MANAGING DISPOSAL OF UNWANTED PHARMACEUTICALS AT HEALTH FACILITIES IN TANZANIA. A CASE OF DAR ES SALAAM REGION PUBLIC HEALTH FACILITIES.

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By

Damas Matiko

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences.

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CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled "**Managing Disposal of Unwanted Pharmaceuticals at Health Facilities in Tanzania. A case of Dar Es Salaam Region Public Health Facilities"** in partial fulfillment of the requirements for the MSc Degree (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences.

……

Dr. Kagashe, G. A.

Supervisor

Date ……

DECLARATION AND COPYRIGHT

I, **DAMAS MATIKO**, declare that I am the sole author of this **Dissertation** as my own original research work, and that it has not been presented and it will not be presented to any other University for the similar or any other degree award; and where other people's research was used, they have been dully acknowledged.

Signature…… Date ……...

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DEDICATION

This dissertation is dedicated to my parents; mother Mgosi M. Nyang'anyi and father the Late Dr. M. Nyang'anyi and my daughters Charity & Michelle. I love you all.

ABSTRACT

Background: In the public sector medicines are the property of the state, for which strict accounting procedures to write-off the unwanted pharmaceutical stock are necessary (Public Finance Act & Regulations, 2004). This applies both to medicines that are procured through the normal channels and to donated medicines. For quite a long time, disposal of unwanted medicines e.g. especially expired pharmaceuticals in the country has not been done systematically and professionally due to a number of factors that are yet to be clearly explained. This has resulted to accumulation of unwanted medicines in health facilities and medicines outlets in the country.

Objectives: The study examined current pharmaceutical disposal practices and identified challenges encountered in the safe disposal of unwanted pharmaceuticals in Tanzania.

Methodology: The study was a descriptive cross sectional survey. Data were collected through interview of medicines store in-charges/pharmacists from a sample of 63 selected health facilities on relevant issues with regard to safe disposal of unwanted pharmaceuticals. Furthermore the investigator reviewed records of previously disposed pharmaceuticals and those of unwanted medicines stock that is awaiting disposal.

Results: Most of the public health facilities' pharmacy stores personnel (73.4%) were non-pharmaceutical professionals hence have inadequate essential pharmaceutical management skills and low knowledge (34%) hence leading to poor handling of unwanted medicines. Since medicines in public health facilities are public properties thus are treated just like other properties like vehicles in their write –off and disposal procedures as per Public Finance Act & Regulations, 2004. Main disposal methods for unwanted drugs from the surveyed health facilities comprised of crushing and burying (72.4%) at the Dar es Salaam dumpsite open burning (31.0%) at the dumpsite, though not advisable under TFDA Guidelines for safe disposal, and incineration (37.9%); this is attributable to inadequate enforcement by TFDA.

Conclusions and Recommendations: Managing disposal of unwanted medicines at public health facilities is highly associated with a number daunting challenges such as inadequate enforcement by TFDA, legal constraints (public Finance Act & Regulations, 2004); long procurement procedures at MSD, donation medicines (with short expiries) prescribing patterns (brand names prescriptions) and inadequate number of pharmaceutical staff. It is recommended that TFDA should now increase efforts such as frequent inspections at public facilities; facilities should only receive donations having 6 months shelf life remaining upon arrival in the country; and the MOHSW should enforces generic drugs prescribing as well as strengthen its efforts of ensuring that staffs of pharmaceutical cadre increase with the demand of service provisions.

Acronyms

ALu	-	Arthemether/Lumefantrine
CPD	-	Continuing Professional Development
EE2	-	17α-ethinylestradiol
HF	-	Health Facility
HCW	-	Healthcare Waste
ILS	-	Integrated Logistic System
MW	–	Medical Waste
MWM	–	Medical Waste Management
WWTP	-	Wastewater Treatment Plants
MOHSW	-	Ministry of Health and Social Welfare
MSD	-	Medical Stores Department
MSH	-	Management Sciences for Health
PhACs	-	Pharmaceutically Active Compounds
STG	-	Standard Treatment Guidelines
SP	-	Sulfadoxine and Pyrimethamine
TFDA	-	Tanzania Food and Medicines Authority
UNEP	-	United Nations Environment Program
WHO	-	World Health Organization

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Definitions of Terms

A drug, medicine or pharmaceutical product means any substance or mixture of substances manufactured, sold or presented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof , in man or animal. (*Note*: *the three terms have been used interchangeably in the entire document*)

Unwanted pharmaceuticals/Pharmaceutical waste: For the purpose of this study, unwanted pharmaceuticals (Pharmaceutical waste) included all expired, unusable, damaged, improperly handled cold chain (e.g. vaccines), improperly sealed and wrongly labeled medicines.

Healthcare Waste (HCW) (including unwanted pharmaceuticals) is defined as all the waste hazardous or not, generated by health institutions during medical activities, clinical trials, research, preventive, curative and/or diagnostic.

Healthcare Waste Management (HCWM): Entail all activities that lead to proper and safe disposal of waste produced from health facilities.

Medical Waste: any waste generated in the diagnosis, treatment, or immunization of human beings or animals, related to research, production or testing of biologicals from all types of healthcare institutions, including hospitals, clinics, dental or veterinary and medical laboratories.

Health facilities (HF): These refer to all healthcare delivery institutions registered and recognized by the Ministry of Health and Social Welfare (MOHSW); they include hospitals, medical and dental clinics, health centres and dispensaries.

Improper Disposal: Usually means disposing medicines in the garbage, indiscriminate throwaway to unauthorized dumpsites in neighbourhoods or even flushing pharmaceuticals down the toilet, whereby they enter the sewage stream.

Medicines Disposal: This entails the procedures by which unwanted medicines are safely handled, professionally and terminally discarded as per relevant national laws and regulatory frameworks.

Medicines Stores Supervisors: Personnel charged with supervision of the health facility medicines stores as their main responsibilities on daily basis.

CHAPTER ONE

INTRODUCTION

1.0 Background

1.1 Structure of National Health & Pharmaceutical System in Tanzania

The healthcare system in Tanzania has two major components; the public and the private sector. The public share is 56%; the private share is 44% (which includes Faith Based Organizations (FBOs) 30% and private for profit 14 %). The system works at four levels; the community, the ward where there is a dispensary and a health centre at the division level. As one moves further there is the district and regional hospitals at district and regional levels respectively whereas at the zonal and national levels, are the consultant/ referral hospitals (MOHSW, 2008)

Currently in Tanzania there are a total of 5,379 health facilities geographically distributed so that 70% of the population is within 5 km of a facility and 90% is within 10 km as at the end of 2005 *(Second Health Sector Strategic Plan - MOHSW, July 2003-June 2008, April 2003*). Administratively, the health system is largely decentralized. The MOHSW has direct responsibility for the referral and regional hospitals, and regulatory power over all health facilities. The district facilities are independently run by the Prime Minister's Office Regional Administration and Local Government (PORALG). Dar es Salaam City alone is estimated to have 92 public health facilities (MOHSW, 2008) of which 37 are in Kinondoni municipality, 26 and 29 are located in Temeke and Ilala respectively including both Muhimbili National Hospital and Ocean Road Cancer Institute.

1.2 Pharmaceutical Services Provision Nationwide

Provision of medicines and medical supplies in Tanzania is through the public non-for-profit system (56%) and private sector (44%). All public facilities receive their supply shares by either using allocated financial budgets or draw supplies for use against established budget sealings. The total medicine budget disbursed for the public sector for the year 2000, 2001 and 2002 and 2007 in US$ was 14.1million, 16.2 million, 18.3 million, 28.5million respectively. It can be deduced that for the 7 years interval the budget has almost been doubled (MOHSW, 2008).

Baseline Survey of the Pharmaceutical Sector in Tanzania (MOHSW & WHO, 2002) indicates that 13% of medicines distributed to health facilities become expired before reaching patients. Converting this figure into monetary terms of the total national medicines procurement budget, one can easily tell how financial resources are lost. In-depth Assessment of the Medicines Supply System in Tanzania Report (MOHSW, 2008) shows the amount of medicines and other medical supplies that expired in 2006 at the Central Medical Store were 3.7% of sales for the year whereas percentage of the products that expired at the Zonal Medical Stores mainly Mwanza, Mbeya and Moshi varied from 0.02-6% of annual sales for the year.

1.3 Legal and Regulatory Frameworks of Pharmaceuticals in Tanzania

In the public sector medicines are the property of the state, for which strict accounting procedures to write-off the pharmaceutical stock are necessary *(Public Finance Act & Regulations, 2004)*. Such procedures tend to be complicated and time-consuming, and in practice the disposal of unwanted medicines stock is difficult. This applies both to medicines that are procured through the normal channels and to donated medicines.

For quite a long time, disposal of unwanted medicines in the country has not been done systematically and professionally due to a number of factors that are yet to be clearly explained. This has resulted to accumulation of unwanted medicines in health facilities and medicines outlets in the country. The accumulation of these products might have been mainly contributed by lack of adequate knowledge on procedure for safe disposal of unwanted medicines among the health professionals serving in these health facilities.

Tanzania Food and Medicines Authority (TFDA) Guidelines for Safe Disposal of Pharmaceuticals stipulates that improper disposal of unwanted medicines is hazardous as it can lead to contamination of water supplies or local sources used by nearby communities or wildlife. Unwanted 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 unwanted medicines being diverted to the market for resale and misuse. Defective medicines disposal practices carry a public health risk. The main

health risks stipulated in these guidelines (i.e WHO, 1999 & TFDA, 2009) include;

a) Contamination of drinking water.
b) Non-biodegradable antibiotics, antineoplastics and disinfectants may kill bacteria necessary for the treatment of sewage.
c) Burning medicines at low temperatures or in open containers results in release of toxic pollutants into the air which should ideally be avoided.
d) Inefficient and insecure unwanted medicines handling and sorting may allow medicines to be diverted for resale to the general public.

According to the TFDA Guidelines medicines are considered unwanted when they are expired, improperly sealed, damaged, improperly labeled, counterfeit, substandard and adulterated, prohibited or unauthorized

1.3.1 Various Procedures that Guide Handling and Disposal of Unwanted Medicines as Per TFDA Guidelines for Safe Disposal of Pharmaceuticals, 2009

1.3.1.1 Procedures for Handling of Unwanted Medicines at Health Facility level

In order to manage properly unwanted medicines at a facility level, the following requirements must be adhered to;

a) Maintain a register book for unwanted medicines
b) Keeping them into different categories by dosage (e.g. Solids, semi-solids, powders and liquids)
c) Keeping separately medicines which fall under controlled medicines, antineoplastics, antibiotics and any other hazardous medicines.
d) Keeping in containers according to their dosage forms to facilitate verification exercise, sorting and selection of disposal method.
e) Demarcating an area for keeping containers of unwanted medicines which shall be conspicuously labeled with words “Unwanted medicines– Not for Sale” or “Unwanted medicines – Not for sale” or “*Dawa hizi muda wake wa matumizi umekwisha – zisiuzwe” au “Dawa hizi hazifai kwa matumizi – zisiuzwe”* in red ink.

f) Maintaining safe custody of unwanted pharmaceutical products in registered premises until they are disposed off to avoid pilferage.

g) The decision of when to initiate disposal of unwanted medicines shall be made by owners of facilities, regional, district or hospital pharmacist, in-charges of facilities, dispensers, and inspectors (including inspectors at ports of entry) to avoid accumulation of such products.

h) Application for disposal of unwanted medicines from Government institutions shall be accompanied by an approval from Accountant General declaring that the products have been written off and that are subject to disposal as required by law under Section 256 of the Public Finance Regulations, 2004.

1.3.1.2 Procedures for Application to Dispose of Unwanted Medicines.

Any person who intends to dispose of unwanted medicines shall adhere to the following procedures:

a) Request in writing to the Director General of TFDA by using application form which is available at TFDA headquarter offices, TFDA zone offices, Regional and District Medical officer's offices and TFDA website: www.tfda.ac.tz.

b) And that the request shall be accompanied with a list of products to be disposed of and should state clearly trade name, generic name and strength (where applicable), dosage form, pack size, quantity, manufacturer, batch number and market value of product.

c) Finally TFDA-HQ or TFDA zone office/Regional/District Medical officer's offices shall send inspectors to the premises to verify and authenticate the information submitted.

