authority to finalize a registered drug although Australian Drug Evaluation Committee (ADEC) provides recommendation. New chemical compounds and petition of that asks for skilled advice are referred to the (ADEC).

1.6.3 Drug Regulatory Organizations of United Kingdom

Drug Regulatory Organizations of United Kingdom the MHRA is an agency of the government of United Kingdom which monitors pharmaceutical products along with medical devices in the United Kingdom. MHRA which is working under the supervision of Department of Health includes the National Institute for Biological Standards and Control NIBSC and the CPRD. The agency was formed after the merger in 2003 of the MCA and the MDA, then in the year 2013 along with the NIBSC. Its activities include the following: supervising UK notified bodies, managing clinical trials, looking at compliance for medicines

and medical devices, and offering technical and regulatory advice for these products (Stothard, 2017)..

1.6.4 Drug Regulatory Organization of Bangladesh

The government of Bangladesh has a Drug Regulatory Organization named Directorate General of Drug Administration (DGDA), which is a part of the Ministry of Health and Family Welfare of Bangladesh. Drug regulation and all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sales, pricing, etc. are controlled and overseen by the DGDA. All kinds of medicines including those of Ayurveda, Unani, Herbal and Homoeopathic drugs, and Allopathic medicines are also regulated by DGDA. The DGDA functions through 47 offices in Bangladesh, where all the officers' role is drug inspection. Their job is to follow and practice the Drug Laws, and help with the Licensing authority to work properly and maintain order. There are some other pertinent committees such as the Drug Control Committee (DCC), the Standing Committee for imports of raw materials and produced drugs, Pricing Committee etc. where many experts of different areas work to maintain a systematic order in the Drug Industry of Bangladesh. They also work togetherly into various steps to recommend and advise each other in their fields.

1.7 WHO's role on making National Drug Policy

WHO is that the guiding and coordinative body for health inside the international organization system and provides leadership on world health affairs. In its work, United Nations agency considers jurisprudence in its work. additionally, to the international drug conventions, United Nations agency „s work associated with narcotics and psychoactive substances is radio-controlled by the United Nations Agency Constitution and by the Organization's governing bodies – in the main through resolutions of the WHA and WHO's regional committees.

1.8 Bangladesh National Drug Policy 2016

NDP 2016 is the newest drug policy of Bangladesh and has been made to reduce irrational use of drug and to ensure safe use of drug. The NDP2016 has replaced the previous one constructed in 2005. In Drug policy 2016 it was mentioned that rational and safe use of drugs would be assured through pursuance of Standard Treatment Guidelines (STG). In order to assure rational use of antibiotics, there ought to be associate in nursing antibiotic user guideline all told the private/public level hospitals. Commercialism and dispensing of

medicine are going to be conducted beneath direct oversight of skilled pharmacists for providing subject matter to patients on the acceptable use and storage of medicine. Selling medication while not registered as a pharmacist is strictly prohibited. To judge the rational use of medicine medical prescription and dispensing system of medicine are going to be monitored often in sure measure. It's consisting of an extended list of essential and provides for restrictions on sales of over-the-counter medicines, in accordance to the policy none should purchase medication while not prescriptions from physicians, except thirty-nine medical aid, twenty-three writing and forty-eight unani medicines. Faroque, faculty member of pharmaceutical technology that "This is that the initial time a drug policy has brought medical aid, ayurvedic, unani and homeopathic medicines underneath one umbrella" (Tushar, 2016).

1.9 Insufficient Regulation and Irrational Drug use in Bangladesh

Even though Bangladesh has specific operational guidelines and policies for drug shops but the gap of knowledge remains among the owners, sellers and dispensers hence disabling the policies. A research done by SIAPS has shown many drug owners aren't even aware about the information that running a drug shop without license is a punishable offense. What's concerning is that due to inadequate education or training, most of the drug sellers fail to understand the importance of following drug trading guidelines. Subsequently, vending incidents of drugs, antibiotics without prescription as well as wrong medicines are escalating rapidly. According to a report of Dhaka Tribune published in 29th June 2017, antibiotics are being purchased without any prescription for common illness, even colds and viral fevers (Ahmed J. , 2017). Careless use of antibiotics coupled with the widespread practice of dropping out of prescribed courses is threatening to give rise to antibiotic-resistant infections (Ahmed J. , 2017). ABM Faroque, professor at the Dhaka University's pharmaceutical technology department stated, "Specific guidelines on how to use antibiotics are there and if the guidelines are not followed, the body will develop resistance". Ingestion of antibiotics more or less than the prescribed amount or not finishing the entire dose along with the consumption of fake or bad quality drugs seem to be the potential reasons of developing resistance. Currently in Bangladesh, 1,06,919 accredited and almost similar number of unlicensed retail pharmacies are dispensing every type of medicines in addition to the (OTC) drugs (Syed Masud Ahmed1, 2017). Selling drug without prescriptions is a very usual scenario in Bangladesh, at the same time Drug sellers have fewer knowledge about proper

storage conditions of drugs. Sometimes the seller even suggests drug by himself via talking to patients. The project aims is to find out to what extent drug sellers are familiar about the current drug policy of Bangladesh. Rational use of Drug can only be achieved if the personnel associated with this field are enriched with proper knowledge.

1.10 Pharmacovigilance Practice for Safety of Medication System in Bangladesh

Pharmacovigilance is alarmed with Adverse Drug Reaction (ADR), which is as described by WHO, a reaction to a medicine that is lethal and unintended and happens at a dose that is normally used for prophylaxis, diagnosis or remedy of disease, or for modification of physiological functions (Suke et al., 2015). Thus, adverse drug reaction has been nominated as the top ten leading causes of death (WHO, 2004). Pharmacovigilance evaluation is very important for every country to ensure appropriate healthcare system and wipe out safety issues regarding treatments (jahan, 2017). In Bangladesh, under the supervision of WHO-UMC (WHO-Uppsala Monitoring Committee), Pharmacovigilance has been introduced and practiced. Adverse drug reaction monitoring (ADRM) cell was set up in DGDA, which is the medication administrative specialist of the nation since 1996 (jahan, 2017). With the help of medical and pharmaceutical professionals from all outlets of health services of the country, the cell is trying in every possible way to commence an organized framework for ADR's regulation in Bangladesh by way of study as well as research of ADRs. Therefore, ADR regulating workshops/meetings are organized by DGDA in the medical centres and hospitals of the country and printed ADR complaining forms are being supplied to the doctors for their immediate response by reporting of ADR cases since 2000 (jahan, 2017). Pharmacovigilance has a relation to the appropriate drug usage and to ensure that drug dispensers should have sound knowledge about the Pharmacovigilance.

