ADDIS ABABA UNIVERSITY

SCHOOL OF COMMERCE

LOGISTIC AND SUPPLY CHAIN MANAGEMENT UNIT

PHARMACEUTICAL WASTE MANAGEMENT PRACTICES AND CHALLENGES IN PHARMACEUTICAL FUND AND SUPPLY AGENCY: THE CASE OF CENTRAL AND REGIONAL MAIN STORES IN ETHIOPIA

BY

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF ART DEGREE IN LOGISTICS AND SUPPLY CHAIN MANAGEMENT

ADVISOR

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DECLARATION

I, Asnake Hailye declare that, this paper prepared for the partial fulfillment of the requirements for Master of Art Degree in Logistics and Supply Chain Management entitled **"Pharmaceutical Waste Management Practice and Challenges in Pharmaceutical Fund and Supply Agency, (PFSA): A Case of PFSA Regional Stores in Ethiopia" is prepared with my own** effort. This thesis is my original work and has not been presented for a Degree in any other University and I have made it independently with the close advice and guidance of my advisor.

Asnake Hailye

Signature ——————

Date ——————

CERTIFICATION

This is to certify that Mr. Asnake Hailye has carried out this thesis work on the topic entitled **"Pharmaceutical Waste Management Practice and Challenges in Pharmaceutical Fund and Supply Agency, (PFSA): A Case of PFSA Central and Regional Main Stores in Ethiopia"** under my supervision. This work is original in nature and it is sufficient for submission for the partial fulfillment for the award of Master of Art Degree in Logistics and Supply Chain Management.

Matiwos Ensermu (PhD)

Signature ——————————

Date ——————————

ADDIS ABABA UNIVERSITY

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DEPARTMENT OF

LOGISTICS AND SUPPLY CHAIN MANAGEMENT

(MA PROGRAM)

This is to certify that the thesis prepared by Asnake Hailye entitled **"Pharmaceutical Waste Management Practice and Challenges in Pharmaceutical Fund and Supply Agency, PFSA: A Case of PFSA Central and Regional Main Stores in Ethiopia",** which is submitted in partial fulfillments of the requirements for the degree of Masters in Logistics and Supply Chain Management complies with the regulation of the university and meet the accepted standard with respect to originality and quality.

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LIST OF ACRONYMS AND ABBREVIATIONS

BMW	Bio Medical Waste
EMs	Essential Medicines
FMHACA	Food, Medicines and Health care Administration and Control Authority
FMOH	Federal Ministry of Health of Ethiopia
LMIC	Low-and Middle-Income Countries
PFSA	Pharmaceuticals Fund and Supply Agency
PSCM	Pharmaceutical Supply Chain Management Systems
RHBs	Regional Health Bureaus
SIPS	System for Improved Access to Pharmaceuticals and Service
SOPs	Standard Operating Procedures
SPS	Strengthening Pharmaceutical System
WHO	World Health Organization

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ABSTRACT

Pharmaceutical waste includes expired, unused, contaminated pharmaceutical products, drugs, vaccines, and sera that are no longer required and need to be disposed of appropriately. In proper disposal of medication waste leads to serious personal and environmental health hazards. There were no established medication waste management programs in most of the developing countries including Africa and Asia. Presence of unique socioeconomic problems in these countries makes the establishment of successful medication waste management program a very challenge. The aim of this study is to assess the pharmaceutical waste management practice and challenges at the Ethiopian Pharmaceutical Fund and Supply Agency. This study is conducted by employing Quantitative (questionnaires and direct observation with check list) and qualitative (structured interview) research approaches. Direct observation and physical verification are carried out, using validated world health organization checklist for segregation, collection, storage and disposal of pharmaceutical waste. The existing waste management policy with respect to collection, storage, transportation, information regarding staff strength, services available, quantities and waste type produced and profile of waste handlers and final disposal is evaluated in structured interviews till the point of saturation. Based on the findings and identified challenges, the study put recommendations on what should be done and improved by all responsible bodies for safe disposal of pharmaceutical wastes. The quantitative data generated is analyzed using appropriate computer software. Descriptive statistics (frequencies, averages and percentages) is run to explore the data. The qualitative data is transformed into categories related to the topics that is discussed and coded on paper individually in order to identify themes and patterns for thematic analysis.

Key Words: *Pharmaceuticals, Pharmaceutical waste, Pharmaceutical waste disposal*

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

Access to medicine as a human right is one of the main objectives of healthcare systems. Pharmaceutical supply chain should provide medicines in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to be consistent with health system's objectives and also it should make benefits for its stockholders (Jaberidoost, 2013). Medication waste management practices and the level of engagement with it can be used as a quality indicator of the health care system of the institution or the country (Vipula, 2016)

Pharmaceutical waste includes expired, unused, contaminated pharmaceutical products, drugs, vaccines, and sera that are no longer required and need to be disposed of appropriately. The category also includes discarded items used in the handling of pharmaceuticals, such as bottles or boxes with residues, gloves, masks, connecting tubing, and drug vials. Hazardous materials used by healthcare institutions that become part of their waste streams include chemotherapeutic agents, anti neo plastic chemicals, solvent, formaldehydes, photographic chemicals, radio nuclides, mercury, anesthetic gases and other toxic, corrosive and miscellaneous chemicals (Bassey, 2006).

Infectious waste is produced from the hospitals during the diagnosis, immunization, surgical procedures and treatment of patients, and can transmit the infections to the hospital staff, attendants and the nearby public. Infectious waste comprises 10-25% of all the waste produced in hospital, which cannot be disposed of with the normal domestic waste (Askarian, 2010). However, this is a common observation in many hospitals of the developing countries. Infectious waste generation rates, normally depends on the size of hospital, number of patients coming to that particular facility, number of beds available, segregation steps and kind of care provided to the patients (Askarian, 2010).

Improper disposal of medication waste leads to serious personal and environmental health hazards. There were no established medication waste management programs in most of the developing countries including Asia. Presence of unique socio economic problems in these countries makes the establishment of successful medication waste management program a challenge (Vipula, 2016).

During conflicts and natural disasters large quantities of pharmaceuticals are often donated as part of humanitarian assistance. Undoubtedly many of the pharmaceuticals save lives and alleviate suffering, but some donations given by well-meaning but uninformed people may cause problems. Pharmaceuticals may arrive past or near their expiry date, may be inappropriate for the needs, and be unrecognizable because they are labeled in a foreign language or may have been sent in unwanted quantities. Donated pharmaceuticals with a long shelf-life may be mismanaged, particularly in the confusion during and after armed conflict or a natural disaster. Staff and storage space may be lacking and the pharmaceutical management system in disarray. Such problems also occur when drug donations form part of development assistance. Smaller quantities of pharmaceutical waste may accumulate in the absence of emergency situations, due to inadequacies in stock management and distribution, and to lack of a routine system of disposal. Safe disposal of these unwanted or expired drugs often creates a major problem (World Health Organization, 1999).

The medication waste disposal *via* normal sewage systems was the main method practiced in most of the countries and that the situation was much worse in developing countries. Return of unused medicines to pharmacies, which is considered to be the best method, was successfully practiced in some developed countries with established systems. Lack of proper mechanism to handle medication waste seems to be the main reason behind substandard medication waste management in developing countries (Bound and Voulvoulis, 2005).

Several recent U.S. studies have revealed the presence of pharmaceutical compounds in both surface and ground waters. Some of these drugs are toxic (*e.g.*, chemo therapy agents), while others cause more limited physiological changes to aquatic organisms and/or other organisms higher in the food chain.

Most unused pharmaceuticals dissolve easily; however, they do not all readily break down into common elements once they are released into the environment, and therefore, they generally remain intact. This allows these drugs to be absorbed by plants, animals, and human beings (Heberer, 2002,).

Studies conducted in Vienna and Oman had cardiovascular medicines as the highest percentage of medication waste comprising 18% and 24% of the samples respectively. Saudi Arabia had respiratory medicines as the highest percentage (16.8%). In Mexico and Nigeria anti-inflammatory and analgesic medicines were the commonest, representing 16.11% and 18.6% of the samples respectively. Antibiotics were also found in higher percentages in most of the studies. Assessment further showed that in Mexico, Germany and Vienna most of the medication waste comes from prescription only medicines in contrast to Nigeria and Kuwait where over the counter medications were the commonest (Bronder and Klimpel., 2001; Abahussain , 2006; Auta, 2011; Gracia-Vásquez, 2015). In a study of 5 big health faculties in Abuja, the average waste generation rate per bed/day was found to be 2.78 kg of solid waste, 26.5% of the total waste was hazardous in nature (Ekpu and Uwagbale, 2016).

1.2 Statement of the Problem

Medication waste management is not given enough priority in developing countries. Improper disposal of medication waste leads to serious personal and environmental health hazards. Environmental pollution is a well-known consequence of improper medication waste management (Fent, 2006; Bronstein, 2008). The occurrence of pharmaceutically active compounds in the aquatic environment has been recognized as one of the serious and emerging problems. Most studies have given much emphasis on assessing the impact on ground water resources. In some investigations carried out in Europe and in the US, more than 80 pharmaceutical compounds and several drug metabolites have been detected in surface and ground water samples (Fent, 2006; Bronstein, 2008).

The major concerns have been increased bacterial resistance to antibiotics and interference with growth and reproduction not only in human echo systems but also inside aquatic organisms such as fish and frogs (Fent , 2006).