1.3.1.3 Sorting, Verification and Disposal Methods as Stipulated in the TFDA Guidelines

During verification exercise, the TFDA medicines inspector supervises sorting exercise of unwanted medicines before determination of disposal method. Some of the examples of category of products and their recommended disposal methods are highlighted on the table 1.3.1.3 below as per TFDA Disposal guidelines:

Table 1.3.1.3 Disposal Methods as Stipulated in the TFDA Guidelines

S/N	Medicines Category	Disposal methods
1.	Solids, semi-solids and powders	Landfill, incineration and waste Immobilization
2.	Liquids	Sewer, high temperature incineration and treated waste
3	Antineoplastics	Treated waste and landfill, high temperature incineration and return to manufacturer
4.	Controlled medicines	Treated waste and landfill, high temperature incineration
5.	Aerosols and inhalers	Landfill without waste inertization
6.	Disinfectants	Sewer or fast-flowing watercourse
7.	PVC plastics, glass (ampoules, bottles and vials)	Landfill and re-cycling
8.	Paper, cardboard	Recycle, burn, landfill

Sorting should be done in an open or in a well ventilated area/building as close as possible to the stock pile in an orderly manner. After verification exercise is completed, a verification form is filled and signed by both parties. Verification process involves the following stages:

a) Identification of the product.

b) Separating medicines which fall under controlled medicines, antineoplastics, antibiotics and any other hazardous medicinal or cosmetic products.

c) Sorting according to disposal Methods

d) Staff involved in sorting exercise shall be provided with protective gears such as gloves, boots, overalls and dust masks and shall be briefed on the sorting exercise, health and safety risks associated with handling the materials.

e) Sorted medicines must be carefully packed into steel drums or cardboard boxes or jute bags and information to be indicated outside the container should include; dosage form(s) and proposed mode of destruction. The materials should be kept in a dry secure and preferably separate room to

avoid being confused with in–date medicines or cosmetics until disposal is carried out.

f) After verification the applicant is informed by either TFDA-HQ or TFDA zone office, Regional or District Authorities through a letter on the proposed mode of destruction and is directed to arrange with the respective local authority e.g Municipal/ District Medical Officer/ Pharmacist to locate a disposal site, cost and date of destruction.

g) The cost of destruction is born by the owner of the product as stipulated under Section 99 of Tanzania Food, Medicines and Cosmetics Act of 2003

1.4 Problem Statement

Effective and proper storage of unwanted pharmaceuticals at health facilities (HF) coupled with their proper disposal is integral part of Good Distribution and Storage Practices (TFDA- *Guidelines for Good Distribution Practices for pharmaceuticals*, 2009; WHO-*Guide to Good Storage Practices for Pharmaceuticals,* 2003) in order to avoid risks that may be associated with unwanted medicines as described in section 1.3 above.

Administrative, legal and regulatory procedures as described in subsections 1.3.1.1 - 1.3.1.3 concerning safe disposal of pharmaceuticals in Tanzania are in place but the main problem is that yet unwanted medicines particularly the expired pharmaceuticals in public health facilities are improperly disposed. In some cases unwanted medicines are not timely disposed hence tend to accumulate to the extent that they constrain storage spaces available for the incoming subsequent consignments. From this perspective, the magnitude and underlying causes of the problem are not known, hence calling for this study to establish reasons for the problem as explained in chapter four.

1.5 Research Questions

The following questions were considered relevant to the study;

a) Which pharmaceutical disposal methods/practices and destruction sites/facilities are used by public health facilities?
b) Is there a problem in managing disposal of unwanted pharmaceuticals?
c) Are there any legal and regulatory framework constraints that impede effective and proper disposal of unwanted pharmaceuticals in the country?
d) Are health personnel in charge of medicines store at public health facilities knowledgeable on proper disposal procedures of unwanted medicines as stipulated in TFDA Guidelines for safe disposal of unwanted medicines?

1.6 Study Objectives.

1.6.1 Broad Objectives.

To assess practices and challenges encountered in managing disposal of unwanted pharmaceuticals at public health facilities in Dar es Salaam.

1.6.2 Specific Objectives

a) To determine medicines disposal methods/practices and destruction sites/facilities used by health facilities in Dar es Salaam.
b) To collect pharmaceutical waste data and previous disposal records maintained at various health facilities.
c) To identify constraints existing in the legal and regulatory framework that hinder proper disposal of pharmaceuticals.
d) To determine the level of knowledge of health staff involved in the daily management of pharmaceutical stores at health facilities on the safe disposal procedures of unwanted medicines.

1.7 Rationale of the Study

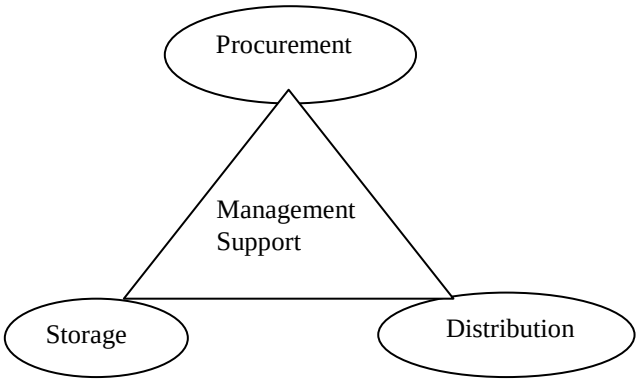
The study added new and relevant knowledge to the available collection of literature on safe disposal of pharmaceuticals. Further it fits well within the current global trend of environmental problems. The study provided valuable information for local health policy makers, Medicines Regulatory Authority, dealers, health services providers, donors and all other stakeholders involved in medicines sector to effectively plan, manage and supervise safe disposal of pharmaceuticals.

1.8 Conceptual Framework

1.8.1 Medicines Supply System for the Public Health Facilities in Tanzania.

In Tanzania Mainland the supply system employs Autonomous Supply Agency (i.e Medical Stores Department/MSD) which is a semi-autonomous institution under the Ministry of Health and Social welfare whose functions include all the activities in the medicines supply management cycle except dispensing/use (MSD Act No, 13, 1993). This ranges from the selection of a list of medicines for its catalog from the National Essential Medicines List (NEML), to procurement, storage and distribution to its customers (fig. 1).

Figure 1.8.1 MSD main functions



MSD operates a self sustaining revolving medicines fund and its main customers are the Zonal Medical Stores (Dar es Salaam, Mwanza, Tabora, Dodoma, Kilimanjaro, Tanga, Iringa, Mtwara, and Mbeya), regional and district hospitals, health centres, dispensaries and Faith based health facilities (www.msd.or.tz, Tanzania Medical Directory, 2009/2010). The supply system of medicines at the health facility level involves four levels; from Central MSD Store, zonal MSD store to district and regional stores then eventually to primary health facilities (i.e health centres and dispensaries). Currently all

health facilities countrywide order their medicines through Integrated Logistics System (ILS) whereby each facility submits its required quantities of medicines according to needs and allocated budget for the period in question to zonal MSD stores.

During planning and budgeting quarters (i.e 3^{th} and 4^{th} quarters of each financial year) the primary health facilities channel their annual medicines requirements to the District Pharmacist who in turn performs reconciliation and compilation of all requirements from primary health facilities within the district and that of the district in question before forwarding them to the Zonal MSD store (Euro Health Group and MSH, 2007).

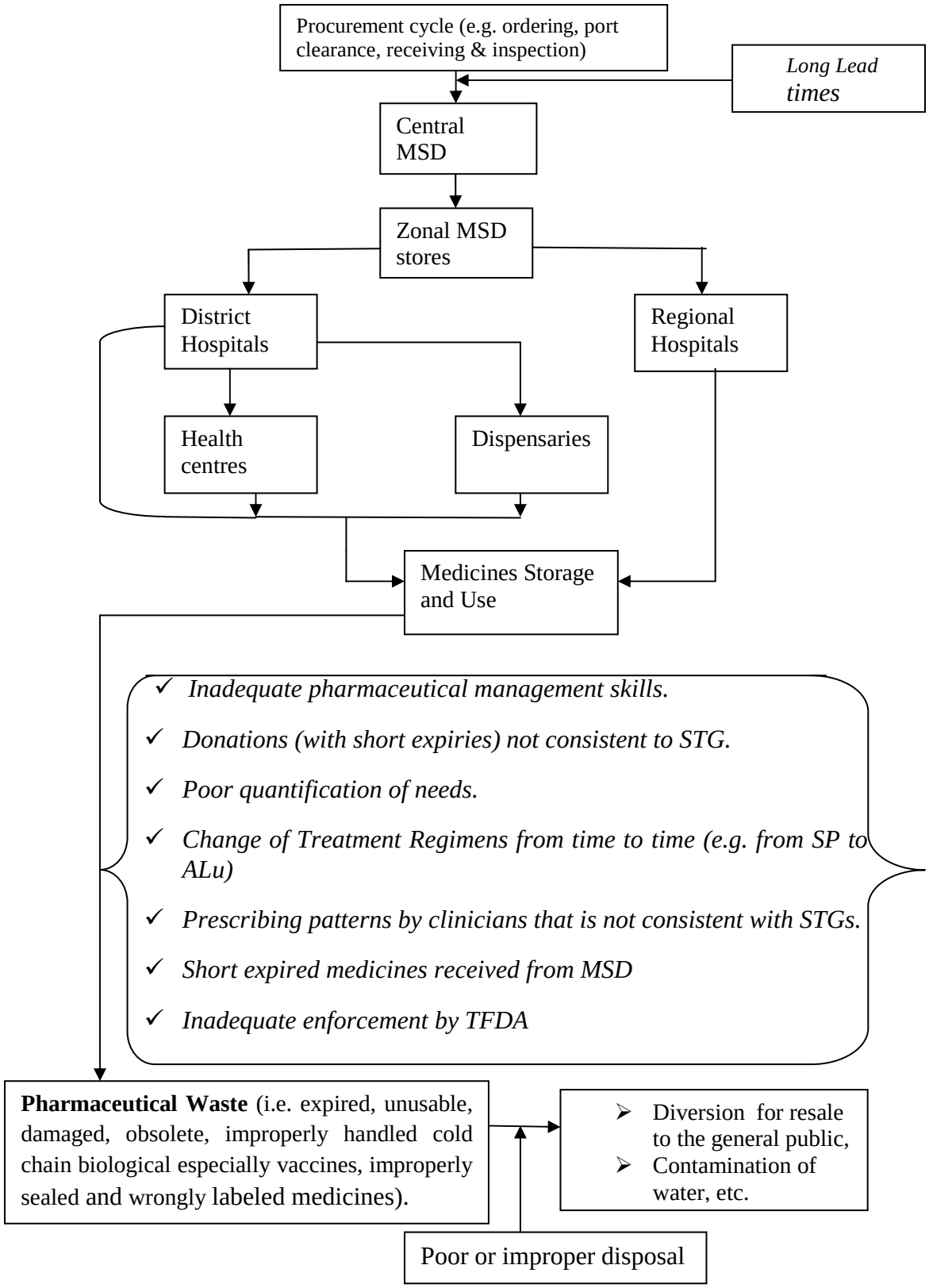
The District Pharmacist is accountable for ensuring that all the annual requirements are sent in time to MSD, timely delivery of medicines from MSD to district store and finally undertakes distribution logistics of the medicines to the respective facilities.
Likewise at Regional level the Regional Pharmacist is responsible for quantification of medicines requirements according to needs and availability of funds (ILS-model) for the regional hospital before forwarding the order to Zonal MSD.

1.8.2 Conceptual Model for Pharmaceutical Waste Generation in Tanzania.

This model tries (fig.1.8.2) to explain some major causes that may lead to pharmaceutical waste generation at the health facilities including the following;

a) *Long Lead Times for International Procurements.* In depth assessment of medicines supply system Report (MOHSW, 2008) showed most of the vertical programs medicines (e.g. Anti-retrovirals) and essential medicines are sourced from international suppliers and that the average lead times for such commodities to get into the country are 5-8 months by sea and 3-4 months by air plus other lengthy customs clearance procedures all of which may lead to late delivery of international consignments and eventually short expiries especially for medicines having short shelf lives e.g. Artemether/Lumefantrine (ALu).