1.11 Essentiality of Pharmacovigilance learning in Bangladesh

Bangladesh is an underprivileged country where most of the people can not afford a physician to seek solution for health problems. In accordance with DGDA, at present we export a huge amount of goods in more than 130 countries all over the world. It subsumes all fundamental therapeutic class and dosage forms as well as high tech products such as inhalers, nasal sprays, suppositories, IV fluids and many more. (Mustansir et al., 2013). On the contrary, a large number of people in Bangladesh are not aware of the health and medicines they take during their illness. They are hardly acknowledged about their health and drugs they take in.

Due to this various health related problems appear like kidney damaged liver disease etc. considering these issues Pharmacovigilance study is very essential for the sake of people lives. (Jahan, 2017).

Chapter 2: Methodology

2.1 Research goals and objectives

The goal of this study was to figure out an effective way for the successful implementation of National Drug Policy 2016 in Bangladesh. Therefore, the objectives of the study were to understand the issues of National Drug Policy 2016 by comparing it with the NDP of developed countries those who have been successful in terms of implementing NDP in their Country. In addition to that assessing the optimum level of knowledge of NDP and understanding the point of view of the dispensers of Model Pharmacy, Model Medicine Shop, and Retail Medicine Shop about the NDP 2016 was also a major concern. The research objectives also include creating awareness about NDP among the root level people who are directly involved in the health care sector. Overall, it can be said the objectives of the research were to find out the answer of few questions, which are

1. How can the NDP 2016 be effectively implemented in our country?
2. How much knowledge about NDP 2016 do the dispensers of Model Pharmacy, Model Medicine Shop, and Retail Medicine Shop have?
3. What will be the impact of NDP 2016 if implemented successfully?

2.2 Research design

The research was designed with a predefined goal and objectives. Secondary data were collected through journals and article review from the internet. A questionnaire for the survey was constructed. Twenty-one questions were designed among them 20 question were closed ended and only one was open ended which was an opinion based question. The questionnaire was constructed in such a way so that the respondent can easily understand the questions.

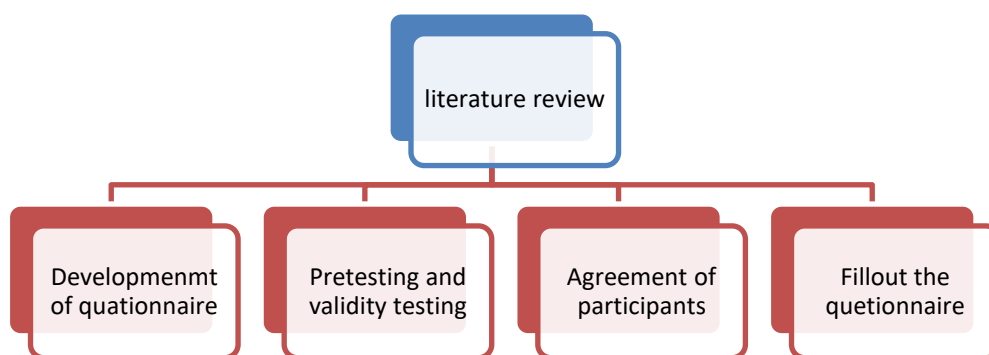


Figure 2.1: Flow Chart on Research Design

2.3 Determination of sample size

According to the DGDA there are 4447 medicine shops in Dhaka City which were considered as the population size for this project. Rousoft an online tool for measuring sample size was used to measure the sample size. 351 was the sample size determined by the online tool with 5 % confidence interval.

2.4 Ethical permission

This survey involves human for collecting information. therefore eethical permission was a major concern to confirm no violation of human rights are. In order to fulfill all the moral requirement of the survey, Department of Pharmacy, BRAC University, examined it. Consent of individual participants were taken by providing them an information sheet which, includes all the informations that the participants should know about the study.

2.5 Questionnaire: Pre-testing, validity testing and finalizing

To check the validity of the survey questionnaire 5 experimental survey was done in 5 different retail pharmacy of dhaka city. The level of understanding of the questions were reviewed and considering the participants response some more questions were added. The words were chosen carefully so that the questions can be easily understood. Before starting the study, guidance was done with an examiner and the overview was settled in like way.

2.6 Data collection and completion of the survey

Information were collected just from the participants who justify the requirements of this study, such as retail drug shop owner, seller and Pharmacists of A, B and C grades. On an average 10 data were collected from 37 Thana of Dhaka City and total number of sample data was 385. All these 385 data were collected by physical visit to 385 different medicine shops.

Distribution of sample data

Name of Police Station	No of Retail Pharmacy	No of Model Pharmacy	No of Model Medicine shop	Total
Adabor	7	2	1	10
Badda	9	0	1	10
Banani	4	5	2	11
Cantonment	10	0	0	10
Chokbazar	9	0	1	10
Darus Salam	10	0	0	10
Demra	8	0	0	8
Dhanmondi	5	3	0	8
Gandaria	9	0	1	10
Gulshan	10	11	1	22
Jatrabari	10	1	0	11
Kafrul	10	0	0	10
Khilga	6	1	0	7
Kodomtoli	10	0	0	10
Kolabagan	8	2	0	10
Kotowali	10	0	0	10
Lalbag	8	0	2	10
Mirpur	10	1	0	11
Mohammadpur	8	2	0	10
Motijheel	10	0	0	10
Mugda	10	0	0	10
Newmarket	10	0	0	10
Pollobi	10	0	0	10
Ramna	9	1	0	10
Rampura	15	0	1	16
Rupnogor	8	2	2	10
Shah Ali	10	0	0	10

Name of Police Station	No of Retail Pharmacy	No of Model Pharmacy	No of Model Medicine shop	Total
Shahbag	8	2	0	10
Shahjahanpur	9	0	2	11
Shemoli	7	1	2	10
Shobujbag	10	0	0	10
Sutrapur	10	0	0	10
Tejga Industrial	9	1	0	10
Tejga	8	2	0	10
Uttora	8	3	0	11
Vatra	10	0	0	10
Wari	10	0	0	10
Total	333	39	13	385

Table 2.1: Distribution of sample Thana in accordance to the Thana

2.7 Specific methods used for data analysis

The survey data analysis was finished by programming Microsoft excel. In the beginning, all information was given into the excel information sheet. After that information cleaning was done, all data were analyzed and data were represented using different charts. Bar, column and pie charts were used to represent data. Percentage for every response of all the questions were calculated in excel sheet.

Chapter 3: Results and Discussion

The collection of data were started on 17th september and data were collected till 3rd september. Almost 400 participants were involved but those who have not responded to all the questions were excluded from the study. We expect that participant's have given their opinions honestly. There for the results of the study can be considered authentic and can be used for further study.