In the surface water, medication derived chemicals are present in lower concentrations posing environmental risks. However, targeted Eco toxicological studies are lacking almost entirely even in developed countries (Heberer, 2002).It has been shown that impaired sexual development and increased feminization of fish have occurred due to the presence of trace amount of oral contraceptive component, ethinyl oestradiol in rivers. According to some sources, landfill disposal of unused medicines reduces surface water releases (Jobling, 2006).

Medicines thrown into garbage bins can be reached by children, animals and other individuals such as garbage collectors exposing them to serious health hazards including life threatening poisoning. Theoretically, medication waste with toxic, erotogenic or mutagenic potential can be accumulated in food chains and re-enter human biological systems. Repeated exposure to these substances can leads to chronic toxic effects or high dose short term exposures can leads to acute toxic effects among humans. These toxic effects will also affect useful microorganisms, insects, animals and plants (Vipula, 2016).

Burning and incineration of medical and municipal waste have been linked to severe public health threat and pollution resulting in the release of toxic dioxin as well as mercury and other toxic substances. These substances produce a remarkable variety of adverse effects in humans at extremely low doses. Putrefaction occurs in portions of refuse, which have not been fully burnt and add to air pollution through foul smells. Sanitary landfill can lead to pollution of ground water if not properly managed (Peele, 1998).

Lack of proper mechanism to handle medication waste seems to be the main reason behind substandard medication waste management in developing countries. Unused medicines can be divided into two categories as expired and non-expired. Expired medicines need to be sorted out separately and incinerated by municipal authorities. But the rural population may not be able to access municipals and therefore other local authorities may need to take the responsibility. Although lack of man power will be an issue, defining the role for each stakeholder group will minimize negative consequences. Offering the consumers with discounts for their purchases
Based on returned medicines will encourage general public to engage more and more with these programs (Vipula, 2016).

The current study is aimed at assessing the pharmaceutical waste management practice and challenges at Ethiopian Pharmaceutical fund supply agency (PFSA) stores.

1.3 Research Question

The research questions of this study are;

- What are the common types of pharmaceutical wastes encountered at PFSA?
- How pharmaceutical wastes at PFSA stores are handled or disposed?
- What are the common methods or techniques of disposing these wastes?
- What are the potential challenges hindering effective implementation of pharmaceutical wastes management techniques at PFSA?

1.4. Objectives of the Study

1.4.1. General objective

The general objective of this study is to assess the pharmaceutical waste management practice and challenges in PFSA

1.4.2 Specific objectives

The specific objectives of this study are;

- To characterize the types of Pharmaceutical wastes encountered in PFSA main and regional supply stores
- To evaluate waste disposal techniques employed in the management of Pharmaceutical wastes generated in PFSA.
- To assess the prevailing challenges of pharmaceutical waste disposal in PFSA.

1.5. Significance of the Study

The results of this study would be expected to contribute:

- To understand the common types pharmaceutical wastes generated in the various regional sores of PFSA and their disposal techniques employed in the management of these wastes.
- To understand the existing challenges that could hinder proper disposal pharmaceutical wastes in the various pharmaceutical facilities of Ethiopian context.
- Help concerned bodies and other health care workers to better understand of the nature of the problem in the facility for targeted and coordinated action. Thus, it will help to boost the quality of pharmaceuticals supply activities.
- Provide baseline information and evidence for concerned bodies and scientific communities for further follow up of the problem.

1.6. Scope of the Study

The scope of the study is pharmaceutical waste management practices and its challenges in PFSA main and regional supply stores which makes it overall generalization on pharmaceutical waste management practices and challenges for all PFSA hubs in Ethiopia. The report of the study centered on paper based recording and reporting system. Appropriate data is collected from the study sites during one month of field work. Even though pharmaceutical waste management practice is a critical issue in health facilities and municipal administrations, the study did not include health facilities and municipal administrations but the findings of the study could make to put overall generalizations and recommendations on the way how all responsible stake holders should proceed for safe and proper management of pharmaceutical wastes.

1.7. Limitation of the Study

Pharmaceutical waste management practice is not only the responsibility of single stake holders but also it is the cumulative efforts of different stake holders. Such as; PFSA, federal to municipal levels government administrations, federal, regional, zonal and Woreda health offices, world health organizations, donors and non-government organizations.

However ever due to time and resource constraint, the study is limited to pharmaceutical waste management practice and its challenges at PFSA hubs. Regardless of these restrictions, the validity of the findings originate from this study is very significant for safe and proper pharmaceutical waste management through the joint efforts of all responsible stake holders.

1.8. Operational Definitions

A pharmaceutical drug, also referred to as medicine, medication and medicament, can be loosely defined as any chemical substance intended for use in the medical diagnosis, cure, treatment, or prevention of diseases (EU, 2004).

Pharmaceutical waste: shall mean Pharmaceuticals that should never be used or items involving

- The all expired pharmaceuticals, all unsealed syrups or eye drops (expired or unexpired, all cold chain damaged unexpired pharmaceuticals that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines), all bulk or loose tablets and capsules.
- If unexpired these should only be used when the container is still sealed, properly labeled or still within the original unbroken blister packs; all unsealed tubes of creams, ointments, etc. (expired or unexpired)
- Medical equipment, beds, wheelchairs, dressings, clothing, laboratory glassware

1.9. Organization of the Study

This study is organized in five chapters. The first chapter deals with the introduction part of the paper including background of the study, statement of the problem, objectives of the study and other appropriate subjects. The second chapter spotlight on important literature review. In this chapter a review the important literatures in relative to the topic under discussion is made. The third chapter is research Methodology; that is, the research design, approaches used throughout the data collection and methods of data analysis processes are discussed. The fourth chapter is results and discussions, which comprise pharmaceutical waste management practices and its associated challenges in central and regional PFSA hubs. Finally, chapter five comprises summary, conclusion and recommendation.

CHAPTER TWO
REVIEW OF RELATED LITERATURE

Introduction

This chapter looks at literature, written by different scholars on concepts and practices of pharmaceutical waste management and its associated challenges, in order to establish and give answers to the research questions

2.1. Theoretical Literature Review

Wastes are the unwanted or unusable materials that people will no longer use for, which are either intended to get rid of or have already been discarded. Moreover, wastes can be hazardous to human or the environment as such, which has to be discarded immediately, else may cause serious health related problems in human. Wastes should else be recycled to another useful product. Wastes may be of different forms like household rubbish, sewage, sludge, wastes from manufacturing activities, packaging items, discarded cars, old televisions, garden waste, old paint containers etc. Thus, daily activities may give rise to a large variety of different wastes arising from different sources. This might be developed from households, commercial activities (e.g., shops, restaurants, hospitals etc.), industry (e.g., pharmaceutical companies, clothes manufacturers etc.), agriculture (e.g., slurry), construction and demolition projects, mining and quarrying activities and from the generation of energy. With such vast quantities of waste production, it is of vital importance that these should be managed in such a way that they does not cause any harm to either human health or to the environment. There are a number of different options available for the treatment and management of wastes including prevention, minimization, re-use, recycling, energy recovery and disposal. Pharmaceutical wastes are of different types mainly hazardous wastes and non hazardous wastes (Muhammed J. Pramod K. and Remya M., 2017).

2. 1.1 Pharmaceutical Wastes

Pharmaceutical wastes are potentially generated through a wide variety of activities in the health care system, including syringes, and are not limited to intravenous (IV) preparation. Generally Pharmaceutical waste may include: Expired drugs, Patients' discarded personal medications;

Waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.); Waste materials containing chemotherapy drug residues; Open containers of drugs that cannot be used; Containers that held acute hazardous waste drugs; Drugs that are discarded; and Contaminated garments, absorbents and spill cleanup material (Sharma N., 2010).

Pharmaceutical waste is further classified in 3 categories:- Hazardous waste, Non-hazardous waste, Chemo waste. Hazardous Wastes are wastes that are dangerous or potentially harmful to human health or the environment. These can be liquids, solids, contained gases, or sludge's. Hazardous wastes are divided into two categories: Listed wastes, and Characteristic wastes. Pharmaceutical wastes come under listed wastes since they contain commercial chemical products. Characteristic wastes are regulated because they exhibit certain hazardous properties, ignitability, corrosives, reactivity and toxicity. Wastes that are not listed and do not exhibit a characteristic are considered solid waste. Solid wastes should be discarded according to state and/or local regulations, including regulated medical waste requirements (Sharma N., 2010).

The objective of the ignitability characteristic is to identify wastes that either present a fire hazard under routine storage, disposal, and transportation or are capable of exacerbating a fire once it has started. There are several ways that a drug formulation can exhibit the ignitability characteristic. Many of the hazardous wastes that pharmacies handle are hazardous because they are ignitable. These wastes often pose the greatest management problems for pharmacies. Ignitable wastes are easily combustible or flammable (Sreekanth K., 2014)

Corrosive wastes corrode metals or other materials or burn the skin. These liquids have a pH of 2 or lower or 12.5 or higher. Examples of acids that exhibit a pH of 2 or lower include glacial acetic acid. Examples of bases that exhibit a pH of 12.5 or higher include Potassium Hydroxide and Sodium Hydroxide. Generation of corrosive pharmaceutical wastes is generally limited to compounding chemicals in the pharmacy (Pratyusha K., 2012)

Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water (Sharma N., 2010)

Wastes are toxic if they contain toxic organic chemicals or certain heavy metals, such as chromium, lead, mercury, or cadmium. Approximately 40 chemicals meet specific leaching 12 concentrations which classify them as toxic. Wastes that exceed these concentrations must be managed as hazardous waste (Pratyusha K., 2012).