Figure 1.8.2: Conceptual framework model for pharmaceutical waste generation in Tanzania



b) *Donations (with short expiries) and not consistent with Standard Treatment Guidelines (STG).* Most donated medicines reach recipients while having 10-20% of their shelf lives remaining and contain product categories which are not consistent with the STGs such that they also get expired before being prescribed and dispensed to the patients.

c) *Inadequate pharmaceutical management skills*. Skills such as inventory management and control, good storage practices and First Expired First Out (FEFO) protocol adherence are all integral part of pharmaceutical management skills which facilitate proper medicines management at health facility level. are not adhered to in many health facilities. For instance "First Expired, First Out" (FEFO) policy is not observed in most facilities. Expired or damaged or obsolete products are not immediately separated from the usable stock and disposed of, instead they pile up to the extent that there is no more space to store incoming stocks (MOHSW, 2008; Euro Health Group and MSH, 2007)).

d) Prescribing patterns by clinicians that is not consistent with STGs especially prescribing of brand names instead of generic names,

e) Poor quantification of needs.

f) Short expired medicines received from MSD.

g) *Change of Treatment Regimens* from time to time (e. g. change from SP to ALu). It should be known that whenever there is enough scientific evidence for treatment failures of some diseases worldwide, e.g. SP was the first line drug for treating Malaria but in 2007 the Government of Tanzania decided to change the Malaria treatment policy to ALu due to resistance to SP.

h) Inadequate enforcement by TFDA to ensure that all medicines are properly disposed of.

CHAPTER TWO

REVIEW OF LITERATURE

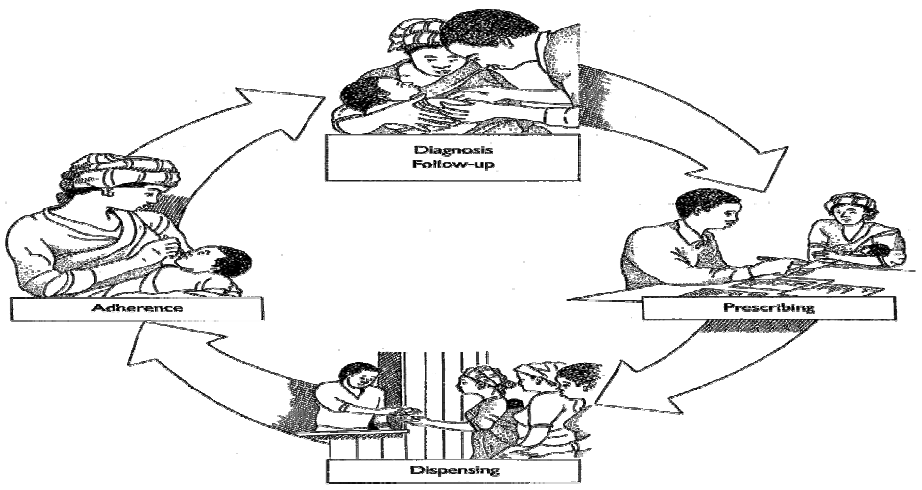
2.1 Introduction

This chapter reviews various empirical studies and literatures on effects, dangers and consequences brought about by improper disposal of unwanted pharmaceuticals in the environment. The chapter examines various studies and reports done both locally (Tanzania), Regionally (Africa) and globally. Besides this, the chapter also reviews the state of scientific understanding of Pharmaceuticals and their metabolites collectively known as pharmaceutically active compounds (PhACs) in the environment

Hospitals and other health facilities (HF) are responsible for the delivery of patient care services (fig. 2.1). In the process of delivering this healthcare, waste such as unwanted pharmaceuticals is generated. Safe management of healthcare waste may be achieved by ensuring care in dealing with such waste in terms of safe handling, segregation, packaging, storage, transport and terminal destruction and disposal in order to mitigate and minimize concerned health risks and eventually prevent environmental contamination as stipulated in various national waste management and environmental protection laws

Figure 2.1: Framework of medicines use process in health facilities

(Source: MSH, 1997)



2.2 Empirical Studies

2.2.1 Global Perspectives on Unwanted Pharmaceuticals

Pharmaceutical waste continually enter the environment as trace pollutants largely resulting from their intended use in human and veterinary medical practices, and personal care. The primary route is their unintentional and largely unavoidable release via excretion and bathing. A secondary route is purposeful disposal to sewerage and garbage of leftover, unwanted medications which also poses acute poisoning risks due to intentional or accidental diversion of unwanted medicines to others. Humans can be inadvertently and chronically exposed to trace residues of pharmaceuticals from the environment by consuming contaminated drinking water (Daughton, C.G, 2007).

Improper disposal of unwanted pharmaceuticals contributes to the loading of Pharmaceuticals and their metabolites collectively known as Pharmaceutically Active Compounds (PhACs) to the environment. (Greiner & Rönnefahrt, 2003) estimate that fraction of medicines which are disposed of rather than consumed range as high as 1/3. Contamination of groundwater by Pharmaceutically Active Compounds (PhACs) from landfill leachate has been documented by several researchers (Barnes et al., 2004; Eckel, Ross, & Isensee, 1993; Holm et al., 1995).

A survey of 91 health facilities in Southern Brazil (Da Silva et al, 2004) found that the medical waste (including pharmaceuticals) was mainly disposed through the municipal collection system. Dumping of healthcare waste in uncontrolled areas can have a direct environmental effect by contaminating soils and underground water. During incineration, if no proper filtering of flue gases is done, air can be polluted causing airborne illnesses to the nearby populations. This has to be taken into consideration when choosing a treatment or a disposal method by carrying out a rapid environmental impact assessment (UNEP/WHO, 2005). Special healthcare wastes such as pharmaceuticals, biologicals and hazardous chemicals requires proper packaging, storage, transportation and disposal (WHO, 1999; World Bank, 2000).

2.2.2 Unwanted Pharmaceuticals across Africa.

In Africa unwanted pharmaceuticals disposal management appears to be more critical as reports from around the continent (from Mozambique, South Africa, Kenya and Swaziland) indicate poor Medical Waste Management (MWM) practices (Leonard, 2003; Manyele et al., 2003, Manyele, 2004a; Manyele 2004b; Manyele and Anicetus, 2006) as it is characterized by illegal and indiscriminate dumping of the medical waste.

Results from a survey of hospitals in Metropolitan Lagos, Nigeria (Longe & Williams, 2006) to assess medical waste management (MWM) practices and their implications to health and environments revealed high non-compliance to the Nigerian National Guidelines for MWM whereby medical waste including pharmaceuticals from the surveyed facilities was co-disposed with the municipal solid waste. The main reason cited was a weak enforcement by the relevant regulatory bodies.

A Report on Needs Assessment for Hospitals in relation to healthcare waste (HCW) management in African Countries (*African Violet Agenda for Environment and Development, 2009*) found out that Africa has over 67,740 of health facilities (HFs) with different levels of capacity whose waste disposal needs to be taken into consideration. The generation of waste in Africa varies considerably between same levels of HFs due to waste management methods, type of HFs, proportion of patients treated daily and the degree of specialization of the health facility. Many of HFs lack specific budget for Healthcare Waste Management (HCWM) and depend much on the government budget to run various services including that of having a HCWM system such as incineration facilities.

Africa is estimated to have more than 1,000 incinerators. The capital costs range between 1,000 USD and 12,677 USD for the De Montfort type and reaches USD 250,582 for sophisticated ones. Construction costs depend on a number of factors, especially the availability and cost of refractory bricks, metal and metal-working facilities. Many of these incinerators have been reported inoperative or operating below standards. In some hospitals they have re-built their incinerators in a number of times due to frequently break

down. Many of countries surveyed lack elaborated legal policy specifically for HCW, institutional framework for HCWM in HFs and proper sanitary landfills that can provide geographical isolation of wastes from the environment (*African Violet Agenda for Environment and Development, 2009*).

2.2.3 Unwanted Pharmaceuticals in Tanzanian Perspective

According to the National Healthcare Waste Management Monitoring Plan (MOHSW, 2007), healthcare waste (including unwanted pharmaceuticals) is defined as all the waste hazardous or not, generated by health institutions during medical activities, preventive, curative and/or diagnostic. Manyele (2004) defines medical waste as any solid waste generated in the diagnosis, treatment, or immunization of human beings or animals, related to research, production or testing of biologicals from all types of healthcare institutions, including hospitals, clinics, dental or veterinary and medical laboratories.

Studies conducted in Tanzania regarding medical waste management has described medical waste management (MWM) in Tanzania as being poor and that the general awareness on issues related to medical waste management, is lacking among the medical waste generators (e.g. health facilities) and handlers (e.g. staff involved in handling waste) (Manyele et al., 2003; Manyele, 2004b; Manyele and Anicetus, 2006). Apart from the poor medical waste management practices reported in Tanzania, steps to combat the problems posed by poor management led to construction of 13 pilot small scale incinerators in various parts of the country, the situation which motivated the government to extend the small scale incinerators to all referral, regional and district hospitals (Manyele, 2004b; Manyele and Anicetus, 2006).

Manyele and Lyasenga (2010) in their recent study cited a serious inadequacy in handling medical solid wastes in the Dar es Salaam City. Due to poor control of wastes, hospital owners are not well inspected on how they handle and dispose of the wastes they produce; as a result, hazardous wastes reach the dumpsite without notice. In addition, they have reported that, data on waste generation in Dar es Salaam is inadequate, making it difficult to plan for an efficient medical waste management (MWM) system.

The main disposal methods for medical waste (MW) as deduced from a survey of 8 regions in Tanzanian health facilities (Manyele and Anicetus, 2006) comprises of open pit burning (48%), though not advisable, burying (29%) and incineration (19%). Very few hospitals (4%) were reported to use autoclave for MW treatment, due to the fact that this is an expensive technology. The same survey showed that health facilities still tend to favour on-site MW treatment to gain control over the ultimate disposal and can thereby limit their liability more easily. The lower preference for off-site incinerator facilities is backed up by the fact that there exist no commercial incineration facilities in Tanzania. Other results from the study indicate that most health workers have low knowledge on medical waste management in Tanzania though similar observations have been reported in other developing countries such as Palestine (Massrouje, 2001), India (Pandit et al., 2005) and Pakistani (Rasheed et al., 2005).

In view of the above studies conducted in Tanzania, it is observed that all previous studies focused on medical waste in totality and that no specific study has been done with a special attention to unwanted pharmaceuticals (pharmaceutical waste). Given this existing gap, this study intended to assess pharmaceutical disposal practices, challenges and health personnel's knowledge on importance of proper handling and safe disposal of pharmaceutical waste at health facilities.

2.3 Scientific Understanding of Pharmaceuticals in the Environment.

This section presents a review of the state of scientific understanding of Pharmaceuticals and their metabolites collectively known as pharmaceutically active compounds (PhACs) in the environment, with a particular focus on human pharmaceuticals.

2.3.1 Overview of Pharmaceuticals in the Environment.

A number of studies (Kolpin et al., 2002a; Metcalfe, Miao, Koenig, & Struger, 2003; Loraine & Pettigrove, 2006) have shown that unwanted pharmaceuticals and their metabolites, collectively known as pharmaceutically active compounds (PhACs) have been detected in surface water and drinking water in a number of countries, especially developed countries. These products include medications for human and veterinary use,

as well as their metabolites. Thus unwanted Pharmaceuticals are environmental contaminants whose presence in the environment can be demonstrated though scientific understanding of PhACs in the environment remains limited.

2.3.2 Short History of PhACs in the environment

Interest in the environmental impacts of PhACs in natural waters has emerged in the past decade, particularly in developed countries, where large quantities of pharmaceuticals are consumed by humans and are used in agriculture. Concerns about environmental contamination by pharmaceuticals were first raised in the 1970s (Tabak & Brunch, 1970). There has been a gradual increase in the detection of PhACs in aquatic environments (Heberer, 2002a) and by 2002 more than 80 PhACs identified in aquatic environments.

2.4. Classes of PhACs of Concern

Several classes of PhACs are of special concern with respect to environmental impacts. Some are produced and consumed in large quantities; others are highly potent at low concentrations; and still others are extremely persistent in the environment.