3.1: Gender of the participants

The data were collected from 385 medicine shops and only 5 female participants were found. The results clearly indicate that women are still far away from this sector. However, 1 % presence of female percipients also demonstrates the facts that there are potential opportunities for women to flourish in this sector.

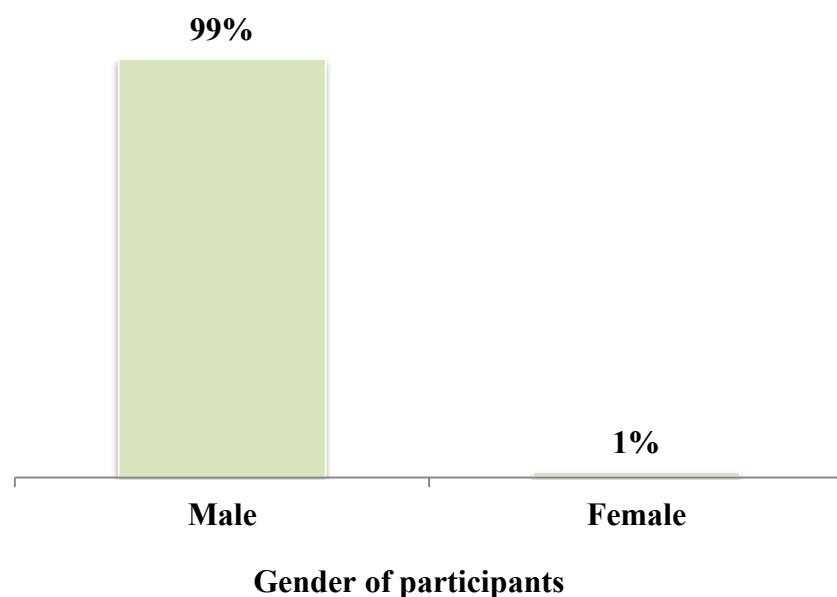


Figure 3.1: Gender group

3.2: Age of the participants

According to the survey the 29 % of dispensers were of 18-23 years old, 25 % were of 24-29 years old, 22% were of over 42 years old, 15 % were of 30-35 old and only 9% were 36-41% old. It is very clear that the young people are more involved in drug selling.

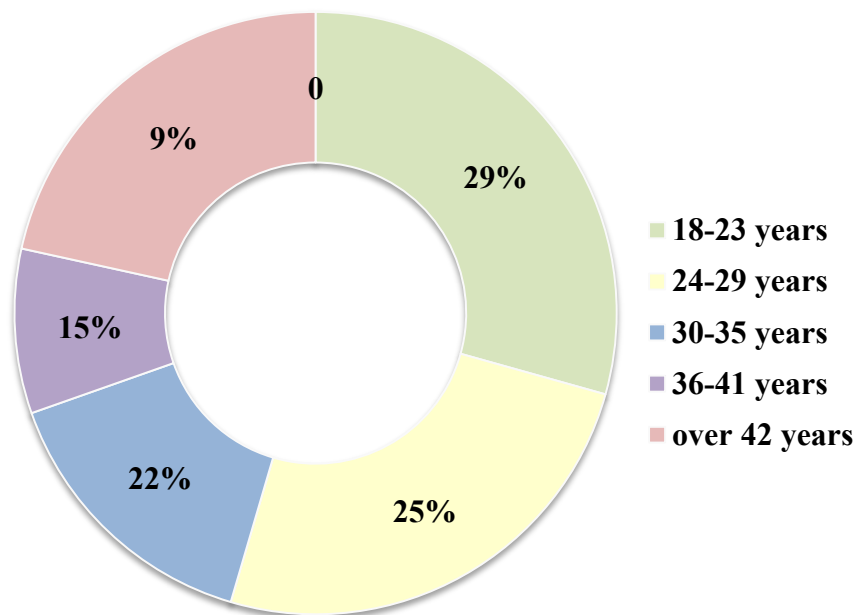


Figure 3.2: Age Group

3.3: Occupation of the participants

The participants of the study were mostly sales man; more specifically 43% were sales man. The percentages of owners are also high which 32% is. Only 15% of C Grade Pharmacist 6% of A Grade Pharmacist and 4% of B grade pharmacists were found who were involved in dispensing and selling Drugs in different Model Pharmacy, Model medicine Shop and Retail Medicine shop. So here, we can see only are following the NDP 2016 as it is mentioned very clearly in NDP 2016 that selling dispensing and distributing of drug should be conducted by a registered pharmacist.

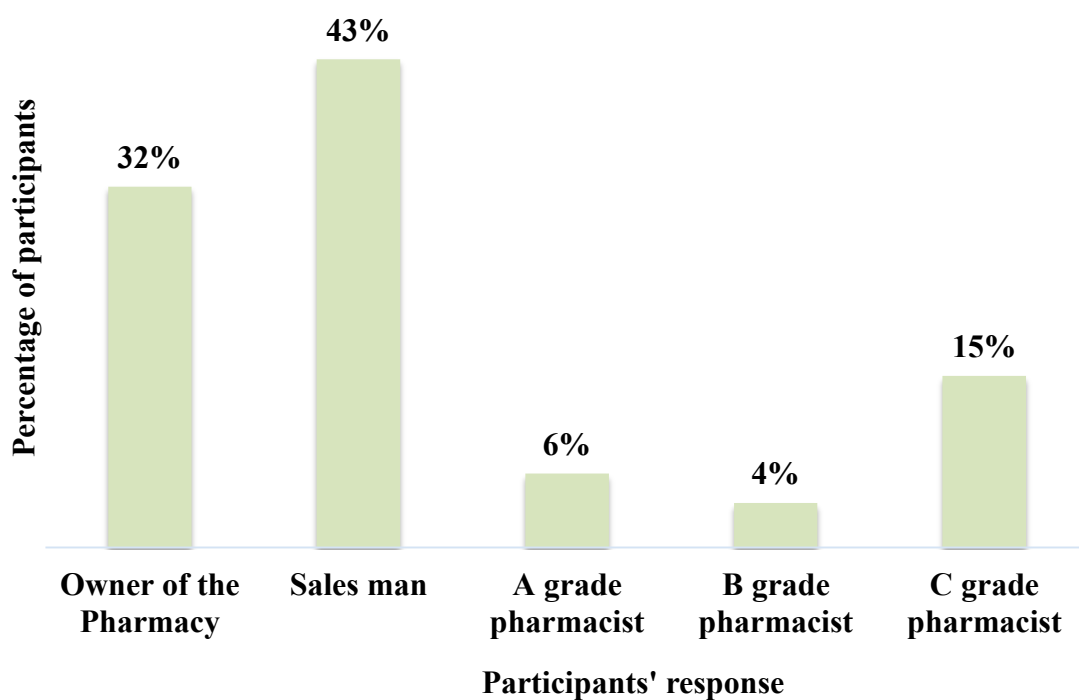


Figure 3.3: Occupation of the participants

3.4: Job experience of the participants

The study shows that the 40% dispensers have been working in this field for more than 5 years. 13% of the dispensers have been working in this field for more than 10 years. 20% of the dispensers have experience of 2 to 3 years and 10% have 3-4 years of working experience. 11% of dispensers have only experience of 0-5 months and 6% have experience of 6 months to one year. The result shows that the numbers of experience dispensers are way larger in number comparing to those who have just started working in this field. Undoubtedly a person who has been working in the sector for more than 5 years have gained so many practical knowledge even though they have no professional degrees.