Non Hazardous Wastes are considered to present no significant hazardous properties. It is worth nothing, however, that this is not an indication that there are no hazardous components present, only that any such components are below the threshold for causing harm to human health. Importantly, this non-hazardous state is subject to change and the addition or removal of specific items from the waste stream may significantly alter the management options available (Sharma N., 2010).

2.1.2 Pharmaceutical Waste Management and Disposal

Pharmaceutical waste management is pharmaceutical waste rules which describe various tools for effective management of wastes as follows (Muhammed J. Pramod K. and Remya M., 2017).

Incineration

Incineration is an effective method used for disposal of wastes, in which solid organic wastes are subjected to combustion so as to convert them into residue and gaseous products. This method is useful for disposal of residue of both solid waste management and solid residue from waste water management. This process reduces the volumes of solid waste to 20 to 30 percent of the original volume. Incineration and other high temperature waste treatment systems are sometimes described as "thermal treatment". Incinerators convert waste materials into heat, gas, steam and ash. Incineration is carried out both on a small scale by individuals and on a large scale by industry. It is used to dispose of solid, liquid and gaseous waste. It is recognized as a practical method of disposing of certain hazardous waste materials (such as biological medical waste) .
Incineration is a controversial method of waste disposal, due to issues such as emission of gaseous pollutants. Incineration is not suitable for such health care wastes as pressurized gas containers, large amounts of reactive chemical wastes, wastes treated with halogenated chemicals, halogenated plastics such as polyvinyl chloride, wastes with mercury or cadmium

(such as broken thermometers, used lead or mercury batteries), or radiographic wastes (Auta A, Omale S, Shalkur D, Abiodun AH, 2011).

Autoclaving

In autoclaving, saturated steam in direct contact with the BMW in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens are used for sterilization.

Minimum temperature, pressure, and residence time for autoclaves for safe disinfection are specified in the Biomedical Waste Rules. Before autoclaving, BMWs require shredding to an acceptable size which is an operation that would involve frequent breakdown. Autoclaving produces a waste that can be land filled with municipal waste. A wastewater stream is generated that needs to be disposed of with appropriate controls. Autoclave operation requires qualified technicians, and medium investment and operating cost. Regardless of all the benefits, autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes (Sharma N., 2010).

Microwaving

Application of an electromagnetic field over the BMW provokes the liquid in the waste to oscillate and heat up, destroying the infectious components by conduction. This technology is effective if the ultraviolet radiation reaches the waste material. Before microwaving, BMWs require shredding to an acceptable size and humidification. Microwaving is not suitable for human anatomical, animal, chemical, or pharmaceutical wastes, or for large metal parts. Microwaving produces a waste that can be land filled with municipal waste. The advantages of this treatment technology are its small electrical energy needs and no steam requirement. The disadvantages include the need for qualified technicians and frequent breakdown of shredders. This technology requires medium investment and operating costs (Sharma N., 2010)

Chemical Disinfection

Chemical disinfection is most suitable for treating liquid wastes such as blood, urine, stools, or health care facility sewage. Addition of strong oxidants-like chlorine compounds, ammonium salts, aldehydes, or phenol compounds-kills or inactivates pathogens in the BMW. However, microbiological cultures, mutilated sharps, or shredded solids can also be treated by chemical

disinfection. Disinfection efficiency depends on such factors as the type and amount of chemical used, and the extent and duration of contact between the disinfectant and the BMW (Sharma N., 2010).

Secure Land Filling

Secure land filling involves disposal of solid BMWs at a landfill designed and operated to receive hazardous wastes. The Biomedical Waste Rules require disposal of discarded medicines, cytotoxic drugs, solid chemical wastes, and incineration ash in secured landfills. Disposing of waste in a landfill involves burying the waste, and this remains a common practice in most countries. Landfills were often established in abandoned or unused quarries, mining voids or borrow pits. A properly designed and well-managed landfill can be a hygienic and relatively inexpensive method of disposing of waste materials. Older, poorly designed or poorly managed landfills can create a number of adverse environmental impacts such as wind-blown litter, attraction of vermin, and generation of liquid leachate. Another common byproduct of landfills is gas (mostly composed of methane and carbon dioxide), which is produced as organic waste breaks down an aerobically. This gas can create odor problems, kill surface vegetation, and is a greenhouse gas.

Design characteristics of a modern landfill include methods to contain leachate such as clay or plastic lining material. Deposited waste is normally compacted to increase its density and stability, and covered to prevent attracting vermin (such as mice or rats). Many landfills also have landfill gas extraction systems installed to extract the landfill gas. Gas is pumped out of the landfill using perforated pipes and flared off or burnt in a gas engine to generate electricity (Auta A, Omale S, Shalkur D, Abiodun AH, 2011).

Waste Immobilization: Encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand. For ease and speed of filling, the drum lids should be cut open and bent back. Care should be taken to avoid cuts to hands when placing

pharmaceuticals in the drums. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. Steel drum lids should then be bent back and sealed, ideally by seam or spot welding. The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. For ease of movement, the drums may be placed on pallets which can then be put on a pallet transporter (Auta A, Omale S, Shalkur D, Abiodun AH, 2011).

Waste Immobilization: Inertization

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals. Pills need to be removed from their blister packs. The pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The process is relatively inexpensive and can be carried out with unsophisticated equipment. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water (Auta A, Omale S, Shalkur D, Abiodun AH, 2011).

Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. The assistance of a hydro geologist or sanitary engineer may be required in situations where sewers are in disrepair or have been war damaged (Sharma N., 2010).

2.2. Empirical Literature

The treatment of pharmaceutical waste varies in different countries of the world. In some of them, like Egypt, it has been accepted that unused medicines should be returned to pharmacies

and reissued to the patients. However, such rationalization of medicines is considered ethically unacceptable because of lack of safety and the inability to monitor the process of storing medicines while they are in the possession of users (Samaa ZI, Heba MM, El-Haddad ZI, 2012). There is a proposal in the Netherlands to attach an indicator strip on each medicine packaging that will change color when the medicine is inadequately stored. That would ensure greater reliability in re-issuing unused medications which are still unexpired (Mols A., 2013)

Different pilot projects have been conducted in Canada. Their aim is to determine whether the adjustment of the amount of medicine issued to every patient could result in decreasing health care costs and the decrease of the unused medicines amount, i.e. the amount of the pharmaceutical waste (Smith AC., 2002).

The problem with this proposal in Serbia is associated with the national legislation which does not permit the issuance or sale of individual medicines, i.e. the medicines out of their original packaging. Sometimes the amount of medicines in the boxes exceeds the need for specific therapy to a large extent, which leads to the growth of the amount of unused medicines. However, there is one more possible solution for this problem to include manufacturers and get them start the production of packages with different number of medicines (Mols A., 2013).

Prescribers of medicines in New Zealand have a legal license to prescribe three months therapy for chronic diseases, and even 6 months for oral contraception. This way of prescribing medicines resulted in a very low percentage of unused ones that are being returned to pharmacies (Braund R, Peake MB, Shieffelbien L., 2009).

The studies in Great Britain show that only 22% of unused medicines are being brought back to pharmacies. In the United States, that percentage is also very low, 23%. However, it is a significantly higher value than the one reached in the study 10 years ago when it was 2% (Bound PJ, Voulvoulis N., 2005). A study conducted in New Zealand shows that the percentage of the medicines returned to pharmacies is between 13% and 24% (Braund R, Peake MB, Shieffelbien L., 2009).

There are 314 independent pharmacies in Denmark and the amount of pharmaceutical waste generated is 120 grams per person per year. Pharmacies are required to collect pharmaceutical waste from households. The town is responsible for the procurement of packaging, collection and treatment of pharmaceutical waste. The collected pharmaceutical waste is taken to the hazardous waste storages before transporting to a facility for treatment. The amount of pharmaceutical waste collected through pharmacies is about 1100 tons per year, or 70 grams per person per year (Mols A., 2013).

Such low percentage of responsible citizens in developed countries, where the education of the population is already at high level, shows that it would take a lot of effort in Serbia to raise awareness about the harmful effects of the improper management of pharmaceutical waste on one hand and to get the first results of the campaigns undertaken on the other (Mols A., 2013).

Some researches show that when it comes to the inadequate pharmaceutical waste management, examinees are mostly feared of the infectious diseases that could develop under these conditions but also of the increased volume of allergic reactions. Such facts should also be considered in the countries where this kind of researches have not been undertaken yet because they could motivate citizens to practice safe and adequate pharmaceutical waste management (Mols A., 2013).

Available data provide consistent indications that the facilities for pharmaceutical waste destruction are often located disproportionately in areas with smaller populations or in places housing ethnic minorities. There are numerous dumps and abandoned industrial zones in Serbia that could be adjusted for the facilities for pharmaceutical waste destruction. This would save health care system financial resources to a great extent (Mols A., 2013).

Most of the pharmacists questioned consider that the financial support in the pharmaceutical waste management is the biggest obstacle for the proper treatment of pharmaceutical waste. The development and implementation of adequate procedures in practice, as well as the development of the facilities for the destruction of this type of waste is the key step towards reducing the amount of pharmaceutical waste in the environment (Smith AC., 2002).