2.4.1 Antimicrobials

Antimicrobials have a high potential for ecosystem impacts because they are designed specifically to be toxic to bacteria (Jorgensen & Halling-Sorensen, 2000; Kümmerer, 2001). Erythromycin also appears to accumulate in soils (Löffler et al., 2005). It is possible that low concentrations of antimicrobials in natural waters may exert selective pressure leading to the development of antibiotic resistance in bacteria (Witte, 2000).

2.4.2 Synthetic hormones

Some synthetic hormones such as *17α-ethinylestradiol (EE2)* which is used as an oral contraceptive have been found in aquatic water samples (Heberer, 2002b) and have the potential to affect the endocrine systems of humans and wildlife at low concentration levels. EE2 is a concern because it is extremely potent at very low concentrations as low concentration in surface water is sufficient to induce production of the female egg protein vitellogenin in male rainbow trout (Purdom et al., 1994). Other studies claim that EE2 is

suspected to be the main cause of intersex fish in U.K rivers and streams (Larsson et al., 1999).

2.4.3. Lipid regulators

Lipid regulators such as *clofibrate* are said to be quite persistent in aquatic environments (Stan et al., 1994). Studies by (Mittelstaedt, 2003; Ternes, 2001) reported that medicines like *Gemfibrozil, Bezafibrate* and *Fenofibrate* were detected drinking water in Canada and in Germany respectively. Environmental levels of *gemfibrozil* have been found to reduce the production of sex hormones in male goldfish (Trudeau et al, 2004).

2.4.4. Anti-inflammatories and Analgesics

Anti-inflammatories and analgesics include some of the most widely used pharmaceuticals such as the over-the-counter pain killers including *paracetamol, ibuprofen, diclofenac and acetylsalicylic acid (ASA).* A good example of anti-inflammatories of special concern is diclofenac, which has received increased attention recently as it has been found to be responsible for the death of more than 95% of the wild birds (i.e oriental white backed vultures). The medicines, present in dead livestock, caused renal failure in the vultures (Oaks et al., 2004).

2.4.5. Antiepileptics

The anti-convulsants especially carbamazepine has been detected in surface water (Ternes, 1998) and in groundwater (Sacher et al., 2001). Carmabazepine is so persistent in water and Ferrari et al. (2003) found a risk quotient of greater than one for carbamazepine in surface water, indicating that it could be harmful to aquatic organisms, particularly invertebrates.

2.4.6. Selective Serotonin Reuptake Inhibitors (SSRIs)

Selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine are usually prescribed as anti depressants. They can exert a wide range of effects on aquatic organisms, especially on invertebrates (Brooks et al., 2003; Fong, 2001), inducing reactions such as the spawning of mussels (Fong, 1998).

CHAPTER THREE

METHODOLOGY

3.0 Introduction

This chapter explains and examines how data were collected using well developed tested tools as means towards realizing study objectives. In general the chapter focuses on the study design, study area, study population, sample size and sampling procedure, data collection tools, data quality control and handling, data analysis, dissemination of results, etc.

3.1 Study Area and Population

The study was conducted in Dar es Salaam region, the study units were health facilities and the study population constituted all public health facilities in the region. For the purpose of this study health facilities included hospitals, health centres and dispensaries.

3.2 Study Design

It was a cross-sectional survey that generated data that helped to articulate the current perceptions and anecdotes regarding improper disposal of pharmaceutical waste to the real practices on the ground.

3.3 Sampling Procedure and Sample Size.

The study employed a stratified random sampling technique in selecting public health facilities that were involved in the study. The strata were the 3 municipalities (Kinondoni- 37, Ilala-29 & Temeke -26 facilities respectively whose total is 92). A random sample of health facilities was selected from the total number of facilities in each municipality and added up to make a large representative sample of 63 facilities that were surveyed during the study period in Dar es Salaam (sample size calculation, page 22).

Sample size calculations:

Population size, N =92

Proportion of pharmacists or medicines store supervisors knowledgeable on safe disposal of unwanted pharmaceuticals, P=50% since it is unknown

Margin of error, d=7%

Confidence level=95% (Z=1.96)

Formula:

$$n = \frac{N*P\,(1-P)}{[(d^2/Z^2_{1-\alpha/2})*(N-1) + P*(1-P)]}$$

Using the above assumptions, a sample of 63 public health facilities was selected and in each selected facility; a medicines store supervisor/pharmacist in-charge was interviewed on relevant issues with regard to practices and knowledge of safe disposal of pharmaceutical waste.

3.4 Personnel for Data Collection.

The principal investigator led the data collection exercise in collaboration with other 2 appointed and trained research assistants who were recruited and oriented before commencement of data collection activities.

3.5 Data Collection Tools

The study employed the following tools and approaches in the course of data collection

a) Field survey of the selected health facilities using facility indicator forms (WHO-modified model)
b) Interview of the health facility pharmacy/medicines store in-charges who regularly supervise medicines stores.

c) Desk reviews (review of available documents that show records of current stocks and previously disposed of stocks of unwanted pharmaceuticals)

3.6 Pre-Testing of Tools

The data collection tools (interview and facility indicator forms) were tested at 3 different facilities in order to validate them prior to roll out to a larger scale.

3.7 Ethical Clearance.

Ethical clearance was granted by the Ethical Review Committee of the Muhimbili University of Health and Allied Sciences (MUHAS). The investigator sought permission from respective Municipal Authorities prior to visiting the selected health facilities. Finally consent was sought from participants before enrolling them into the study. The consent form is appended (Appendix 5).

3.8 Inclusion Criteria

Pharmacist in-charges of the health facilities or any other health personnel employed as in-charges and supervisors of the medicines store in respective health facilities for a period of not less than 6 months.

3.9 Exclusion Criteria

Those who were unwilling to participate and those who were on leave during the study.

3.10 Study Procedure

Data were collected after administering consent forms to study participants however this activity was preceded by explanation of study objectives to the interviewees. Consented candidates were interviewed using structured questionnaires. The investigator reviewed available records of unwanted stocks and previously disposed of stocks of unwanted pharmaceuticals.

3.11 Data Quality Control

The following measures were undertaken in order to ensure consistence of data quality;

a) Translation of questionnaire and consent form from English to Kiswahili with similar meaning in back translation. As the study targeted different cadres with different qualification and level of education, both languages (Kiswahili and English) were be used depending on the situation. This ensured that same information is captured from different cadres.
b) Verification of filled questionnaires and
c) Coding of the questionnaires and facility indicator forms (annexes 1-6).

3.12 Study Variables

The study involved an assessment of knowledge and practices of HF medicines store personnel on safe disposal of unwanted pharmaceuticals.

3.13 Data Treatment, Analysis and Reporting of Results.

The preliminary analysis and reporting were done on site at the facility level in order to give feedback to in-charges of the facilities in question. Thorough and further analysis of the collected data was accomplished by using computer software SPSS. Study results have been presented by use of tables, histograms and other relevant graphics as exhibited in chapter four of this manuscript.

3.14 Dissemination of Results

The study report is intended to be submitted to Muhimbili University of Health and Allied Sciences as partial fulfillment of Master of Science degree in Pharmaceutical Management. It is also intended to be submitted to TFDA as a sole authority mandated to regulate all issues that are related to safe disposal of medicines and MOHSW as an input for policy making. The report serves as a benchmark for possible interventions to be made in the future.

CHAPTER FOUR

ANALYSIS AND SUMMARY OF RESULTS AND FINDINGS

4.0 Introduction

This chapter provides a detailed analysis of the data collected from the field. It starts by analyzing data according to the research questions which guided this study. Various non parametric tests were used at various stages of data analysis.

4.1 Response Rate

Of the selected 63 public health facilities (i.e. hospitals, health centres and dispensaries) only 60 respondents agreed and participated in the study. The overall response rate of the interview that was conducted is 95.2%, however minor discrepancies in some respondents were observed due to respondents' inability to provide answers to some of the questions. Those cases were considered as missing values in the analysis.

4.2 Data Cleaning

This refers to data preparation, which includes editing and eliminating errors in coding and transmitting the data to the computer (Kothari, 2004). The editing was done so as to detect errors and omissions at the same time correcting them where possible in order to meet the minimum quality standard of data. In the process of data cleaning the responses were studied and compared in order to assess their accuracy and consistency with other information as well as uniformity since some respondents used different terms to give the same information.

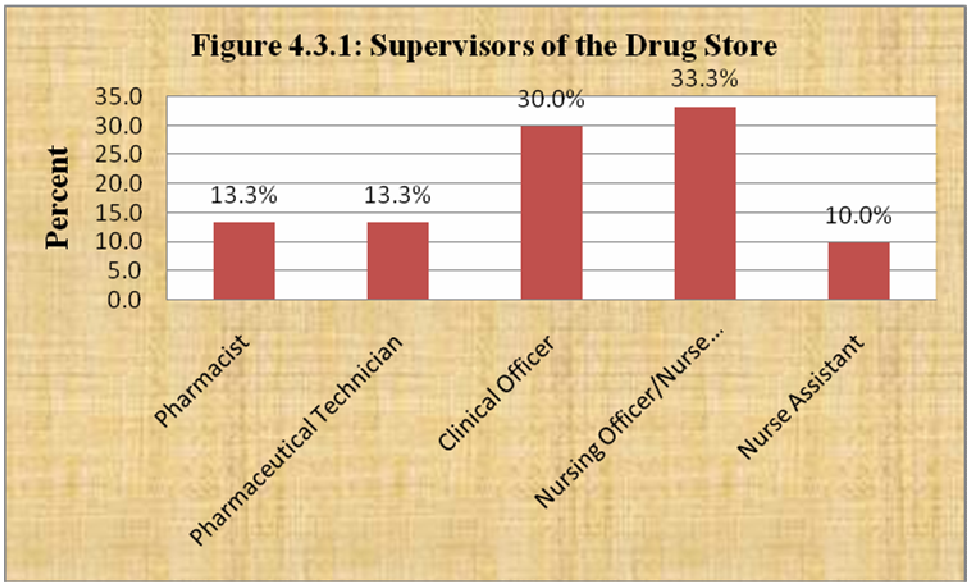
4.3 Characteristics of the Sample Profile

This section describes the general characteristics of the sample used in the study. While this helps to provide a profile of the sample surveyed, some of the information is useful on its own because it may highlight various features of the challenges encountered in managing disposal of unwanted pharmaceuticals at public healthcare facilities in Tanzania. The sample comprised of 6 major hospitals (Muhimbili National Hospital, Ocean Road Cancer Institute, Mwananyamala, Amana, Temeke and Vijibweni

Hospitals), 4 health centres and 50 dispensaries. This section therefore serves as a prelude to a more focused and descriptive analysis in subsequent sections of the chapter.

4.3.1 Distribution of Responses by Professional Cadres

During data collection various health facility medicines store in-charges/supervisors of different cadres and qualifications including; pharmacist, pharmaceutical technician, clinical officers, nursing officers/nursing midwives and nursing assistants were interviewed as shown in the figure below.



From fig.4.3.1 above, the findings show that, 13.3% of the supervisors of the medicines store were pharmacists, 13.3% were Pharmaceutical Technicians, 30% were Clinical Officers, 33.3% were Nursing Officers, and 10% were Nursing Assistants.