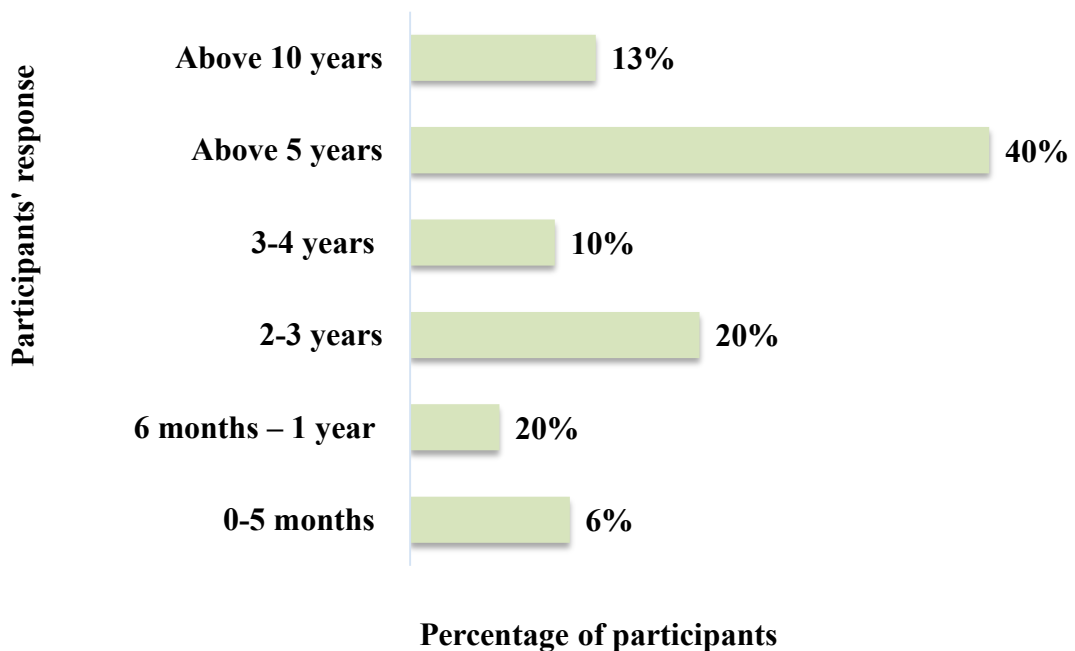


Figure 3.4: Experience of participants in the concerned field

3.5: Participation ration in training programs/workshops related to pharmacy

The participants were asked if they ever attended any training program, which is related to pharmacy. 51 % participants agreed that they have attended training programs and 49% agreed that they have never attended any training program related to pharmacy. However, when they were asked to mention the time and place of the training program, only few of the participants were eager to answer. Most of the participants did not make any comment on this particular question. Those who have answered mentioned that they have attended programs organized by pharmaceutical companies such as ACI, ACME.

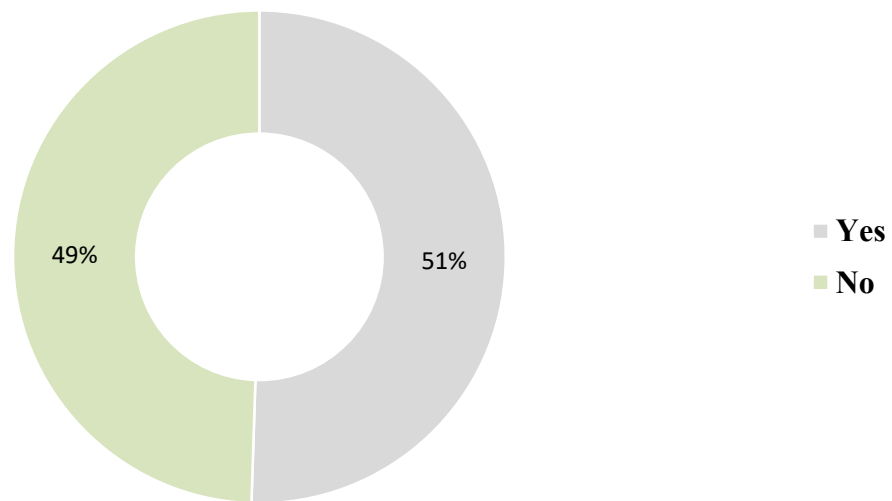


Figure 3.5: Training participation ratio of the participants

3.7: Ratio of interested participants who wanted to attend training program in future.

When the participants were asked whether they are interested in participating training programs in future or not 71% gave positive answer where as 29% said they would not attend in any program. Some of them do not feel there is any necessity for attending such training programs and some of them said that there too busy to attend such training programs.

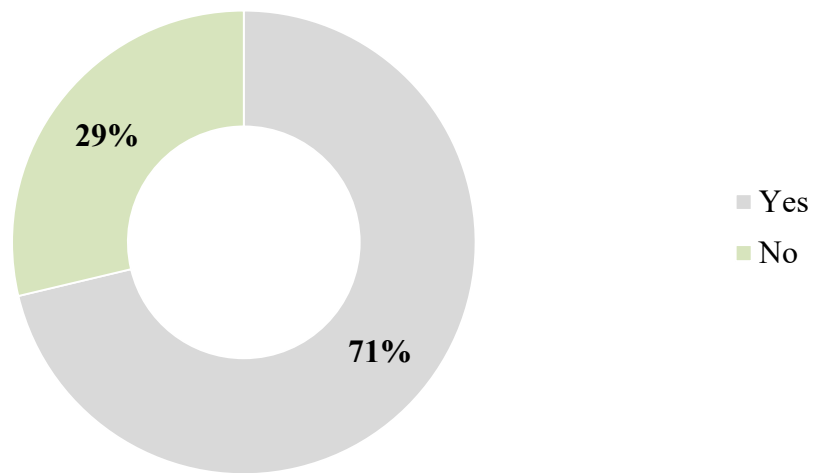


Figure 3.7: Interest of the participants for attending training program in future

3.8: Participants' source of knowledge about National drug Policy 2016

Those who responded positively were further questioned about their source of knowledge and 49% participants said they have seen it on Newspaper. 17% responded that they have seen it on internet and another 17% responded that they have seen it on internet. 8% gained the knowledge from other sources. From our study, we have found big portions of young people are working as dispensers in different medicine shops. Therefore, NDP 2016 can reach more relevant people if it is promoted on internet.