2.3. Conceptual Framework of the Study

2.3.1. Overview of Pharmaceutical Waste Management in Ethiopia

Medicines are substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. They are indispensable products in the course of health care service delivery. Continuous availability of quality assured medicines is crucial for uninterrupted delivery of health care services. Accordingly, the appropriate management of medicines is one of the key functions of the health care delivery system (E.Ejigu, H. Tadeg, N. Mekonnen, 2012). However, while working to ensure that adequate quantities of medicines are available, some medicines may expire or be damaged before they are used, making them unsafe for use. In addition, medicines left over from patients and those identified to be of defective quality may accumulate over time adding to the stock of unsafe medicines. The resulting stock piling of these unfit for use medicines is usually called medicines waste. The lack of safe handling and timely disposal of these products can be a threat to public health (E.Ejigu, H. Tadeg, N. Mekonnen, 2012).

The continued accumulation of medicines waste may create administrative burdens and can be a threat to the environmental and health of the public. Improper disposal may be hazardous if it leads to contamination of water supplies used by nearby communities or wildlife. Expired medicines may come into the hands of scavengers and children if a landfill is insecure. Pilfering from a stockpile of waste medicines or during sorting may result in expired medicines being diverted to the market for resale and misuse. Most medicines after expiry become less effective and a few may develop a different adverse drug reaction profile. In general the main sources of health risks as a result of medicines waste are contamination of drinking water, air pollution caused by release of toxic pollutants, endangered aquatic life due to non-biodegradable chemicals, and reuse of expired medicines (E.Ejigu, H. Tadeg, N. Mekonnen, 2012).

The Ethiopian situation is not different from the rest of the world and there are large volumes of medicines waste accumulation across the pharmaceutical supply chain. The lack of clear directives and guidelines has resulted in continued frustration to professionals at public and private health facilities as to what to do with the existing stock of unfit for use pharmaceuticals.

This has forced some health facilities to follow disposal practices that are hazardous to the environment and health of the public. Therefore, there was an urgent need for systems and policy directions to guide the management of medicines waste (E.Ejigu, H. Tadeg, N. Mekonnen, 2012).

Having acknowledged the challenges and risks involved, the USAID funded program, Strengthening Pharmaceuticals Systems (SPS) and its follow on Systems for Improved Access to Pharmaceuticals and Services (SIAPS), was requested by the mission to assist the government of Ethiopia in establishing systems for managing medicines waste disposal. Accordingly, SPS and its follow on SIAPS program provided financial and technical assistance to the Food, Medicines and Health Care Administration and Control Authority (FMHACA) of Ethiopia in developing such a system (E.Ejigu, H. Tadeg, N. Mekonnen, 2012).

Based on the mandate given to FMHACA through proclamation no. 661/2009, the collaborative effort resulted in the development of a medicines waste management and disposal directives. To guide the effective implementation of the directives, a national strategic framework on medicines waste management and disposal was developed.

The directive has acknowledged multiple feasible alternatives for managing medicines waste disposal including the private sector providing medicines waste disposal services, which was not allowed previously. The directive has also clearly outlined as to how safe disposal systems should be established and practiced in the country. The document is the first of its kind in Ethiopia providing a thorough guidance and direction on the management of medicines waste disposal (E.Ejigu, H. Tadeg, N. Mekonnen, 2012).

These policy documents were developed after a series of consultative workshops among the key stakeholders selected from different institutions including the Ethiopian Environment Protection Authority, Addis Ababa City Administration Solid Waste Management Agency, Pharmaceutical Fund and Supply Agency (PFSA), Federal Ministry of Health (FMOH), and Regional Health Bureaus (RHBs). Following its development and printing, FMHACA collaborated with SIAPS to hold five workshops in Bahir Dar, Hawassa, Adama (2 workshops for stakeholders from Oromia and Addis Ababa), and Mekele for the key regional stakeholders so as to familiarize them with the directive and facilitate its proper implementation (E.Ejigu, H. Tadeg, N. Mekonnen, 2012).

In the world there is a raising fear in the medical and environmental protection communities regarding the existing handling and disposal methods for pharmaceutical waste and other waste materials from health facilities and pharmaceuticals stores.

Proper pharmaceutical waste management is a highly difficult new leading edge in environmental management for healthcare facilities. It needs trained persons and equipments for collecting, treating and disposal of pharmaceutical wastes. Practically, however, pharmacists, nurses and store officers generally do not receive training on hazardous waste management during their academic studies and safety and environmental services managers may not be familiar with the active ingredients and formulations of pharmaceutical products (Practice Green Health, 2008).

2.3.2. WHO Guideline for Disposal Methods of Certain Pharmaceuticals

WHO guideline for the management of pharmaceuticals wastes advice on the implementation of safe disposal of unusable pharmaceuticals in emergencies and in countries in transition where official assistance and advice may not be available. They are not meant to replace local, regional or national laws regarding disposal of drugs, but to provide assistance where there is insufficient guidance or none at all. The WHO guidelines propose a number of marginally less safe treatments and disposal methods, which are however acceptable from the relative risk point of view, when balanced against the risks related to improper or non disposal.

In this section, the researcher tries to explore recommended or acceptable disposal methods of certain pharmaceuticals wastes in accordance with WHO guideline. The selected pharmaceuticals are; Solids, Semi-solids and Powders, Liquids, Anti-infective Drugs, Controlled substances, Antineoplastiscs, Disinfectants, Aerosol canisters (sprays and inhalers), PVC plastic, Glass, Paper, Cardboard, Medical equipment, beds, wheelchairs, Dressings, Clothing, Laboratory Glassware and Biodegradable Organic Material include liquid vitamins.

i Solids, Semi-solids and Powders

Small quantities of solid and semi-solid pharmaceuticals, typically not more than 1% of the total daily waste, can be disposed of directly in a landfill. Large quantities of solid and semi-solid pharmaceuticals are best destroyed by high temperature incineration.

Medium temperature incineration is however widely practiced for solid form pharmaceuticals, provided that the pharmaceuticals are diluted in large quantities of municipal waste. Many countries however do not have access to either high or medium temperature incineration plants, and the use of the encapsulation method represents an acceptable, but not always feasible, method of disposal for large quantities of pharmaceuticals. Powders can be disposed by Waste inertization or medium and high temperature incineration.

ii Liquids

Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer. Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed of in sewers.

Small quantities of other liquid pharmaceuticals, which are not controlled substances, anti infective drugs, or anti neoplastics, can be flushed into sewers. If there are no sewers or there is no functioning sewage treatment plant, liquid pharmaceuticals can be first diluted with large volumes of water and poured into large water courses, providing they are immediately dispersed and diluted by the flowing river water.

Liquid pharmaceutical waste may be disposed of using the cement encapsulation procedure, high temperature incineration or in cement kilns. It is not acceptable to discharge liquid pharmaceuticals, diluted or not, into slow moving or stagnant surface waters.

iii Anti-infective Drugs

Anti-infective drugs should not be discarded in an untreated form. Generally they are unstable and are best incinerated, and if that is not possible encapsulated or inertized. Liquid anti-infective drugs may be diluted in water, left for two weeks and disposed to the sewer.

iv Controlled Substances

Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

v Antineoplastiscs

Antineoplastic drugs, previously called cytotoxics or anti-cancer drugs have the ability to kill or stop growth of living cells. They are used in the chemotherapy of cancer which is usually performed in specialized treatment centres. Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. They should ideally be safely packaged and returned to the supplier for disposal. If this option is not possible they must be destroyed in a two chamber incinerator which operates at a high temperature of at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment. An after-burner (i.e. the secondary chamber) is important for the destruction of cytotoxic waste, as it is possible that antineoplastic solutions could become aerosolized following the initial combustion in the primary chamber.

vi Disinfectants

In general disinfectants do not have an expiry date. They can be stored and gradually used over time so there is no real need to dispose of them. Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage. Similarly large quantities should not be put into water courses since the disinfectants will damage aquatic life. Small quantities of diluted disinfectant may be disposed of by discharge to a sewer providing the operation is supervised by a pharmacist and the quantities are strictly controlled to set limits. The guideline control proposed is 50 litres total per day, with the disposal spread over the whole working day. If possible, disinfectants should be used, for example for toilet cleaning in hospitals. Some disinfectants with strong bactericidal and antiviral activity, such as Lysol (50% cresylic acid), may have an expiry date. If this date has past, the material can still be used for general disinfection purposes at an appropriate dilution decided by a pharmacist, or disposed of in a chemical waste disposal facility or a cement kiln. Many countries do not have chemical waste disposal facilities, so the materials may have to be shipped out of the country. However this is an expensive and complicated operation and should only be contemplated if there is no viable alternative.

vii Aerosol canisters (sprays and inhalers)

Disposable aerosol canisters and inhalers should not be burnt or incinerated, as high temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator. Provided they do not contain poisonous substances they should be disposed of in a landfill, dispersed among municipal solid wastes.

Finally PVC plastics and glass can be disposed in landfill not burned in an open container and paper and cardboard can be recycled or can be disposed by landfill or burning.

2.4. Identified Literature Gap

The study aimed to assess pharmaceutical waste management practice and its associate challenges in central and regional pharmaceutical fund and supply agency hubs. It is in the interest of the researcher that pharmaceutical waste management is not the only problems of health facilities but also pharmaceutical waste management is a crucial problem in PFSA and since health facilities are re-supplied by PFSA, problems related pharmaceutical waste management in PFSA is correlated with the health facilities. Therefore this study identified challenges of pharmaceutical waste management practice from the foundation and put an input for other researchers from which point they should start for further study on this aspect.

CHAPTER THREE
METHODOLOGIES OF THE STUDY

3.1. Study Area

This study was conducted in 10 central and regional stores of pharmaceutical fund supply agency (PFSA); which comprise Negelle Borena hub, Hawassa hub, Adama hub, Diredawa hub, Bahirdar hub, Jimma hub, Nekemet hub and Dessie hub from 01 to 31 May /2018.