4.3.2 Demographic Variables Distribution

Gender and sex of the interviewees were other demographic variables that were examined and their distribution is summarized in the table below

Table 4.3.2 Demographic Distribution of the Medicines Store Supervisors

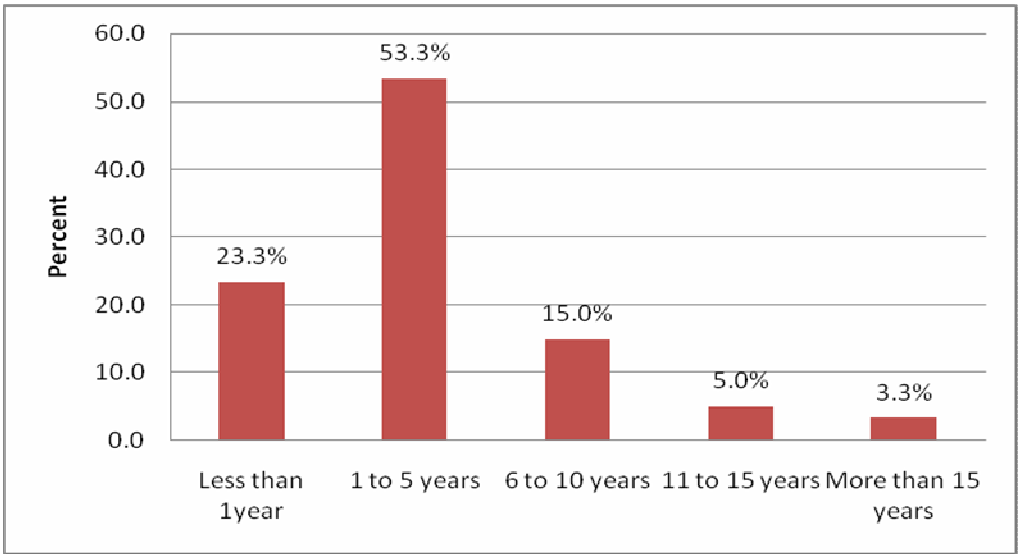
Demographic Variables		**Number of Respondents**	**Percent**
GENDER/SEX	Male	13	21.7
	Female	47	78.3
	Total	60	100.0
AGE	25 – 31	7	11.7
	32 – 38	23	38.3
	Above 39	30	50
	Total	60	100.0

From table 4.3.2 above, the results show that 78.3% of the contacted respondents were female while 21.7% were male. Regarding to the age distribution, 11.7% of the contacted supervisors of the medicines store were in age group of 25 – 31, the 38.3% were in 32 – 38 age group while 50% were of ages of above 39 years.

4.3.3 Distribution of the Responses by Experience at Work

The contacted supervisors of the medicines store were of different experiences at work. Some of them were of less than a year, others within one to fifteen years, while others were of above fifteen years as summarized in the figure below.

Figure 4.3.3: Experiences at Work of the Medicines Stores Supervisors



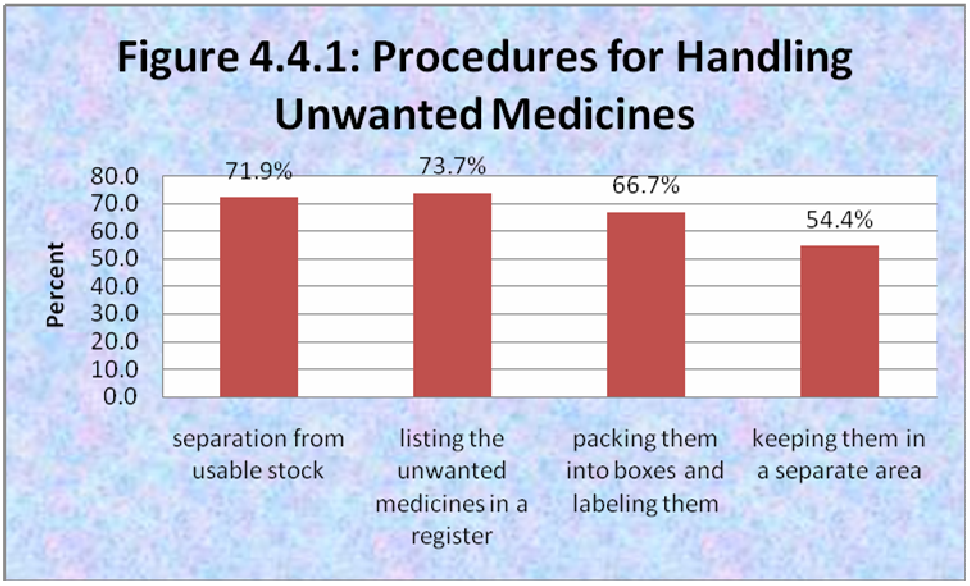
From fig. 4.3.3 above, many (53.3%) of the medicines store supervisors were having between 1-5 years experience at work, followed by 23.3% who had worked for less than a year as medicines stores supervisors. On the other hand, 15.0 % had 6-10 years experience, 5.0% of them had worked for a period of between 11-15 years and only 3.3% had worked for more than fifteen years of experience.

4.4 Unwanted Medicines Handling Procedures, Practices, Disposal Methods And Sites Used By Public Health Facilities.

In order to determine current methods/practices as well as sites that public health facilities employ in disposal of unwanted medicines. Health facility medicines stores in-charges were required to list methods, procedures/practices and sites/facilities used handle unwanted medicines prior to terminal disposal as described in the subsequent subsections (4.4.1, 4.4.2, 4.4.3 & 4.4.4).

4.4.1 Procedures for Handling Unwanted Medicines Prior to Terminal Disposal.

Below (fig. 4.4.1) is a summary of most common procedures mentioned by interviewed medicines stores in-charges on how to handle unwanted medicines prior to terminal disposal.



From fig. 4.4.1 above, 71.9% of the contacted medicines store supervisors listed separation from usable stock as one of the procedure for handling unwanted medicines prior to terminal disposal. On the other hand, 73.7% cited entry (listing) of the unwanted medicines into a register. Further findings show that 66.7% of the medicines store supervisors listed packing them into boxes and labeling them, while 54.4% listed keeping them in a separate area as the other procedure of handling unwanted medicines prior to terminal disposal.

4.4.2: Frequency of Disposal of Unwanted Stock of Pharmaceuticals

Responses with regard to the frequency of disposal of unwanted stock of pharmaceuticals by the health facilities were summarized in the table below;

Table 4.4.2: Frequency of Disposal of Unwanted Stock of Pharmaceuticals

Frequency		Facilities	Percent	Valid Percent	Cumulative Percent
Valid	once a year	3	5.0	5.2	5.2
	when necessary	55	91.7	94.8	100.0
	Total	58	96.7	100.0	

Table 4.4.2 above shows that 5.2% of the health facilities dispose of unwanted medicines once a year whereas 94.8% undertake the disposal of unwanted pharmaceuticals when necessary.

4.4.3: Last Disposal Date of Unwanted Pharmaceutical Stock

Regarding to the question when last disposal of unwanted pharmaceutical stock was undertaken by the facilities, the following are responses were summarized in the table below;

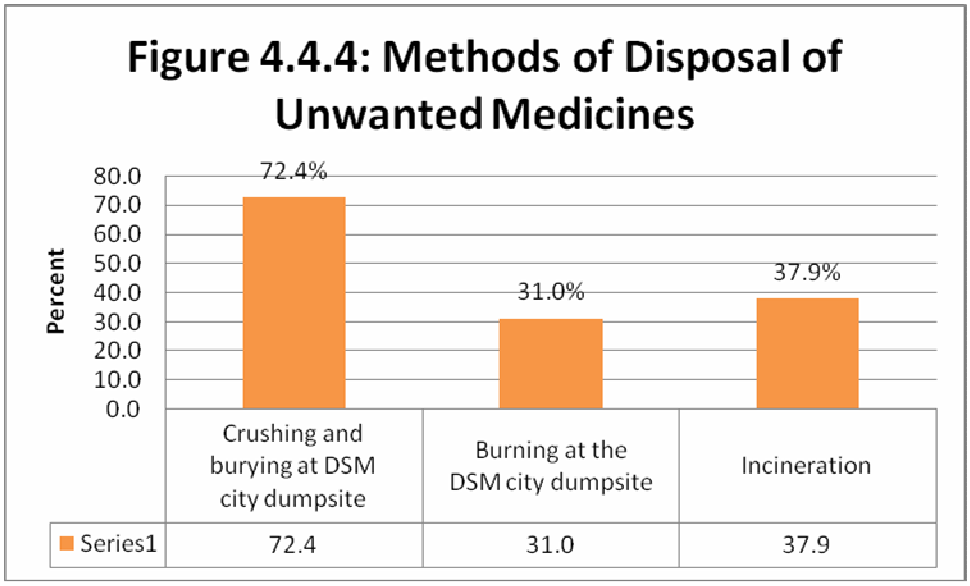
Table 4.4.3: Last Disposal Date of Unwanted Pharmaceutical Stock

Last Disposal Date		Health Facilities	Percent	Valid Percent	Cumulative Percent
Valid	2006	5	8.3	17.9	17.9
	2007	6	10.0	21.4	39.3
	2008	1	1.7	3.6	42.9
	2009	4	6.7	14.3	57.1
	2010	6	10.0	21.4	78.6
	2011	6	10.0	21.4	100.0
	Total	28	46.7	100.0	

The findings in table 4.4.2 above show that 5 (17.9%) of health facilities had their unwanted medicines disposed of in 2006, whereas 22 of the health facilities had their stock disposed of between 2007 -2011.

4.4.4 Disposal Methods of Unwanted Medicines

In order to ascertain disposal methods that are commonly used by the health facilities, interviewees listed the following as the commonest methods that are currently employed by them.



As seen in the fig. 4.4.4 above, 72.4% of the health facilities listed crushing and burying at DSM city dumpsite as the method of dispose of the unwanted stock of medicines they often use while 31.0% listed burning at the DSM city dumpsite, and 37.9% listed incineration.

4.5 Pharmaceutical Waste and Previous Disposal Data Maintained at Various Health Facilities

In examining the process of handling of unwanted stock at the healthcare facilities, medicines store supervisors were interviewed on presence of number of miscellaneous items of unwanted medicines and previous disposal records maintained at their respective health facilities as described in the subsequent subsections (4.5.1 & 4.5.2) that follow.

4.5.1 Unwanted Pharmaceuticals Maintained at Different Facilities.

In the process of identifying different types (miscellaneous) of unwanted medicines still maintained at the health facility, the medicines store supervisors were asked to avail a list of a variety of unwanted medicines of which 23 out of 60 facilities had a total of 1954 miscellaneous types of unwanted pharmaceutical items still waiting to be disposed,

4.5.2 Previous Disposal Records of Unwanted Medicines.

In order to establish whether or not previous disposal records of unwanted medicines are maintained at the facilities, the responses were either 'Yes' for presence of the records or 'No' for a absence of records, the results of which are as shown in the table below:-

Table 4.5.2 Previous Disposal Records Maintained at the Health Facility.

Presence of Previous Disposal Records		
Response	Health Facilities	Percentage
YES	18	34.6%
NO	34	65.4%
Total	52	100

Table 4.5.2 above shows that only 34.6% of the health facilities had previous disposal records while majority (34) (65.4%) did not keep such records at the facilities.

4.6 Constraints Existing in the Legal and Regulatory Framework that Hinder Proper Disposal of Unwanted Pharmaceuticals.

4.6.1 Factors that Lead to Unwanted Medicines

In identifying constraints existing in the regulatory framework, a number of factors that lead to unwanted pharmaceuticals were examined. The following results were obtained as shown in the figure 4.6.1;