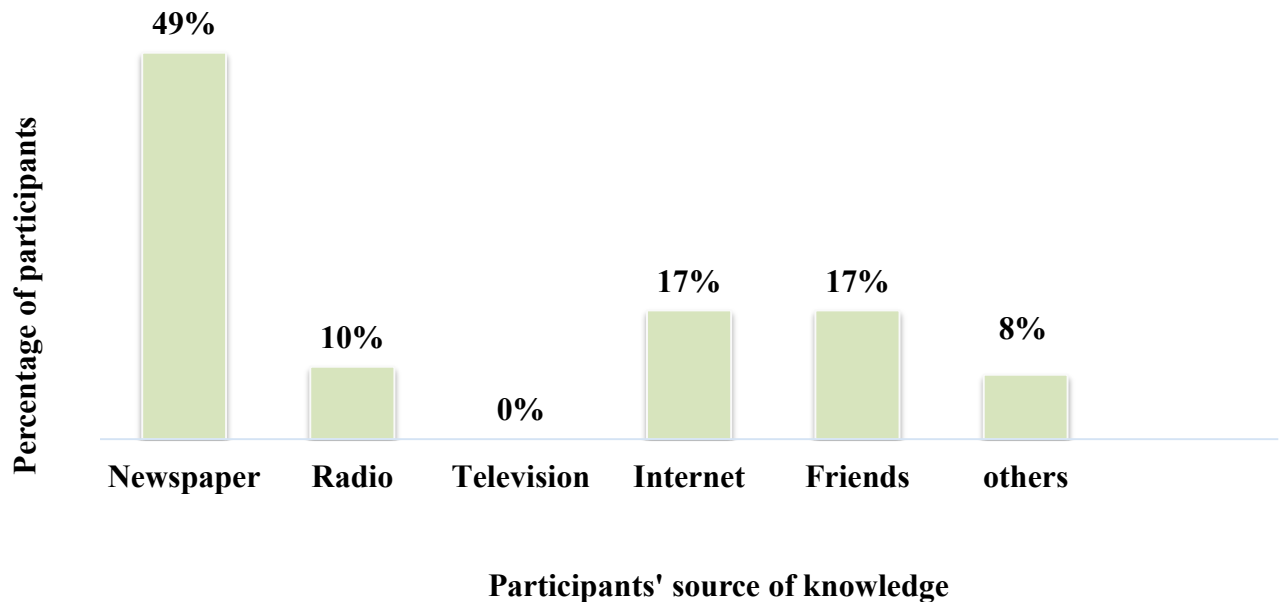


Figure 3.8: Participants' source of knowledge

3.9: Participants' knowledge about the direct involvement of pharmacist in selling and dispensing drugs

According to the study 90% of participants have said that they know about this rule. Only 10% said that they never heard about it.

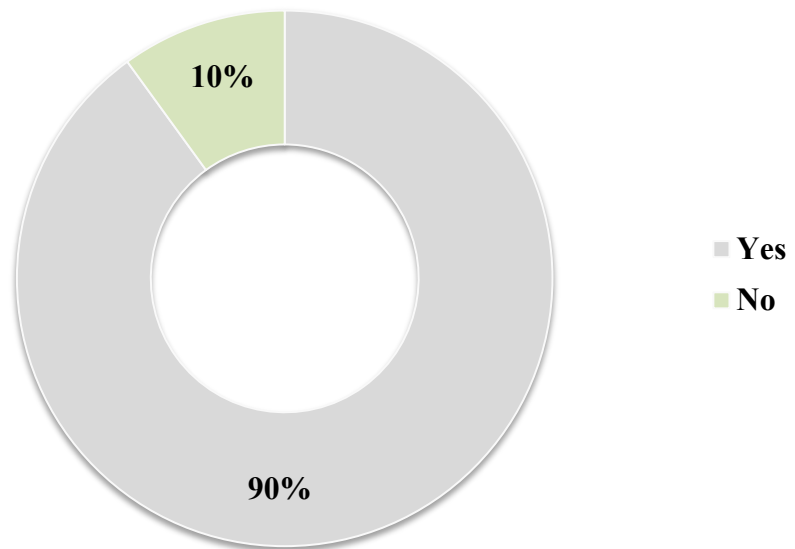


Figure 3.9: Knowledge about pharmacists' mandatory involvement in dispensing.

3.10: Opinion of the participants on the involvement of registered pharmacists in selling and dispensing drugs

The participants were asked about their opinion on the involvement of registered pharmacists in selling, dispensing and distributing of Drugs. 90 % agreed that if the selling and dispensing of drugs are conducted under the supervision of registered pharmacists, the consumer will get better healthcare service. 10% responded negatively. Most of them also mentioned why they have such opinion. They said a pharmacist does not as much knowledge as a person who is selling drug for last 10 years have. Some of them also said the owners of medicine shops would not bear a burden of extra expense for appointing a registered pharmacist.

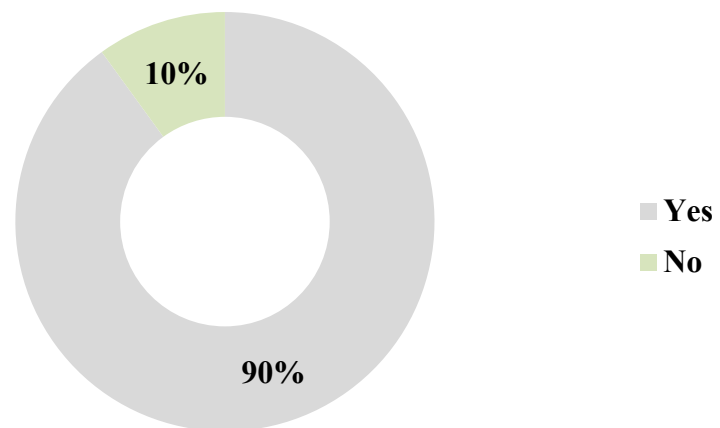


Figure 3.10: Opinion on the involvement of professional pharmacists' in dispensing

3.11: Participant's opinion on increase of cost

The study has shown that 63% of participants think that appointing pharmacists will increase the cost in health care sector. 37% of the participants think it will not affect the cost of health care sector but can become burden for the owners to appoint a registered pharmacist.