3.2. Research Design

This study is a non-experimental and cross-sectional assessment utilizing quantitative (questionnaires) and qualitative (structured interviews) techniques of data collection at a definite time period from 01 to 31 May /2018. Hence the research design techniques are both quantitative and qualitative. Utilizing both approaches assists the researcher to get a full image and profound understanding of the investigated phenomenon by linking complementary findings to each other. Yin (2009, p. 64) states that a mixed research approach can enable the researcher to address either broader or more complicated research questions. In mixed research approach quantitative results are expressed in numerical and quantifiable terms, while qualitative results are expressed verbally in order to create an understanding of relationships or complex interactions.

3.3. Population

The source population constitutes of all professional employees of 10 selected central and regional PFSA hubs. The total number of population in the ten selected and regional PFSA hubs is 320(three hundred twenty).

3.4. Sample Size

This study is adopted purposive sampling to choose respondents for the interviews and questionnaires involving stock and distribution experts, storage main officers engaged in store handling and waste management and general service officers at central and regional PFSA store. 120 (one hundred twenty) respondents are chosen purposely on the basis of their direct relation in store handling and waste management in PFSA central and regional main hubs.

3.5. Methods of Data Collection

Two qualitative approaches, direct observation and structured interviews are conducted during the study period. Direct observation and physical verification are carried out, using validated WHO checklist for segregation, collection, storage and disposal of pharmaceutical waste (WHO, 1999). The existing waste management policy with respect to collection, storage, transportation and final disposal is evaluated. Information regarding staff strength, services available, quantities and waste type produced and profile of waste handlers is collected through administered questionnaires. In addition, structured interviews are conducted till the point of saturation. Principal investigator himself is con duct ten structured interviews, after taking the appointment and written consent. Respondents planned to be included is the main storage focal officer engaged in store handling and waste management at central and regional PFSA hubs.

3.6. Data Quality Management Plan

The data collection tool is pretested to ensure completeness and consistence of the data collection instrument. Training is given for the data collectors on how to approach to the facilities, and communicate the officials and how to record pertinent information. Regular as well on spot supervisors is carried out. Every day after data collection, each filled questionnaires is reviewed and checked for completeness, accuracy and clarity.

3.7. Data Analysis

The quantitative data generated is analyzed using SPSS software version 21.0 for windows. Descriptive statistics (frequencies, averages and percentages) is run to explore the data. The qualitative data is transformed into categories related to the topics that is discussed and coded on paper individually in order to identify themes and patterns for thematic analysis. Verbatim notes are taken and interviews were recorded, with permission. Data collected is transcribed and a thematic content analysis is done. Specific nodes were developed for the questions, and significant findings and responses is aggregated as sub nodes, which is later developed into themes. Information from literature and responses is then triangulate in the discussion section.

3.8. Ethical Consideration

The study is commenced after ethical clearance is obtained from ethical review committee of the school of commerce Addis Ababa University. The aims and purpose for conducting the study is explained and approval to conduct the study is also obtained from General Director of PFSA. During the study, all records are kept confidential such that each facility and key informants are identified only by a code. Otherwise, the name of respondents and other identifier is not written in the questionnaire.

3.9. Validity and Reliability Test

Validity is the degree to which a test measurement or other device measures what it is planned to measure. A data collection tool should accurately reveal the concept that it is planned to measure.

Reliability is the degree to which results are reliable over time and an exact depiction of the total population under study is refereed under a similar methodology then the research instrument is considered to be reliable (Joppe 2000).

To make sure validity and reliability of the instrument for data collection, the researcher, pre tested the instruments such as questionnaire and interview guided by doing a direct study with some of the respondents.

CHAPTER FOUR
RESULT, DISCUSSIONS AND INTERPRETATION

4.1 Introduction

The main objective of this study is to examine pharmaceuticals waste management practice and challenges in PFSA by taking a case of the main PFSA regional stores. In this regard, this chapter presents the results and findings of the study as collected from the sample population. The data is gathered exclusively from in-depth interview, observation and physical verification, and questionnaire as the research instrument. The data have been presented by tabulation, and some figures. The chapter covers respondents' general information based on demographic information and findings based on the research questions and objectives.

4.2. Quantitative Data Analysis

Informants are asked to rate their judgment about waste management practices at PFSA using self administered Questionnaire. Using descriptive statistics; frequency and percentage the responses are summarized and presented as follows by dividing the response of the informants to the questionnaire into sub sections.

4.2.1. Response Rate of the Respondents

For this study, the researcher chooses 120 respondents purposely on the basis of their direct relation in store handling and waste management in PFSA central and regional main stores.

Response Rate	Number of Respondents	Percentage
Responded	120	100%
Not Responded	-	-
Total	120	100%

Table 4.1: Response Rate of the Respondents

Table 4.1 shows a total of 120 respondents responded properly for given or prepared data collection formats in which the researcher dispensed individually for each respondents. Hence the response rate of the respondents is 100% (N=120).

4.2.2. Demographic Characteristics of the Respondents

In this section, the researcher analyzed and discussed demographic information of the respondents which are summarized on the tables here below and the frequencies and percentages are calculated and described.

Gender Composition of the Respondents

Gender compositions of the respondents are shown in the figure 4.1 below;

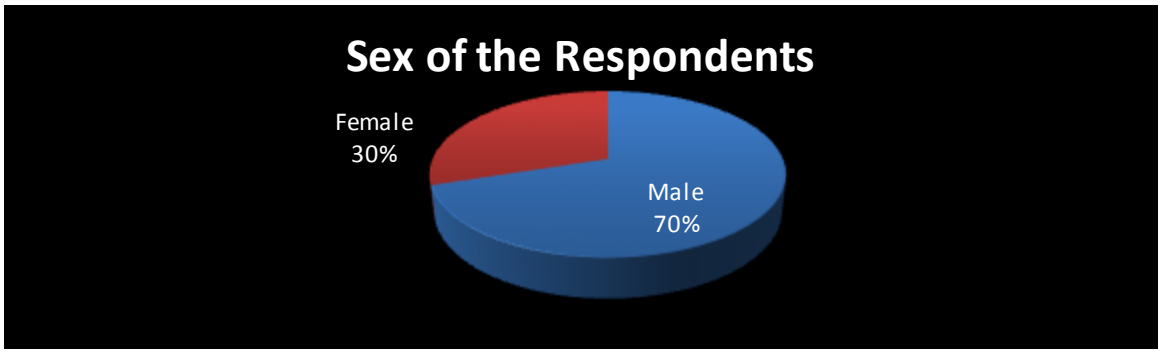

Figure 4.1: Gender Composition of Respondent

The result of figure 4.1 shows that, the majority of the respondents are male at 70% (N=84) while female are 30% (N=36).

Educational Background of the Respondents

The respondents are asked to show their highest attained education level as shown in Fig. 4.2

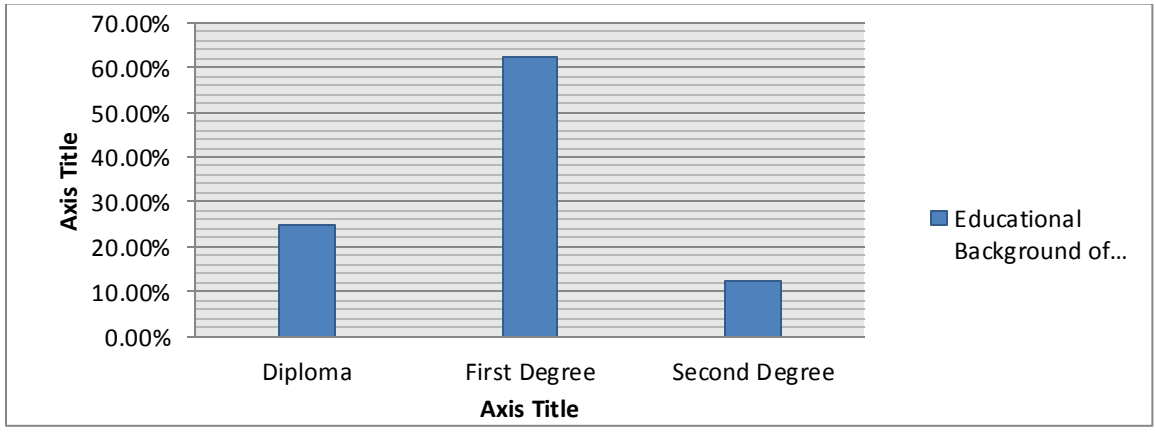

Figure 4.2: Educational Level Representation

Figure 4.2 shows that majority of the respondents 62.5% (N=75) attained their education up to degree level, 12.5% (N=15) of the respondents attained their education up to post graduate and 25% (N=30) attained their education up to diploma level. This means that majority of the respondents attained education up to university level and gained rich information and they are acquainted with the process, therefore they are appropriate for responding to our study questions.

Work Experience of the Respondents

PFSA was established in 2007 therefore the researcher only considers work experience of the respondents in this organization. The findings below in figure 4.3 indicates that majority of the respondents 52.5% (N=63) have been working in the organization for a period between 6 -11 years, 32.5% (N=39) have been working in the organization for a period between 3 -5 years and 15% (N=18) have been working in the organization for a period between 0 -2 years. Hence, based on their work experience results, it is evident that their work experience is efficient enough and therefore be valuable to the realization of the research objectives.