Figure 4.6.1: Factors that Lead to Unwanted Medicines

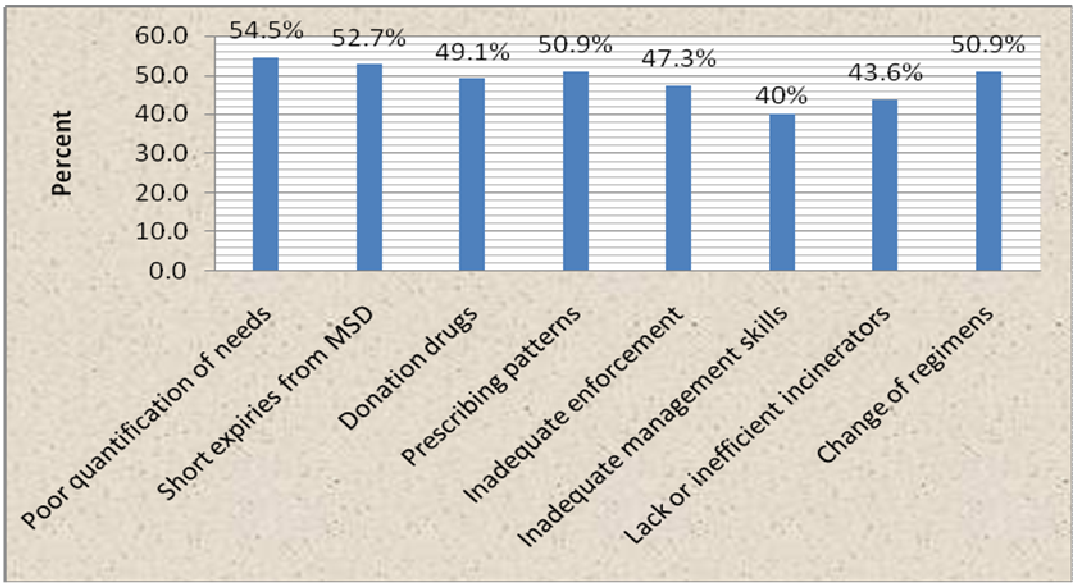
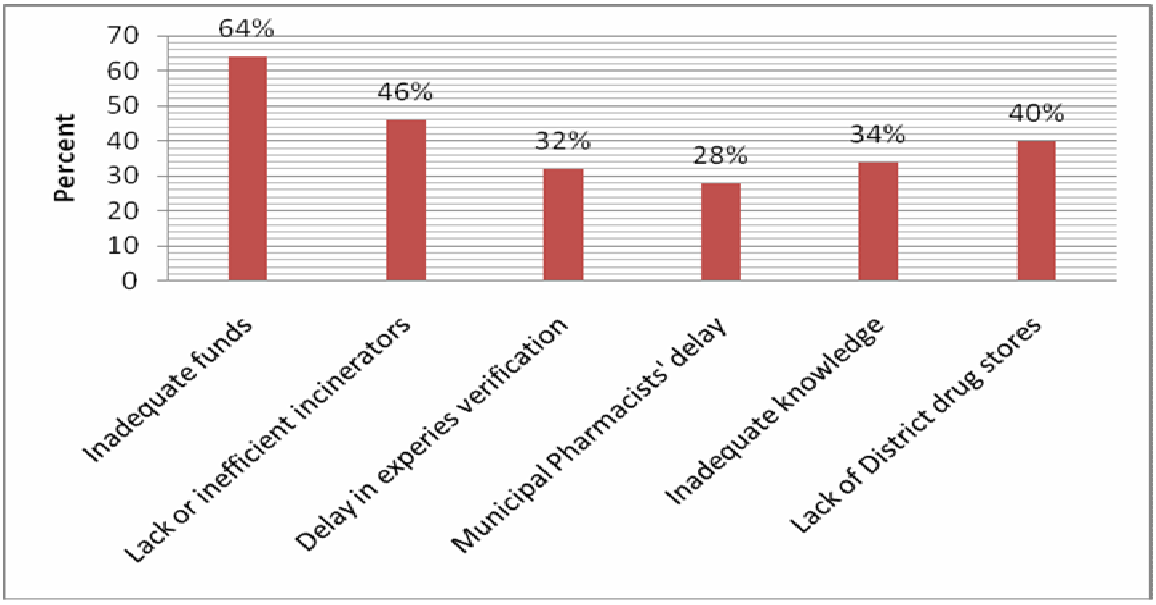


Fig. 4.6.1 above shows that 54.5% of the medicines store supervisors cited poor quantification of needs as one of the factors that lead to unwanted pharmaceuticals. This means that quantities ordered do not match with facility needs and in most cases needs exceed quantity ordered hence leading to expiries. The other findings show that 52.7% of the medicines store supervisors listed short expired medicines received from MSD. It was also noted that 49.1% of the medicines store supervisors listed donation medicines (with short expiries) and not consistent with STGs as the other factor that lead to unwanted pharmaceuticals. The study also revealed that prescribing patterns by clinicians that is not consistent with STGs account for this problem by 50.9%. At the same time 50.9% of the store supervisors listed *Change of Treatment Regimens* from time to time (e. g. change from SP to ALu).The other findings show that 47.3% of the supervisors listed inadequate enforcement by TFDA to ensure that all medicines are properly disposed of. It was also noted that 43.6% of the medicines store supervisors listed lack or inefficient incinerators for destruction of unwanted medicines. Further analysis show that 40.0% of the medicines store supervisors attributed inadequate pharmaceutical management skills (such as inventory management and control, First Expired First Out (FEFO) protocol adherence) account for unwanted medicines at health facility level.

4.6.2 Barriers to Proper Disposal of Unwanted Pharmaceuticals

The study looked into barriers to proper disposal of unwanted pharmaceuticals that health facilities face whenever they plan to dispose them of, results of which have been summarized below.

Figure 4.6.2: Barriers to Proper Disposal of Unwanted Medicines

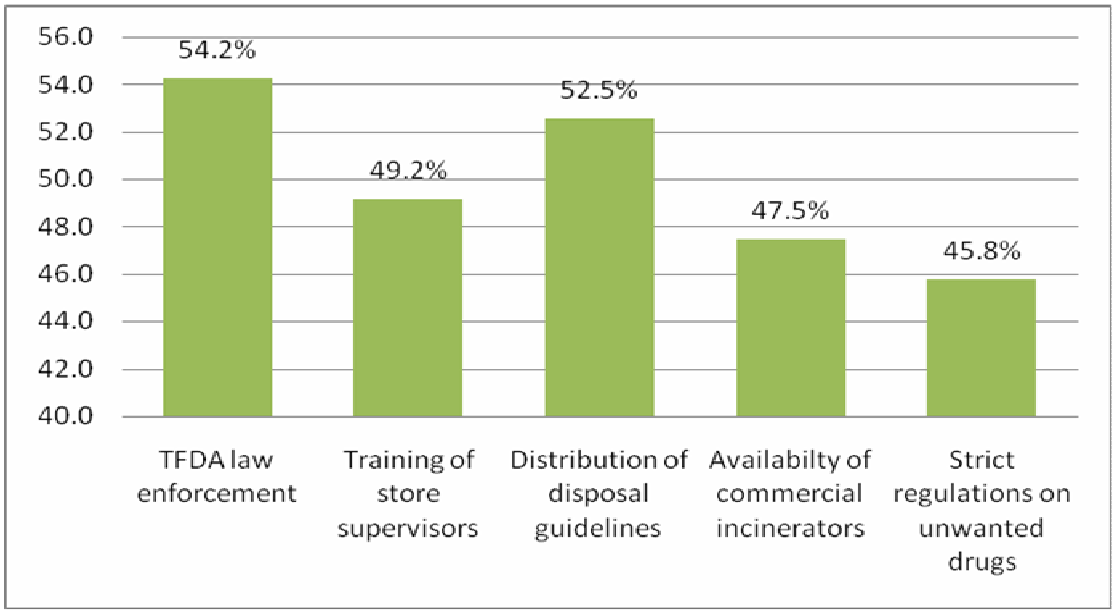


In response to identification of barriers to proper disposal of unwanted pharmaceuticals, 64% of the contacted medicines store supervisors attributed inadequate funds to finance all logistics pertaining to medicines disposal at facility level. The other findings show that 46% of the medicines store supervisors listed lack or inefficient incinerators for destruction of unwanted medicines. 40% of the respondents cited lack of district medicines stores where all unwanted medicines from lower facilities could be collected and stored while awaiting other disposal procedures. 34% cited inadequate knowledge on the potential hazards associated with a delay or improper disposal of unwanted medicines. It was also noted that 32% of the medicines store supervisors listed delay in verification of unwanted medicines stock done by stock verifiers from the Ministry of Finance as required by law for all public assets (as per Public Finance Act & Regulations, 2004). Further analysis show that 28% of the medicines store supervisors listed delay by the Municipal Pharmacist to collect all unwanted medicines from health centres and dispensaries for further action.

4.6.3 Medicines Store Supervisors' Recommendations to the National Medicines Regulatory Authority (TFDA)

The following recommendations (fig. 4.6.3) were made by the interviewed facility store supervisors with regard to the functioning of the National Medicines Regulatory Authority (TFDA) on various issues relating to the disposal of unwanted pharmaceuticals;

Figure 4.6.3 Recommendations to the National Medicines Regulatory Authority



From fig.4.6.3 above, 54.2% of the contacted medicines store supervisors recommended strengthening law enforcement (by TFDA) through frequent inspections of public health facilities so as to ensure that unwanted medicines are disposed timely. It was noted that 52.5% of the contacted medicines store supervisors recommended that TFDA should distribute the Guidelines for Safe Disposal of Unwanted Pharmaceuticals and other relevant guidelines to the health facilities. Interestingly, 49.2% recommended regular training of the health facility medicines stores supervisors on proper medicines management and other TFDA regulations as part of the Continuous Professional Development training. The other findings revealed that 47.5% of the medicines store supervisors recommended that TFDA should facilitate availability of large commercially run incinerators through private investments. Further analysis show that 45.8% of the

medicines store supervisors recommended that TFDA should strictly and clearly stipulate in its regulations the maximum period the expired medicines can be kept in health facility prior to terminal disposal.

4.6.4 Availability of TFDA Guidelines for Safe Disposal of Unwanted Pharmaceuticals.

Health facilities were assessed on presence of TFDA Guidelines for Safe Disposal of Unwanted Pharmaceuticals which is a very important tool for health professionals engaged in daily medicines store management transactions, results of which are presented in the table below

Table 4.6.4: Availability of TFDA Guidelines for Safe Disposal of Unwanted Pharmaceuticals

Presence of TFDA Guidelines for Safe Disposal of Unwanted Pharmaceuticals		
Response	Health Facilities	Percentage (%)
YES	1	1.7
NO	59	98.3
Total	60	100

Table 4.6.4 above entails that of all the 60 visited health facilities, only one facility had the Guidelines as a reference material in its store transactions.

4.6.5 Previous Training on Disposal and Handling Procedures of Unwanted Pharmaceuticals at Health Facility Level.

In order to establish whether or not the health facility medicines store personnel have attended any training on disposal and handling procedures of unwanted pharmaceuticals as a parameter to measure their level of knowledge; the responses were either YES or NO, and results are tabulated (table 4.6.5) as follows.

Table 4.6.5: Previous Training on Disposal and Handling Procedures of Unwanted Medicines.

	Response	Health Facilities	Percent	Valid Percent	Cumulative Percent
Valid	Yes	0	0	98.3	100.0
	No	59	98.3	1.7	
	Total	59	98.3	100.0	

It can now be deduced from table 4.6.5 above that none of the respondents had undergone training in disposal and handling procedures of unwanted pharmaceuticals at facility level.

4.7 Medicines Stores Personnel's Knowledge Level on Handling and Disposal Procedures of Unwanted Medicines.

In the process of measuring the level of knowledge, the following focal areas were used as criteria to measure knowledge;

a) Handling procedures of unwanted medicines as stipulated in the TFDA Guidelines (table 4.7.1)
b) Dangers and problems associated with any delay and improper disposal of unwanted medicines (fig. 4.7.2)
c) Professional training on pharmaceutical disposal (tables 4.7.3, 4.7.4 & 4.7.4.1)

4.7.1 Knowledge on Handling Procedures of Unwanted Medicines Prior to Disposal.

In order to know the practice on the ground the following parameters (table 4.7.1) were used to measure knowledge on the procedures on how to handle such unwanted medicines prior to terminal disposal.

Table 4.7.1: Knowledge on Handling Procedures of Unwanted Medicines Prior to Disposal.

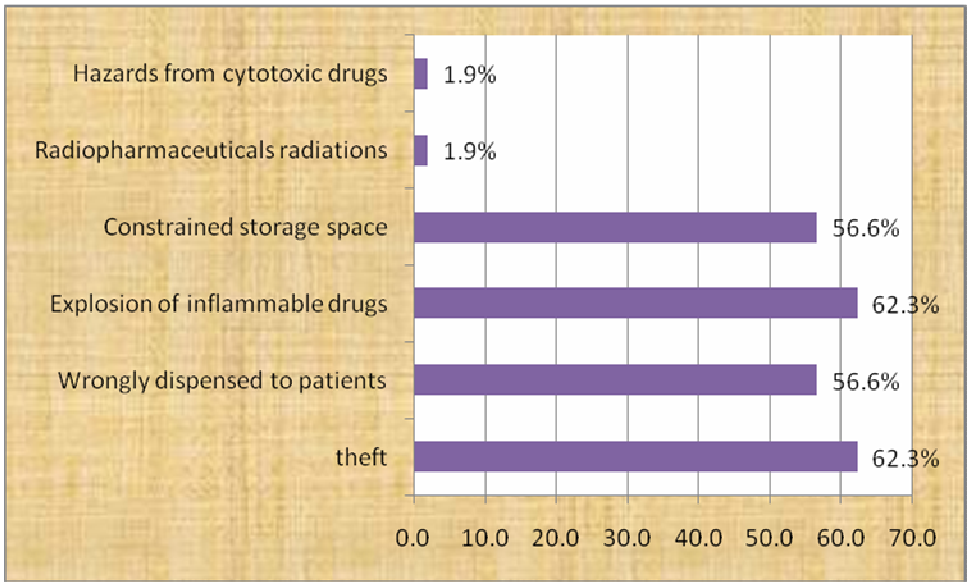
Parameters Description	Yes	No	Total
Presence of maintained register book for recording unwanted pharmaceuticals	13	45	58
Unwanted medicines segregated from the usable medicines stocks	48	7	55
Presence of a separate area to keep the unwanted medicines	17	39	56

From table 4.7.1 above, only 13 out of 58 facilities were found to have a maintained register book for recording unwanted pharmaceutical stocks. On the other hand 48 out of 55 health facilities had their unwanted medicines segregated from the usable stocks. Meanwhile, few (17) out of 56 facilities had a separate area to keep the unwanted medicines stocks.