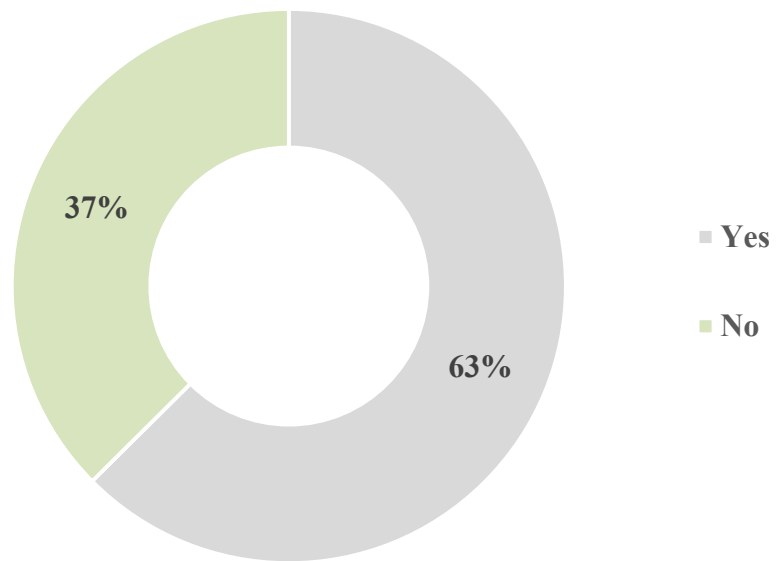


Figure3.11: Participant's opinion on Increase of cost

3.12.1: Participants' awareness level about selling drug without prescription

The study clearly shows that a large portion of the participants are aware about the law. 95% participants have responded yes to this question. Only 5% responded no. Some of them said that they know that selling drug without prescription is forbidden but they did not that it is a punishable offense.

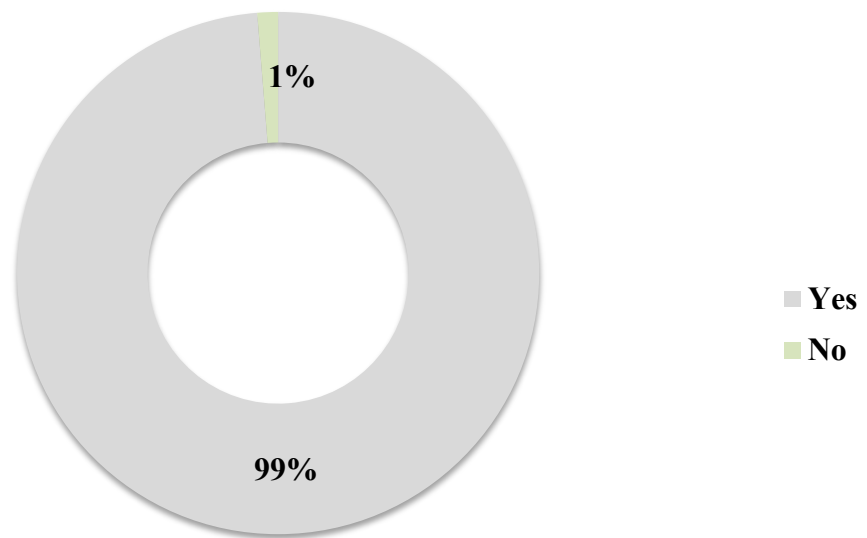


Figure 3.12.1: Participants' awareness level about selling drug without

3.12.2: Participants' opinion on the improvement of health sector

90% of the participants responded yes and 10 % responded no. During the questionnaire survey we tried to understand their logic behind such response. Those who said yes they clearly mentioned that it will be helpful for the patients but those who said no they have made a very strong argument as well. They said that a big population of the country is poor. They cannot afford to visit doctor so they seek help from the dispensers. If they don't sell drug without prescription to those patient then ultimately the patients will suffer from health issues.

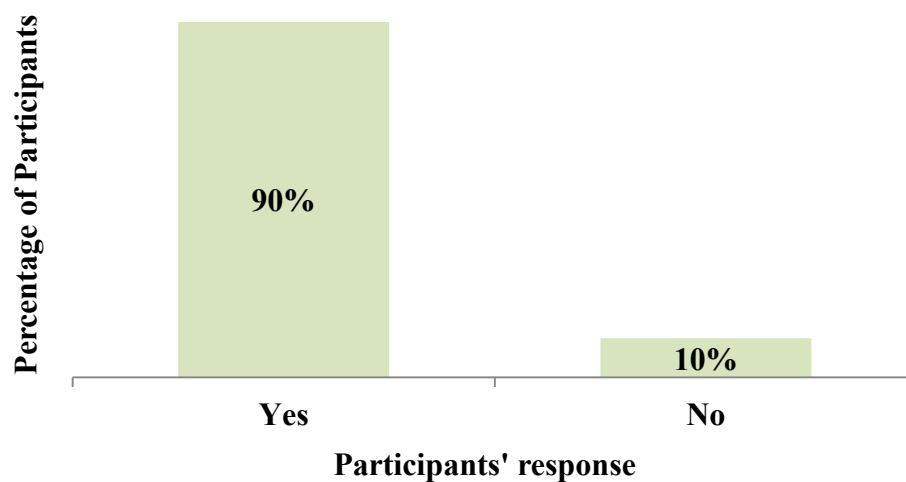


Figure 3.12.2: Participants' opinion on the improvement of health sector

3.13: Participant's knowledge about fixation the price of essential Drugs

75 %ofparticipants responded positively and 25% responded negatively. Those who have responded negatively have also said that they didn't even know what essential drug is, they just know there is government pharmaceutical company which is named as Essential drugs.

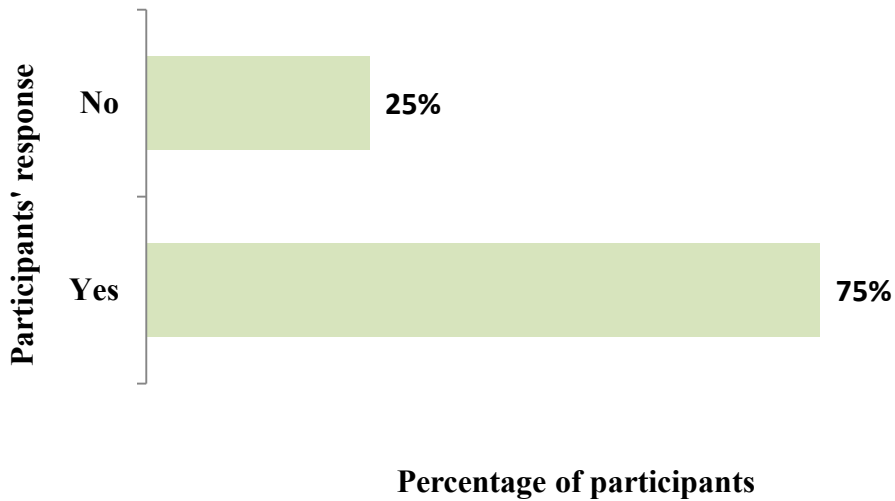


Figure 3.13: Participant's knowledge about fixation the price essential Drugs

3.14: Participants' knowledge on selling Drug at higher price as a punishable offense

Most of the participants were aware about this law. 93% of participants responded yes and only 7 % responded no.