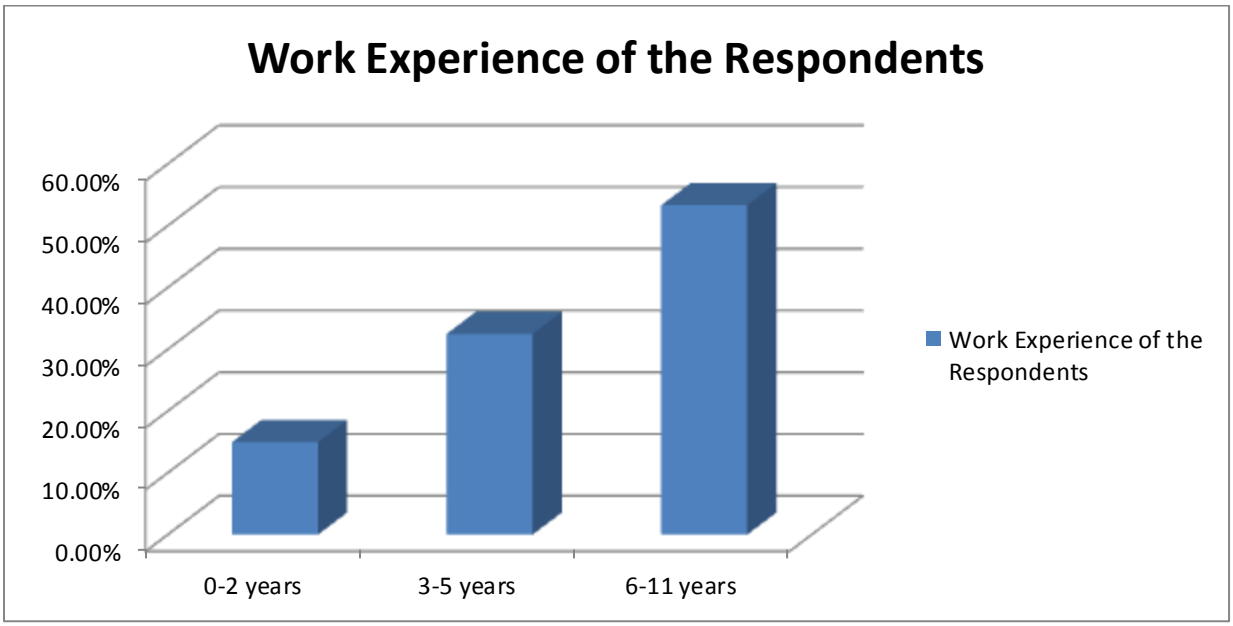

Figure 4.3: Work Experience of the Respondents

Work Position of the Respondents

The majority of the respondents as shown by table 4.2 are stock and distribution experts which comprise 33.33% (N=40), 16.67% (N=20) of the respondents are warehouse managers, 25% (N=30) of the respondents are general service officers and 25% (N=30) of the respondents are key experts. Therefore the majorities of the respondents' position are direct relation in store handling and waste management and are valuable for the realization of the objectives and the research questions of the study.

Positions of the Respondents	No. of Respondents	Percentage
Stock and Distribution Experts	40	33.33%
Warehouse Managers	20	16.67%
Human Resources and General Service Officers	30	25%
Key Experts	30	25%
Total	120	100%

Table 4.2: Work Position of the Respondents

4.2.3. Procedure of Handling Pharmaceuticals Wastes in PFSA Stores

Respondents rated the level of agreement on procedure of handling pharmaceuticals wastes in PFSA central and regional main stores by marking yes if they agree and No if they are not agree.

No	Parameters	Yes	NO
1	Waste items are sorted into categories that require different disposal methods.	93.33%	6.67%
2	Controlled substances, anti neo plastic drugs chemical waste and the radioactive waste are stored in separate; secure designated areas prior to safe disposal.	3.33%	96.67%
3	Unwanted pharmaceuticals are sorted into different categories by dosage form (capsules, powders, solutions, suppositories, syrups, tablets)	50.83%	59.17%
4	Optimum conditions for sorting are maintained (open or well ventilated area close to the stockpile in an orderly way and all sorted material clearly labeled and separated at all times.	30%	70%

Table 4.3: Respondents View on Procedure of Handling Pharmaceuticals Wastes in PFSA Stores

From table 4.3 above, the degree of sorting waste items into categories that require different disposal methods in central and regional PFSA stores is 93.33%, which is very high achievement. Whereas the level of storing Controlled substances (e.g. narcotics), anti neo plastic (cytotoxic-anti-cancer) drugs chemical waste and radioactive waste in separate and secure designated areas prior to safe disposal in central and regional PFSA stores is a very low achievement, which is 3.33%. While the extent of sorting unwanted pharmaceuticals into different categories by dosage forms (capsules, powders, solutions, suppositories, syrups, tablets) in PFSA stores is 50.83%, which is somewhat moderate. Finally the respondents rated on maintaining optimum conditions for sorting (open or well ventilated area close to the stockpile in an orderly way and all sorted material clearly labeled and separated at all times) in PFSA stores which is 30% level of achievement. Generally on the basis of respondents view, on average the achievement of PFSA central and regional stores in handling pharmaceuticals wastes using acceptable procedures is 44.37%.

4.2.4. Recruitment of Trained Waste Management Officers in PFSA Hubs

Pharmaceuticals wastes should Handle and dispose in appropriate way in order to avoid the danger of pharmaceuticals wastes to human beings and the environment. Pharmaceuticals stores should have responsible officers that control and mange pharmaceuticals wastes in day today routine work. In this sub section the researcher try to analyze the level of recruiting waste management officers by PFSA central and regional hubs. This is done on the basis of respondents view on the parameter of the questionnaire.

No.	Parameters	Yes	NO
1	Dedicated waste management officers are recruited?	0%	100%
2	The waste management officers are trained?	0%	100%

Table 4.4: Percentage of Perception of Respondents on Recruitment of Waste Management Officers in PFSA Central and Regional Hubs

Based on table 4.4 the level of recruiting waste management officers in central and regional PFSA hubs is 0% which is a very low performance.

4.2.5. Disposal Methods of Pharmaceuticals Wastes in PFSA Hubs

Environmentally sound management of Pharmaceuticals wastes involves taking all practical measures to protect both humans and the environment from the harmful effects of wastes. This involves strict control and special attention to the management of hazardous wastes which cannot be disposed just like any other waste. If these wastes are not properly disposed, they can gain entry into the environment where they may cause significant harm to the public. In this sub section the researcher try to explore findings on the basis of respondents' reaction to the parameters of the questionnaire on disposal methods of pharmaceutical wastes in PFSA central and regional stores.

No.	Parameters	Yes	NO
1	Waste is collected and transported by the sanitary workers/waste management workers in a simple trolley.	7.5%	92.5%
2	The sanitary workers/ waste management workers use personal protective equipment (PPE) such as gloves, long rubber boots, aprons and masks during waste collection.	10%	90%
3	Incinerators are present	0%	100%
4	Operating temperatures of current medical waste incinerators are efficient (>200^{o}C)	0%	0%

Table 4.5: Percentage of Perception of Respondents on Disposal Methods of Pharmaceuticals Wastes

Based on table 4.5 the level of utilizing simple trolley to collect and transport pharmaceuticals wastes and the level of utilizing personal protective equipment (PPE) such as gloves, long rubber boots, aprons and masks during waste collection by the sanitary workers or waste management workers in PFSA central and regional hubs are 7.5% and 10% respectively. And also the degree of availability of efficient Incinerators is 0%.

The finding shows that the level of utilizing common and acceptable disposal methods of pharmaceuticals wastes in PFSA central and regional hubs is very low. Lack of availability of Incinerators is a common problem for all PFSA hubs.

4.2.6. Availability of Documentation System of Waste Management in PFSA Hubs

Availability documentation system of waste management in waste generation and disposal is a very important tool for safe handling and disposal of pharmaceuticals wastes. The result of which presented in figure below, explore respondents' level of view in the availability of documentation system of waste management or PFSA hubs keeps records of waste generation and disposal.

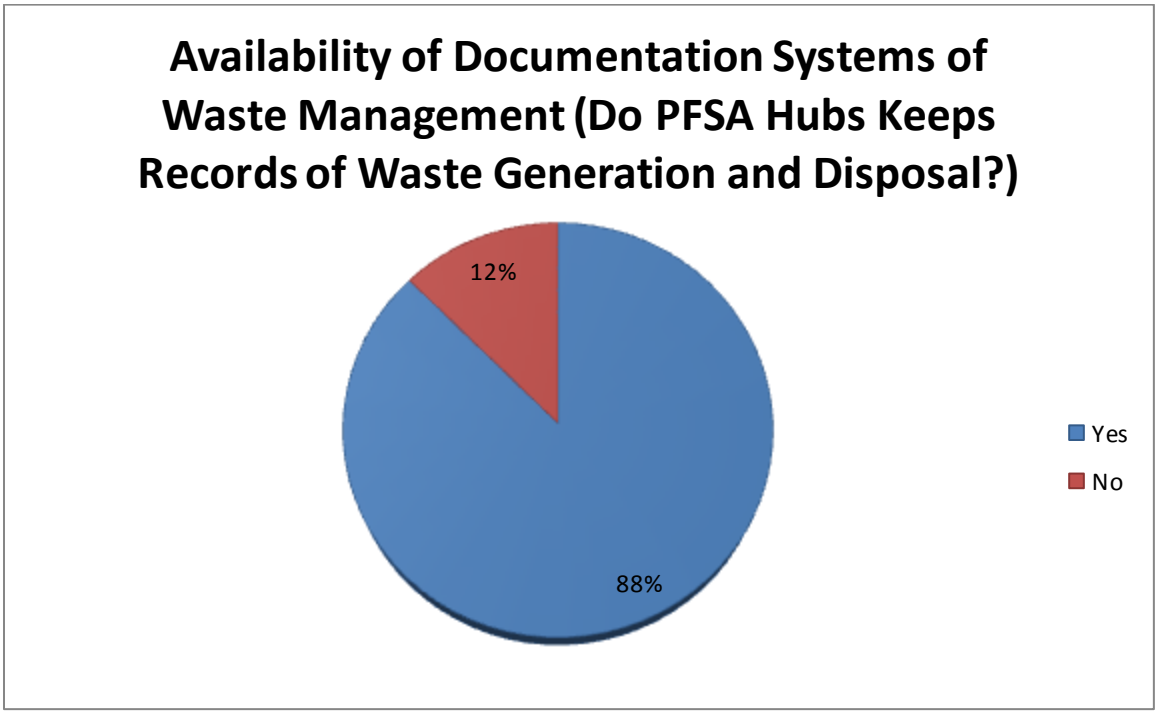

Figure 4.4: Availability of Documentation System of Waste Management in PFSA Hubs

From figure 4.4, the level of availability of documentation system of waste management or the degree of keeping records of waste generation and disposal in PFSA Central and regional hubs is 87%, which is high level of achievement.