4.7.2 Knowledge Level on Dangers and Problems Associated with Delay and Improper Disposal of Unwanted Pharmaceuticals.

The study wanted also the respondents to list the most common dangers and problems associated with any delay and improper disposal of unwanted pharmaceuticals, the results of which have been presented in the figure below.

Figure 4.7.2: Dangers and Problems Due to Delay and Improper Disposal of Unwanted Medicines



As seen from fig 4.7.2 above, the findings show that 62.3% of the respondents cited that "in case of theft" the unwanted medicines can be relabeled and resold into the market as dangers and problems associated with delay and improper disposal of unwanted pharmaceuticals. Other findings revealed that 62.3% of the medicines store supervisors indicated that "extremely hot temperatures can cause explosion of highly inflammable pharmaceutical liquids" if stored for long periods without disposal. 56.6% of the respondents mentioned that unwanted medicines can be wrongly dispensed to patients if not properly separated from the usable stock. The other 56.6% of the contacted medicines store supervisors attributed "constrained storage space for incoming subsequent new medicines stocks as a problem associated with delay in disposal of

unwanted medicines. Interestingly, on one hand, one facility store supervisor (1.9%) indicated that any delay in disposal of unwanted *Radiopharmaceuticals* may lead to continuous emission of dangerous radiations to the environment and on the other hand, further analysis showed that long storage of unwanted *cytotoxic* medicines (1.9%) may pose unknown potential and occupational hazards.

4.7.3 Need for Professional Training on Pharmaceutical Disposal.

In identifying the need for professional training on pharmaceutical disposal as part of the Continuous Professional Development (CPD) so as to enhance pharmaceutical management skills of the medicines store personnel, the responses were either YES for needs of such training or NO for no needs of the training, and results are summarize as follows;

Table 4.7.3: Need for More Professional Training on Pharmaceutical Disposal

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	58	96.7	100.0	100.0
	NO	0	0		

Deductions from table 4.7.3 above show that, 96.7% of the contacted medicines store supervisors wanted professional training on pharmaceutical disposal so as to impart them with more exposure.

4.7.3.1 Important Areas that Medicines Store Supervisors Need More Exposure with Regard to Professional Training on Pharmaceutical Disposal.

In order to gain insights of what kind of professional training the medicines store personnel at health facilities need so as to enhance their skills, they were required to mention few important areas and the results of identified areas have been summarized in the table below

Table 4.7.3.1: Few Areas Medicines Store Supervisors Need More Exposure

	Needed Areas of Professional Exposure	Health Facilities	Percent	Valid Percent	Cumulative Percent
Valid	Areas in relation to handling and disposal of unwanted medicines	31	51.7	63.3	63.3
	Pharmaceuticals management skills	18	30.0	36.7	100.0
	Total	49	81.7	100.0	

From the table 4.7.3.1 above, 63.3% of the contacted medicines store supervisors mentioned any relevant area in relation to handling unwanted medicines whereas 36.7% of them mentioned Pharmaceuticals management skills as a requisite area.

CHAPTER FIVE

DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.0 Introduction

This chapter presents detailed discussions, conclusions and recommendations pertaining to the study. Obtained results in chapter four formed the basis for these discussions, conclusions and recommendations for way forward in addressing the problem of unwanted medicines at public health facilities. Areas for further research have also been presented

5.1 Discussions

5.1.1 Handling Procedures, Disposal Methods, Practices, and Sites Used in Managing Disposal of Unwanted Medicines at Public Health Facilities.

We all know that medicines are vital for saving and preserving life in conditions of morbidity and that sometimes availability of medicines in our heath service delivery settings has been roughly taken as good health service delivery indicator but yet these medicines become obsolete without reaching the needy people. It should be known that when medicines become unwanted (i.e. expired, unusable, damaged, obsolete, improperly handled cold chain biological especially vaccines, improperly sealed and wrongly labeled medicines); they need even more special care and handling than before , hence calling for more elaborate handling procedures (WHO, 2009 & TFDA Guidelines for Safe Disposal, 2009) to take care of them.

First, the study desired to examine prevailing handling procedures of unwanted medicines that most public health facilities use so as to ensure safe custody of such medicines prior to terminal disposal. Most medicines store personnel who were interviewed centred on 4 four procedures namely separation of these medicines from usable stock, listing the medicines in a register, packing them into boxes and labeling them, and keeping them in separate area. Main observation from this scenario is that the TFDA Guidelines for Safe Disposal of Pharmaceuticals stipulate more than eight procedures (subsections 1.3.1.1 - 1.3.1.3) of handling unwanted medicines at facility level prior to final disposal, therefore

it can deduced that most procedures are not known to the health facility medicines store personnel due to the fact that such guidelines have never been distributed to public health facilities by TFDA. Furthermore, physical check up of the stores revealed poor storage management practices as some of the unwanted medicines were yet to be separated from the usable stock as opposed to what the personnel described as the their normal routines once the medicines become unfit for use.

Secondly, the study looked into other practices particularly frequencies with which unwanted pharmaceuticals are disposed of; whereby it was revealed that most of the facilities (94.8%) undertake disposal of unwanted pharmaceuticals when necessary. This entails that no facility had standard operating procedures (SOPs) to guide them on the timing and frequency with which disposal should be conducted. As a consequence, pharmaceutical wastes tend to accumulate in the health facilities coupled with poor handling and storage.

Thirdly, linking the disposal frequency, the study examined last disposal date of unwanted pharmaceutical stock by the facilities; it was established that more than half of the visited facilities undertaken their pharmaceutical waste disposal between 2-5 years ago.

Fourthly, the most common disposal methods and sites used by most public health facilities that were identified included crushing and burying; open burning (though not advisable) at Dar Es Salaam city dumpsite as well as incineration. A big discrepancy of these methods is observed from those mentioned in TFDA Guidelines for Safe Disposal of Unwanted Pharmaceuticals (as described in subsection 1.3.1.2) whereby the methods have been placed according to medicines categories, for instance solids, semi-solids and powders altogether correspond to Landfill, Incineration and waste Immobilization as their safe disposal methods that have been stipulated in the Guidelines. The likely contributing factor for this is attributable to weak enforcement and supervision of disposal activities by TFDA and unavailability of the Medicines Disposal Guidelines at public health facilities. *Da Silva et al, 2004* reported similar results of indiscriminate and haphazard disposal of unwanted medicines into the municipal collection systems in Southern Brazil.

5.1.2 Pharmaceutical Waste and Disposal Data Maintained at Health Facilities.

In another instance the study examined the amount of pharmaceutical waste maintained at the facility through documentation reviews (i.e. going through the maintained register for unwanted medicines) and found out that 23 facilities had at least more than one type of obsolete items in waiting for terminal disposal and the total number of varieties of pharmaceutical items regardless of their pack size, dosage forms or strength was 1954 unwanted items in these facilities. However a big discrepancy was that, most registers were not being updated regularly in the same pace as medicines become obsolete such that the unwanted pharmaceutical items listed on registers did not match with physical amount in the facility pharmaceutical stores.

Besides the above scenario, verification of previous disposal records of unwanted medicines maintained at the facilities found out that most of them were incomplete and some were missing contrary to what was stated in subsection 4.4.3 which scrutinized last disposal date of unwanted pharmaceutical stock that was undertaken by the facilities. This is considered to be attributable to poor record keeping, lack or inadequate pharmaceutical skills as exhibited by the professional cadres' hierarchy (fig.4.3.1) whereby most of the medicines stores personnel (73.4%) were of non-pharmaceutical cadre. In another development, work experience (fig.4.3.4) may also have a contributory effect on this state of affairs as it was observed that 23.3% of the medicines store supervisors were having less than a year of experience at work as supervisors of the medicines stores.

5.1.3 Constraints Existing in the Legal, Regulatory and Administrative Framework that Hinder Proper Disposal of Unwanted Pharmaceuticals.

In identifying constraints existing in the legal and regulatory framework, study first examined possible factors that lead to unwanted pharmaceuticals with the aim of focusing only on those which can be enforced by law or any other regulations. There are five about factors (Fig. 4.6.1) found to contribute to unwanted medicines in public health facilities but also connected to legal and regulatory framework of medicines services in Tanzania and these include short expired medicines received from MSD, donation medicines (with short expiries) and not consistent with Standard Treatment Guidelines (STGs), Change of Treatment Regimens from time to time (e. g. change from SP to ALu), inadequate enforcement by TFDA to ensure that all medicines are properly disposed of as echoed in similar results from a survey of hospitals in Nigeria (Longe & Williams, 2006) and prescribing patterns by clinicians that are not consistent with STG.

Secondly, another focus was to look into barriers/constraints that account for delay in proper disposal of unwanted pharmaceuticals that health facilities face whenever they plan to dispose of unwanted medicines namely; inadequate funds to finance all logistics pertaining to medicines disposal by public health facilities as exhibited by similar observations in a Report on Needs Assessment for Hospitals in relation to healthcare waste (HCW) management in African Countries (*African Violet Agenda for Environment and Development, 2009)* where many of HFs had no specific budget for Healthcare Waste Management (HCWM) including pharmaceutical waste; lack of district main pharmaceutical stores where all unwanted medicines from lower facilities could be collected and stored while awaiting other disposal procedures; delay in verification of unwanted medicines done by stock verifiers from the Ministry of Finance as per *Public Finance Act & Regulations, 2004* for all public assets and delay by the Municipal Pharmacists to collect all unwanted medicines from health centres and dispensaries for further action.

Various recommendations (fig. 4.6.3) solicited from the respondents pertaining to the functioning of the National Medicines Regulatory Authority (TFDA) on issues relating to the disposal of unwanted pharmaceuticals as strategies to overcome the problem in the country centred on the following; strengthening law enforcement (by TFDA) through frequent inspections of public health facilities so as to ensure that unwanted medicines are disposed of timely; TFDA should distribute the Guidelines for Safe Disposal of unwanted pharmaceuticals and other relevant guidelines to the health facilities because it was found that out of the 60 visited health facilities (table 4.6.4) only one facility had such guidelines; regular training of the health facility medicines stores supervisors on proper medicines management and other TFDA regulations as part of the Continuous Professional Development (CPD) training; TFDA should facilitate availability of large commercially run incinerators through private investments where unwanted medicines can be incinerated in a regulated and professional way and TFDA should strictly and clearly stipulate in its disposal regulations the maximum period the unwanted medicines can be kept in health facility prior to terminal disposal beyond which becomes a criminal offence punishable under the law.

It is clear that there is gross demand for stakeholders in the pharmaceutical sector especially health facility professionals in control of the pharmaceutical stores to be sensitized and enlightened by TFDA through training/workshops on disposal and handling procedures of unwanted pharmaceuticals at health facility level as part of its enforcement strategy once TFDA had new guidelines or regulations issued. It has been found out that since the introduction of the new TFDA guidelines for safe disposal of unwanted medicines in 2009; none of the health professional got exposed to such guidelines (table 4.6.5) in a formal arrangement that is why almost all of the respondents are not aware of the availability of such guidelines at TFDA.

5.1.4 Medicines Stores Personnel's Knowledge Level on Handling and Disposal Procedures of Unwanted Medicines.

The study wanted to ascertain whether health staff involved in managing health facility medicines stores are knowledgeable enough to properly handle unwanted medicines prior to final disposal and knowledgeable on dangers and problems associated with any delay and improper disposal of unwanted medicines; and if they need professional training on pharmaceutical disposal.