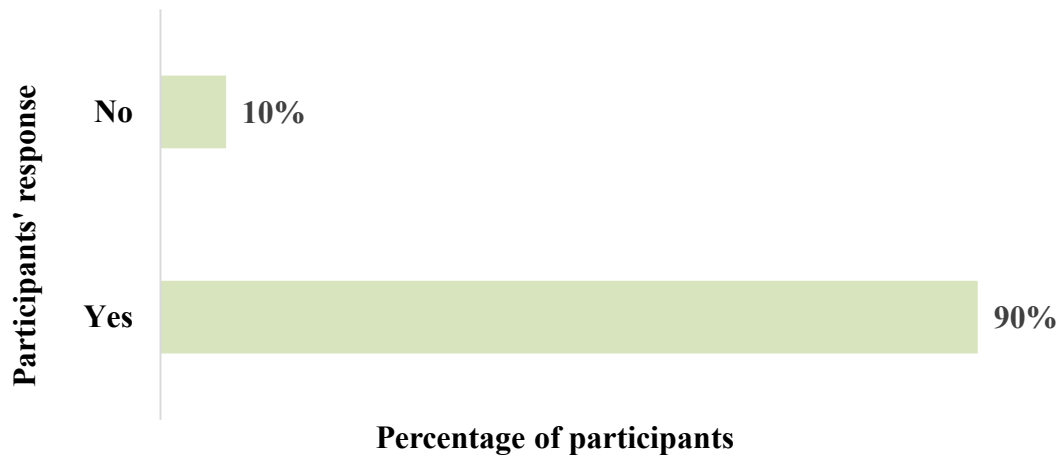


Figure 3.14: Participants' knowledge on selling Drug at higher price as a punishable offense

3.15: Participants knowledge on expiry date

All the participants responded positively to this question. No participants were found who does not about expiry date

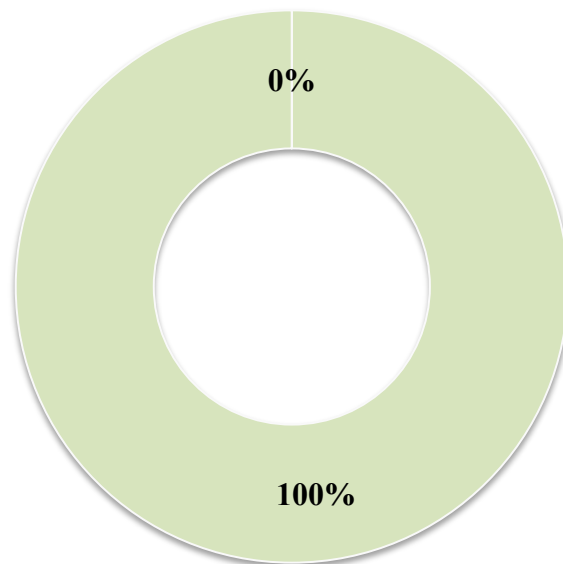


Figure 3.15 : Participants knowledge on expiry date

3.16: Participants' knowledge on expired Drug

50% of the participants said they return the Drug to the company. 39% participants said they dispose the expired Drugs by themselves. 11% of participants said they do both.

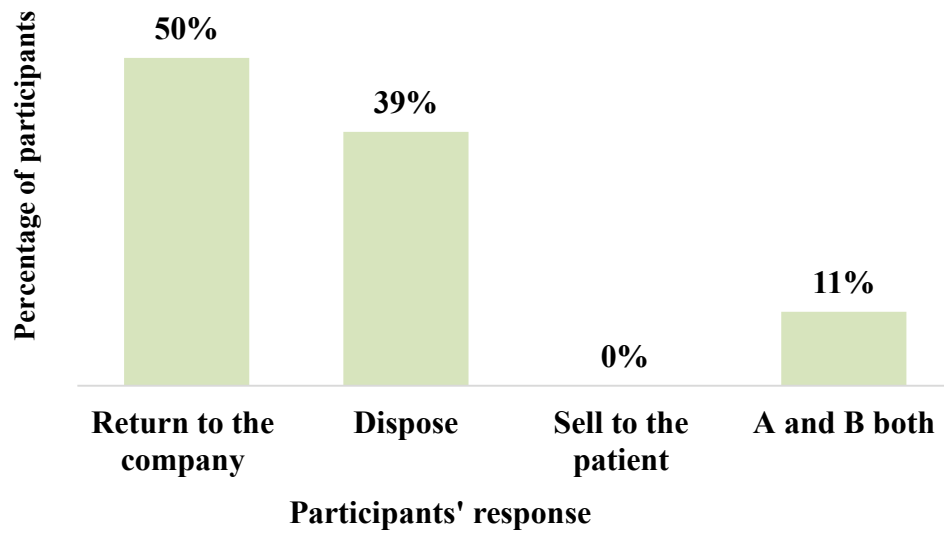


Figure 3.16: Participants' knowledge on expired Drug

3.17: Selling of expired drug as punishable offense

96 % of the participants responded positively. Only 4% participants gave negative response. They said that they knew selling expired drug is wrong but didn't know about the punishments.



Figure 3.17 : Selling of expired drug as punishable offense

3.18: Opinion of participants' regarding National Drug Policy 2016 and how this policy can be implemented successfully.