4.2.7. The Level of Utilizing Recommended WHO Disposal Methods for Certain Pharmaceuticals by PFSA Hubs

In this sub section the researcher tries to rate respondents' view on the degree of utilizing WHO disposal methods in PFSA hubs for certain pharmaceuticals wastes mentioned above. The parameter to rate the degree of utilizing WHO disposal methods for certain pharmaceuticals says; **DO Disposal methods of the following pharmaceutical wastes are according to the standard/WHO guideline?**

No.	Pharmaceutical Types	Yes	NO
1	Solids, semi-solids and powders	70%	30%
2	Liquids	77.5%	22.5%
3	Ampoules	0%	100%
4	Anti-infective Drugs	0%	100%
5	Controlled Substances	0%	100%
6	Antineoplastiscs	0%	100%
7	Disinfectants	0%	100%
8	Aerosol canisters (Sprays and Inhalers)	0%	100%
9	PVC Plastic	27.5%	72.5%
10	Glass	16.67%	83.33%
11	Paper	6.67%	93.33%
12	Cardboard	20.83%	79.17%
13	Medical Equipment, Beds, Wheelchairs, Dressings, Clothing, Laboratory Glassware	0%	100%
14	Biodegradable organic material include liquid vitamins	0%	100%
Average		15.66%	84.34%

Table 4.6: Percentage of Perception of Respondents on Disposal Methods of Certain Pharmaceuticals Wastes in Accordance with WHO Guideline

Table 4.6 explores the level of utilizing WHO guideline for disposal of certain pharmaceuticals wastes. Based on respondents' view, the degree of utilizing WHO guideline for disposal of liquids is 77.5% which is the highest value and the level of utilizing WHO guideline for disposal of Ampoules, Anti-infective Drugs, Controlled Substances, Antineoplastiscs, Disinfectants, Aerosol canisters (Sprays and Inhalers), Medical Equipment, Beds, Wheelchairs, Dressings, Clothing, Laboratory Glassware and Biodegradable organic material include liquid vitamins is 0% which is the smallest value. And also the level of utilizing WHO guideline for disposal of Solids, semi-solids and powders, PVC Plastic, Glass, Paper and Cardboard are 70%, 27.5%, 16.67%, 6.67% and 20.83% respectively.

On average, the level of utilizing WHO guideline for disposal of pharmaceuticals wastes in PFSA hubs is 15.66%. From the result of the finding we can deduce that the PFSA hubs have very low performance in utilizing acceptable or safe disposal methods for pharmaceuticals wastes.

4.3. Qualitative Data Analysis

To triangulate some of the quantitative data with qualitative data, structured interview were conducted with 30 key experts of central and regional PFSA hubs. Data regarding about their perception on store and storage condition of pharmaceuticals in PFSA hubs, the current level of strength and limitation in storage practices in PFSA hubs, handling pharmaceutical wastes and its methods of disposal in PFSA hubs, common pharmaceutical wastes encountered in PFSA hubs, disposal methods of controlled pharmaceuticals in PFSA hubs in PFSA hubs, documentation system of waste management in PFSA hubs, conditions that facilitates for managing of pharmaceuticals waste in PFSA hubs, challenges or barriers or the strengths and limitations PFSA hubs encountered in handling and disposing pharmaceutical wastes and finally recommendations of interviewed respondents in improving the pharmaceuticals waste management.

The result is organized as follows;

4.3.1. Pharmaceuticals Stores and Storage Condition of PFSA Hubs

To assess pharmaceuticals stores and storage condition of PFSA hubs, 30 respondents were interviewed. These data have been analyzed by merging correlated questions and sectioning the

questions into coherent way in which the readers to understand easily. The first result of the interview is assessment of pharmaceutical store and storage condition giving emphasis on its strength and limitation with respect to the size and design of the store and handling of drugs and sanitation.

Almost all respondents pointed the following strengths on pharmaceutical stores and storage conditions of PFSA central and regional hubs; pharmaceuticals are arranged systematically (pharmacological/ alphabetical), cartons and pharmaceuticals are protected from water during all seasons, pharmaceuticals that need cold temperature are stored in a functional refrigerator, pharmaceuticals are protected from direct sunlight, pharmaceuticals are arranged so that identification labels are visible, pharmaceuticals area is visually free from harmful insects and rodents and pharmaceuticals are organized in a manner accessible for first-to expire, first-out (FEFO).

All the respondents remarked the following limitation on pharmaceutical stores and storage conditions of PFSA central and regional hubs; pharmaceutical stores are not standardized in terms of its size and design, storerooms are not in good condition (not clean, all trash not removed lack of strong shelves and organized boxes), lack of well trained store officers, lack of store equipments like pallets, trolley, fore -Clift and fire extinguisher, lack of enough storage place for pharmaceutical wastes and lack of separate places for controlled substances

4.3.2. Pharmaceutical Waste Handling Practices in PFSA Hubs

In this sub section the researcher tries to analyze the result of the interview of 30 respondents on pharmaceutical waste handling practices in PFSA hubs by giving emphasis on; pharmaceutical waste categories in the hubs, utilization of pharmaceutical waste management standard if any, Potential risk associated with wastes, for how long medicine wastes are kept in the PFSA facilities, pharmaceutical waste collection centers and having waste management officers.

The majority of the respondents mentioned the following pharmaceutical waste handling practices in PFSA hubs; most of the time wastes in PFSA hubs are categorized as pharmaceutical, supplies and reagents, there is no standard or policy implemented for waste management in PFSA hubs, the potential risk associated with wastes of PFSA hubs are environmental pollution, health impact on employees in PFSA hubs such as contamination and

loss of resources, wastes are kept in PFSA hubs for a year and more than a year, there is no separate and safe waste collection centers in PFSA hubs all PFSA hubs have no well trained waste management officers

4.3.3. Methods of Pharmaceuticals Waste Disposal in PFSA Hubs

In this part, the researcher tries to explore the results of 4 questions of the interview from the respondents on methods of pharmaceuticals waste disposal in PFSA Hubs by giving emphasis on the common types of pharmaceutical wastes encountered in PFSA hubs, commonly practiced techniques or methods of pharmaceutical waste disposal at PFSA stores, method of controlled pharmaceutical wastes disposal like narcotics, Anti neo plastic (cytotoxic-anti-cancer) drugs and radioactive wastes and Anti-infective, the efficiency of operating temperatures of current pharmaceutical waste incinerators in PFSA hubs and finally documentation system of waste management in PFSA hubs.

The majority of the respondents mentioned the following methods of pharmaceutical waste disposal in PFSA hubs; the most common types of pharmaceutical wastes encountered in PFSA hubs are pharmaceuticals, reagents and supplies, the most commonly practiced techniques or methods of pharmaceutical waste disposal at PFSA stores is burning in an open pits, wastes are not segregated into the different waste streams or categories and there is no a take back program to a supplier or a manufacturing company. The most challenges for this aspect is lack of experts in this aspect, lack of budget, lack of clear policy and manual and lack of enforcing regulation and body, in all PFSA hubs there is no special techniques for the disposal of controlled substance or all the hubs do not utilize acceptable methods outlined by WHO for the disposal of controlled substance like narcotics, Anti neo plastic (cytotoxic-anti-cancer) drugs and Radioactive wastes and Anti-infective, all PFSA hubs do not utilize incinerator for disposal of pharmaceutical wastes and pharmaceutical wastes are disposed in open pit and open air and in all PFSA hubs documentation system of waste management is applied that means records are available for disposed pharmaceutical wastes.

4.3.4. Barriers in Handling and Disposing Pharmaceutical Wastes

On the basis of the interview result of the respondents, the study looked into barriers in handling and disposing pharmaceutical wastes in PFSA hubs, results of which have been summarized below.

The main challenges remarked by the respondents in handling and disposing pharmaceutical wastes are; lack of well educated and well trained human resources that are needed for handling and disposing pharmaceutical wastes, lack of funds to train responsible staffs for the management of pharmaceutical wastes and to dispose pharmaceutical wastes in acceptable and recommended ways, standard operating manuals are not implemented for handling and disposal of pharmaceutical wastes, pharmaceutical waste disposal methods are not aligned with the environmental strategy of the country and lack of proper national policy that enforce the management of pharmaceutical wastes.