Many people answered this question in many ways. Some of the common suggestions will be presented among them: -

1. Many people do not know about National Drug Policy 2016, so such initiative should be taken by which dispensers can gain knowledge of National Drug Policy 2016
2. The policy makers should consult with the dispenser and owners of the medicine shops before making any policy
3. Socio economic condition of the country should be taken in consideration
4. Policy for Doctors should be made
5. Awareness among general people should be increased
6. Effective monitoring should be done
7. Doctors should prescribe generic name instead of brand name
8. Pharmaceuticals Companies should take away the expired drug and replace it with new drug
9. Government should circulate NDP 2016 in leaflet form to educate the dispensers about policies
10. Before banning the foreign drugs government should ensure good quality of local drugs

Discussions

The results of the study are a warning for the nation which indicates that lack of regulations and indiscipline activities in the health care sector is giving rise to the conditions which may lead to irrational and inappropriate use of drugs for instance over prescribing of drugs, inappropriate antibiotics selling, multidrug prescribing and can develop drug resistance among the people of the country. More alarming fact is that if the condition of capital of the country is like these then what would be the condition of the other cities and villages of Bangladesh. Further research is necessary to see the whole picture. Additionally, general people are very reluctant about the serious consequences. Besides, running a research seems very difficult in the city as people in this sector are very skeptical. It took almost 20 days to collect all the data and many obstacles came into the path Traffic jam in the city was a very big challenge In addition, in fact medicine dispensers did not want to respond in the first place. It took lots of effort to convince them and let them understand that this study will not harm them anyway. Such kind of fear is a big obstacle for any research work. Although very less research work was done in this sector as a result it was very difficult to collect authentic information. Despite of all the negative aspects there is still light of hope as a group of people related to this field wish for the change. If the people of every concerned area related to this field work hand by hand, it is possible to build a good health care system for Bangladesh

Chapter 4: Conclusion

Comparing to the developed countries Bangladesh is far behind in terms of implementing NDP effectively. The health care sector can be more developed if the regulatory authorities effectively monitor every sector. The National Drug Policy 2016 included some very valid and important points and if these can be implemented effectively then the health care sector will be developed very soon. However effective implementation is only possible when all the stake holder will work side by side, from top to bottom every sector need strict monitoring. Awareness program for general people should be arranged. General people should be encouraged more to buy medicines with prescriptions. General people should also learn how should they report to DGDA if the find any adverse Drug reaction. The dispensers need to be educated. Suddenly cutting them off from this field will not be an efficient step because their experience can add value, instead of that step should be taken by which all the sales man and owners can be taken under a general certification. Bangladesh have adopted NDP very soon and also many improvements have been made but if we compare our country with developed one's we can see there are still lacking in many sectors. We should look for the solutions to provide best health care service to the citizens of our country

Chapter 5: Recommendations

Bangladesh has now risen to developing country from under developed country. Development in many sectors is taking place spontaneously. However, many developments are also taking part in the healthcare sector as well. For uninterrupted development in health care sectors some effective measures should be taken to regulate and monitor the medicine shops in Bangladesh.

- Drug regulatory authority should visit the medicine shops at least once in a month
- Pharmaceuticals training program should be mandatory for the salesman and owner of the drug shops.
- The drug sellers' knowledge should be judged by certification exam more often after a specific period of time.
- Public awareness should be increased about the harmful effect of drug resistance. Importance of Pharmacovigilance should be more promoted in schools and colleges to increase awareness.
- Policy makers should notify the dispenser about new policies by different electronic medium which are now very available. For example text messages in mobile phone, Internet etc.
- Informative videos can play an important role in creating awareness. Informative should be promoted in social media to educate the people about the health hazards of taking medicines inappropriately.

However before pointing finger at the people who are not educated we should share the same amount of guilt for the current scenario. Even being educated many of us purchase medicine without consulting a physician. So we need stop that and we need to understand change begins within self.

Chapter 5: References

- Ahmed. (2012.). Availability and rational use of drugs in primary healthcare facilities following the national drug policy of 1982: is Bangladesh on the right track. *J Health Popul Nutr.*
- Ahmed, J. (2017). The antibiotics death trap. Dhaka: Dhaka Tribune.
- Bangladesh: A Tough Battle for a National Drug Policy 123. (n.d.).
- Cathy, G. a. (2002). Minimising the Harm of Illicit Drug Use: Drug Policies in Australia. Queensland Parliamentary Library.
- Dean G. Kilpatrick, P. (2000). National violence Against Women Prevention Research Centre.
- Islam, N. (1984). on a national Drug policy for Bangladesh. dhaka: Tropical Doctor..
- Katers, N. (2017). Drug Regulation in Canada. Bizfluent.
- Kilpatrick. (2000). National violence Against Women Prevention Research Centre.
- Manobkonth0. (2013). reports on Substandard vitamin A.
- Ogory, T. (12 – 16 March, 2012). Effectiveness of National Drug Policies. *West African Journal of Pharmacy*
- Owen, B.J.(2017). Chair of the Advisory Council on the Misuse of Drugs.
- Stothard, B. (2017). The UK drugs strategy 2017: contexts and analysis. *Drugs and Alcohol Today*, Vol. 17 Issue 4.
- Syed Masud Ahmed1*, N. N. (2017). Exploring the status of retail private drug. *Journal of Pharmaceutical Policy and Practice.*
- Tushar, h. J. (2016). Updated drug policy okayed by cabinet. Dhaka: The Daily STar.
- Taylor, o. (2012). Effectiveness of National Drug Policies. *West African Journal of Pharmacy* (2012) 23 (2) 27 – 33.
- WHO (2003). How to develop and implement. World Health Organization.

- Chowdhury, P.M. 2010. "An overview of the pharmaceutical sector in Bangladesh." BRAC EPL Stock Brokerage LTD, Dhaka.
- Chuc, N. 2002. "Towards good pharmacy practice in hanoi: a multi-intervention study in private sector." PhD thesis. Stockholm: KarolinskaInstitutet.
- Drug Seller Initiatives (DSI). 2014. Sustainable drug seller initiatives. Available from: <http://www.drugsellerinitiatives.org/about/projects/> (accessed 10 Sept. 2015)
- Goodman, C., W. Brieger, A. Unwin, A. Mills, S. Meek, and G. Greer. 2007. "Medicine sellers and malaria treatment in sub-Saharan Africa: what do they do and how can their practice be improved?" *American Journal of Tropical Medicine and Hygiene* 77(6 Suppl): 203–18.
- HIP (High Impact Practices in Family Planning). 2013. "Drug Shops and Pharmacies: Sources for Family Planning Commodities and Information." Washington DC: USAgency for International Development (USAID)
- Stevens, A: 2017: Principles of pragmatism and prohibition: in: *The Oxford Handbook of Criminology*: eds. Liebling, A, Maruna, S and McAra, L: 825 -845: Oxford University Press, Oxford
- United Nations Office on Drugs and Crime: 2017: *World Drug Report 2017*: United Nations Publications, New York
- Majesty's Stationery Office, London. HMSO: 1998: *Tackling drugs to build a better Britain: The government's ten-year strategy for tackling drugs misuse*: Her Majesty's Stationery Office, London.
- Home Office: 2008: *Drugs: protecting families and communities*: Home Office, London
- Home Office: 2010: *Reducing demand, restricting supply and building recovery: Supporting people to live a drug free life*: Home Office, London