4.3.5. Respondents Recommended Points on Conditions that Facilitates for Managing Pharmaceutical Wastes

The Interviewed respondents are recommended the following key points or activities that should be done by the responsible stake holders on conditions that facilitates for managing pharmaceutical wastes; minimizing wastage rate by identifying the main factors that lead unwanted pharmaceuticals, recruiting responsible waste management officers for PFSA hubs, preparing enough and separate spaces for pharmaceutical wastes, provide training for concerned staffs who are responsible for the management of pharmaceutical wastes, there should be national policy enforcement and regulations for management of pharmaceutical wastes and PFSA hubs should have adequate and efficient incinerators.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1. Introduction

This chapter presents conclusions and recommendations pertaining to the study. Results and Discussions in chapter four created the source for these conclusions and recommendations for the way forward in addressing the problem of pharmaceutical waste management practices in PFSA central and regional hubs.

5.2. Summary

This study critically examines pharmaceutical waste management practices of central and regional hubs of pharmaceutical fund and supply agency in Ethiopia and identified key challenges or barriers in managing pharmaceutical wastes; these include lack of standardized pharmaceutical stores and storage condition, lack of utilizing appropriate or acceptable methods in handling and disposing pharmaceutical wastes, lack of well trained pharmaceutical waste management officers, lack of professional trainings in pharmaceutical waste management, lack of adequate store equipments for waste disposal, unavailability of efficient incinerators, Standard operating manuals are not implemented for handling and disposal of pharmaceutical wastes, inadequate participation of responsible stake holders for the management of pharmaceutical wastes, unavailability of pharmaceutical waste take back program to a supplier or a manufacturing company, lack of budget for the disposal of pharmaceutical waste and lastly inadequate government policy enforcement.

5.3. Conclusion

Advantages of pharmaceuticals to treat humans and animals must outweigh its disadvantages of polluting the environment in order to be considered valid for its cause. However, looking at the rate at which pollution from pharmaceutical waste is spreading across the globe there is a lot to be desired. In as much as all players involved are doing their best to mitigate the situation little has been done in focusing about the future trend of pollution arising from pharmaceutical waste.

This is partly due to lack of established policies, legislation, sources, handling, methods, testing standards and not forgetting the risks that await us now and in the near future.

In conclusion, if the sub divisions of pharmaceutical waste management can efficiently work back to back, environmental pollution and dangers to human health can reduce significantly today and in the years to come. Failure to efficiently work in one policy or one portion of pharmaceutical waste management leads to the declaration of the entire pharmaceutical waste management process redundant. Managing disposal of pharmaceutical wastes at pharmaceutical store is highly associated with overwhelming challenges that cannot be sorted out by just one stake holder but rather all stake holders involved in the pharmaceutical supply chain such as PFSA, public health facilities, FMHACA (Food, Medicines and Health care Administration and Control Authority), donors, the Federal Ministry of Health, health bureaus from regional to Woreda level at large.

5.4. Recommendations

Based on the key challenges which are identified by this study, the following points are recommended;

- PFSA should coordinate and facilitate training of pharmaceuticals store personnel with emphasis on handling and disposal procedures of pharmaceutical wastes and find out the way to have adequate and efficient incinerators.
- PFSA should upgrade the existed pharmaceuticals stores to acceptable and recommended standard level.
- All higher managements and experts of PFSA central and regional hub should conduct supportive supervision and inspection to enforce the implementation of standard operating manuals in handling and disposing pharmaceutical wastes.
- PFSA should organize a campaign for pharmaceutical waste disposal by mobilizing financial, material and technical resources from FMOH, FMHACA, PFSA, donors, importer, exporter and environmental protection agencies.
- Adequate and reliable information with regard to the volume and type of pharmaceutical waste accumulated has to be made available to make informed decisions on subsequent

- interventions. The information will help concerned bodies to allocate budget for safe disposal practices.
- PFSA should prepare proper pharmaceutical waste disposal sites by close contact with federal, regional, Zonal and Woreda government administrations.
- PFSA should conduct studies on the extent and its associated risks in handling and disposing pharmaceutical wastes to enhance and strengthen national policy enforcement in handling and disposing pharmaceutical wastes.
- PFSA should conduct studies in order to bring good experiences from other countries on handling and disposing pharmaceutical wastes with the available resources.
- PFSA should use automated or computerized recording system for the documentation of pharmaceutical wastes.
- PFSA should organize meeting with community leaders and government officials in order create awareness about the practice and challenges of pharmaceutical waste handling and disposal methods used by PFSA to protect environmental and human life.

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ANNEX

Annex 1: Dissemination Plan

The results obtained from this study will be presented to the staff of the school of Commerce, Addis Ababa University. In addition to this, attempts will be made to publish the findings of this study to scientific journal. The final (report paper) will be submitted and finding will be communicated with PFSA and other concerned bodies. The study result will also be presented in the annual scientific conferences of health professional associations'.

Annex 2: Data Collection Formats

<<Assessment of the Pharmaceutical Waste Management Practice and Challenges in PFSA>>

Name: _____ **Sex:** $(Male)$_____ $(Female)$_____

Educational Level: $(Second\ Degree)$_____ $(First\ Degree)$___ $(Diploma)$___

Work Experience in the Organization: _____

Current Position in the Organization: _____

PFSA Hub: _____

Telephone/Mobile_____

Put × or √ Mark for your Level of Agreement for Each Questions

1=Yes, 2= No

Questionnaire Guide (English Version)

No.	Parameters	1	2
1	Waste items are sorted into categories that require different disposal methods.		
2	Controlled substances (e.g. narcotics), anti neoplastic (cytotoxic-anti-cancer) drugs chemical waste and the radioactive waste are stored in separate, secure designated areas prior to their separate, safe disposal.		
3	Unwanted pharmaceuticals are sorted into different categories by dosage form (capsules, powders, solutions, suppositories, syrups, tablets)		
4	Optimum conditions for sorting are maintained (the open or in a well ventilated, close to the stockpile in an orderly way, with all sorted material clearly labeled and separated at all times.		
5	Dedicated waste management officers are recruited?		
6	The waste management officers are trained?		
7	Waste is collected and transported by the sanitary workers/waste management workers in a simple trolley.		
8	The sanitary workers/ waste management workers use personal protective equipment (PPE) such as gloves, long rubber boots, aprons and masks during waste collection.		

9	Availability documentation system of waste management (Do PFSA hubs keep records of waste generation and disposal?)		
10	Incinerators are present		
11	Operating temperatures of current medical waste incinerators are efficient (>200^{o}C)		
12	**Disposal methods of the following pharmaceutical wastes are according to the standard/WHO guideline**		
	Solids, semi-solids and powders		
	Liquids		
	Ampoules		
	Anti-infective drugs		
	Controlled substances		
	Antineoplastiscs		
	Disinfectants		
	Aerosol canisters (sprays and inhalers)		
	PVC plastic		
	Glass		
	Paper,		
	Cardboard		
	Medical equipment, beds, wheelchairs, dressings, clothing, laboratory glassware		
	Biodegradable organic material include liquid vitamins		

<<Assessment of the Pharmaceutical Waste Management Practice and Challenges in PFSA>>

Interview Guide (English Version)

1. How do you assess the pharmaceutical store and storage condition giving emphasis to the strengths and limitations?

Probing: With respect to:

a. The size and design of the store

b. Handling of drugs and sanitation

2. What facilitates for the current level of strength in the storage and storage practice in the facility and what barriers have you encountered?

3. How do you assess the medicine waste handling and disposal in the facility?

Probing: giving emphasis to:

(a). pharmaceutical waste categories in your facility

(b). with respect to using Medicine waste standard if any? Do you have policy or a standard on pharmaceutical waste management?

(c) Potential risk associated with wastes?

(d) For how long medicine wastes are kept in the PFSA facilities?

(e) Are there any dedicated collection centers? (How are wastes dumped?)

(f) Do you have waste management officers?(If No, why?, if yes, are they trained?)

4. What are the common types of pharmaceutical wastes encountered? What are the techniques (methods) of pharmaceutical waste disposal at PFSA stores commonly practiced? (Dumping into municipal dump sites, burying, incineration, burn waste in open pits, Return to donor or manufacturer/ Landfill/ Waste immobilization: encapsulation/ Waste immobilization: inertization/ Sewer/ Burning in open containers/ Medium temperature incineration/ Novel high temperature incineration/ Chemical decomposition, etc)

Probing: a. Are wastes segregated into the different waste streams/categories?

b. Do you have a take back program to a supplier or a manufacturing company?

c. What are the challenges in this aspect?

5. How do you dispose controlled pharmaceutical wastes?

Probing: narcotics

Anti neo plastic (cytotoxic-anti-cancer) drugs and

Radioactive wastes
Anti-infective

6. What is the efficiency of operating temperatures of current pharmaceutical waste incinerators you use? What is the implication?

7. Do you keep records of waste generation and disposal?(i.e., documentation system of waste management?

8. What conditions facilitates for managing of pharmaceutical waste?

9. What challenges /barriers or the strengths and limitations have you encountered in handling disposing pharmaceutical wastes? (How do you see the burden of the waste in your facility and at country level at large?

Probing: With respect to:

a. Human resource challenge?
b. Cost issue?
c. Training
d. National/policy strategy?

10. What is your recommendation in improving the pharmaceutical waste management?

Annex 3: Questionnaires Result

120 Respondents Reactions to 26 Questions of the Questionnaire (1=Yes, 2=No)

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