In the first case of having knowledge on handling procedures of unwanted medicines prior to terminal disposal (table 4.7.1), three parameters were used to gauge knowledge namely presence of a maintained register book for recording unwanted pharmaceuticals, segregation of unwanted medicines from the usable medicines stocks and presence of a separate area to keep the unwanted medicines; it was revealed that most store personnel were not knowledgeable enough on the importance of having special register book for unwanted medicines and the value of a separate area/store for keeping medicines once they become obsolete, however they were somewhat knowledgeable on the significance of separating unwanted medicines from the usable ones.

Secondly, It is also evident from the study that, the medicines stores personnel were slightly knowledgeable on some of the imminent dangers and problems (fig. 4.7.2) associated with any delay and improper disposal of unwanted pharmaceuticals in particular theft of such medicines and hence be diverted, relabeled and resold into the market; explosion of highly inflammable pharmaceutical liquids if stored for long periods under extremely hot temperatures without disposal; constrained storage space for incoming subsequent new medicines stocks; emission of dangerous radiations from *Radiopharmaceuticals* to the environment and that unwanted *cytotoxic* medicines may pose unknown potential and occupational hazards. Similar results from other studies also indicate that most health workers have low knowledge on both pharmaceutical and medical waste management in developing countries such as Palestine (Massrouje, 2001), India (Pandit et al., 2005) and Pakistani (Rasheed et al., 2005). Despite the above mentioned dangers yet the medicines are not disposed timely because of constraints

(section 5.1.3) faced in the whole supply chain systems of medicines in Tanzania whereby emphasis is put much on ensuring that medicines reach the public facilities but there is no proper channel to guide how these medicines should be rendered harmless once they fall obsolete or damaged.

Given the fact that the health personnel had limited and partial knowledgeable on handling and disposal procedures as well as the perils posed by unwanted medicines they appealed for urgent need for professional training on pharmaceutical disposal management as part of the Continuing Professional Development (CPD) so as to enhance their pharmaceutical management skills because all who were interviewed (table4.7.3) called for such trainings. In addition to this, they went further into recommending two explicit and important areas namely training on handling and disposal of unwanted medicines, and pharmaceutical management skills such as supply chain management and good storage practices (table 4.7.3.1)

5.1.5 Challenges Facing TFDA in the Context of Regulating Unwanted Medicines under a Liberalized Drug Market in Tanzania

Given the dynamism of the global business environment, medicines are no exceptions to on-going trade liberalizations worldwide. It is therefore required that TFDA must stay vigilant and responsive to these phenomenal changes in order to strengthen its roles as a National Drug Regulator and hence inspire confidence and trust to the Tanzania Public at large.

Despite tremendous advantages of liberalized drug marketing in the country, yet there are several negative impacts fetched by it mainly increase in expired medicines in the shelves in both public and private health and pharmaceutical outlets which in turn can be diverted, relabeled and eventually resold into the market; inadequate and weak enforcement in public health facilities; Inadequate qualified human resources who can be deployed in the enforcement activities especially frequent inspections of all facilities (both public and private); presence of numerous porous and unmanned borders through which medicines can be imported into the country without TFDA approval; absence of commercial incinerators and appropriate sites where obsolete medicines can be disposed

safely, general public low level of awareness and knowledge on medicine safety due to possibly absence of medicines consumer councils which could regularly educate and inform the public.

5.2 Conclusions

Managing disposal of unwanted medicines at public health facilities is highly associated with daunting challenges that cannot be sorted out by just one player but rather all players involved in the medicines supply chain such as MSD, public health facilities, TFDA, donors, medicines funding agencies and the Ministry of Health and Social Welfare at large.

The study has identified about 10 main challenges that hamper proper and safe disposal of unwanted medicines in the country; these include inadequate enforcement by TFDA such as regular inspections of public health facilities and supervision of disposals leading to medicines being disposed using inappropriate methods (fig. 4.4.4); unwanted medicines being treated just like other public assets as per *Public Finance Act & Regulations, 2004* in disposal procedures without taking into account their unique nature and the dangers posed by them; inadequate number of pharmaceutical staff to manage pharmaceutical stores as required by law; short expiry medicines supplies from MSD due to long lead times resulting from international procurements; donation medicines (with short expiries) and not consistent with STGs; prescribing patterns by clinicians that are not consistent with STGs especially prescribing of brand names instead of generic names; inadequate funds to cover medicines disposal costs; laxity by District pharmacists in ensuring that unwanted medicines from lower facilities are collected and disposed of timely; lack of Continuous Professional Development (CPD) training with special emphasis on unwanted medicines; and unavailability of large commercially run incinerators to cater for large volumes of unwanted medicines.

5.3 Recommendations

The following are recommended in response to the above challenges revealed by the study

5.3.1 TFDA being the only Government Agency mandated to oversee and regulate medicines in the country; should now enhance and strengthen its enforcement wings with focal points being public health facilities through inspections and distribution of relevant guidelines (including Disposal Guidelines, 2009) and regulations to these stakeholders.

5.3.2 Since medicines supplied to public health facilities are public assets whose disposal approval must be sought from the Government Accountant General declaring that the products have been written off and that are subject to disposal as required by law under Section 256 of the Public Finance Regulations, 2004. It is recommended that these finance regulations should be amended to recognize medicines as unique products that need specific procedures.

5.3.3 Ministry of Health and Social Welfare (MOHSW) in collaboration of the Ministry of Education and Vocational Training (MOEVT) must spearhead efforts to ensure that as a country we reduce shortage of health staff of pharmaceutical cadre (i.e. pharmacists, pharmaceutical technicians and pharmaceutical assistants).

5.3.4 It is high time for MSD to conduct a thorough and comprehensive study to find out ways that can expedite the procurement cycle activities in order to do away with the problems short expiries attributable to long procurement procedures especially for medicines having short shelf lives.

5.3.5 Ministry of Health and Social Welfare (MOHSW) and District Authorities (i.e. District Medical Officer and District Pharmacists) should abide to the National Medicines Donation Guidelines.

5.3.6 The MOHSW which has the mandate to regulate the general conduct of clinicians including prescribing practices needs to institute a mechanism that will ensure that prescribers adhere to the STGs on regular basis.

5.3.7 District Health Authorities (DMO and District Pharmacists) should now recognize the importance of budgeting for disposal activities including constructing District

medical stores, and ensure that unwanted medicines from lower health facilities are collected and disposed of timely.

5.3.8 TFDA should coordinate and facilitate training of medicines store personnel with emphasis on handling and disposal procedures of unwanted medicines and find out how private sector can be involved in investing in large commercially incinerators.

5.4 Areas for Further Research

5.4.1 Because this study just focused on public health facilities located in Dar Es Salaam, further research can be carried out to cover the whole country to assess the magnitude of the problem.

5.4.2 Comparative research can be undertaken in private health facilities to assess extent of unwanted medicines.

5.4.3 Study can be carried out to identify motivating factors for brand names (extravagant) prescribing and an assessment of cost implications to patients brought about by this vice mainly in the public health facilities.

5.5 Study Limitations

More meaningful results would have been produced if the scope of the study was extended to more than one region for one to get a better understanding of the prevailing challenges of managing disposal at public health facilities, various medicines disposal methods/practices employed and level of knowledge of medicines stores personnel on handling procedures of unwanted medicines across the country.

It should also be noted that the composition of the sample units was not homogeneous since it comprised of referral hospitals, municipal hospitals, health centres and dispensaries each having different capacities of operations hence introducing some outliers in the data analysis for some parameters. Besides this the view of the National Drug Regulatory Authority (TFDA) were not sought in order to be able to clarify some of the issues such as reasons for unavailability of disposal guidelines at facility level.

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APPENDICES

APPENDEX 1

QUESTIONNAIRE *(English version)*

INTERVIEW QUESTIONNAIRE TO ASSESS KNOWLEDGE AND DISPOSAL PRACTICES OF UNWANTED PHARMACEUTICALS USED BY HEALTH FACILITIES IN DAR ES SALAAM REGION.

Code No…….

Name of Health facility (i.e Hospital, Clinic, Health centre, Dispensary, MSD) …….

1. In-charge/supervisor of the facility pharmacy or medicines store
    a) Pharmacist
    b) Pharmaceutical technician
    c) Clinical officer
    d) Nursing officer/Nurse midwife
    e) Nurse assistant
    f) Others (mention)……..
2. Sex
    a) Male
    b) Female
3. Age (in years) …….
    a) 18-24
    b) 25-31
    c) 32 - 38
    d) Above 39

4. Experience at work of the medicines store supervisor (in years)
   a) Less than 1
   b) 1 to 5
   c) 6 to 10
   d) 11 to 15
   e) More than 15

5. Have you ever attended training on disposal and handling procedures of unwanted pharmaceuticals?
   a) Yes (go to next Question)
   b) No

6. How many times have you attended such a course within last two years?
   a) Once
   b) Twice
   c) Thrice
   d) More than thrice

7. Does it happen that some of your medicines in stock get expired/damaged before use?
   a) Yes (if yes go to question)
   b) No

8. What do you think are underlying factors that lead to unwanted pharmaceuticals (e.g. expiries) at your facility?

   ……
   ……
   ……
   ……
   …….

9. Explain how you handle such unwanted medicines prior to terminal disposal……
……
……
……
…….

10. What reference material(s) is (are) available in your pharmacy store used as reference during your practice?
    a) TFDA Guidelines for Safe Disposal of Unfit Pharmaceuticals
    b) TFDA Guidelines for Good Distribution Practices of Pharmaceuticals.
    c) Good Dispensing Manual
    d) Others (Mention)……..

11. If you have the TFDA Guidelines for Safe Disposal of Unfit Pharmaceuticals, have ever gone through it to find out proper ways of handling unwanted/expired medicines at your facility prior to terminal disposal?

    a) Yes (if yes go to next question)
    b) No

12. Did you find the TFDA Guidelines for Safe Disposal of Unfit Pharmaceuticals useful for routine storage management and disposal of your unwanted stock of medicines?

    a) Yes
    b) No (if No) state/mention any deficiencies that you think should be rectified to smoothen the handling and disposal procedures
    ……
    ……
    ……
    ……
    ……..

13. How often do you dispose of unwanted stock of pharmaceuticals?
    a) Once a year
    b) Twice a year
    c) After every 2 years
    d) After every 3 years
    e) After every 4 years
    f) After every 5 years
    g) When necessary (no specified time period)

14. When was your last disposal of unwanted stock? Mention (month and year if you remember both) ……..……

15. List all the methods that you regularly use to dispose of the unwanted stock of medicines at your facility
    ……...
    ……
    ……
    ……
    ……..

16. What do you think are dangers and problems associated with any delay and improper disposal of unwanted pharmaceuticals? Mention them
    ..……
    ……
    …….....
    .....
    .....

17. In your opinion, what do you think are the barriers to proper disposal of unwanted pharmaceuticals?

……
……
……
……..

18. Do you think you need more professional training on pharmaceutical disposal in order to enhance your pharmaceutical management skills at your facility?

    a) Yes
    b) No

    If yes, mention few areas that you need more exposure

    …….
    …….....
    .....

19. What do you finally recommend to the National Medicines Regulatory Authority (TFDA)?

    ……
    ……
    …….

Thank you for your participation

APPENDEX 2

QUESTIONNAIRE *(Swahili version)*

DODOSO KWA AJILI YA KUPIMA UFAHAMU NA NJIA ZINAZOTUMIKA KATIKA UTUNZAJI NA UTEKETEZAJI WA DAWA ZISIZOFAA KWA MATUMIZI YA BINADAMU KATIKA HOSPITALI, VITUO VYA AFYA NA ZAHANATI MBALIMBALI ZA UMMA MKOANI DAR ES SALAAM .

Fomu Namba…….

Jina la Hospitali, Kituo cha Afya, Klinic au Zahanati ……

1. Taaluma ya msimamizi wa stoo ya dawa/famasi katika hospitali au kituo cha afya
   a) Mfamasia
   b) Fundi dawa sanifu
   c) Afisa tabibu
   d) Muuguzi/Muuguzi Mkunga
   e) Muuguzi Msaidizi
   f) Nyingine (taja) …….

2. Jinsia
   a) Mme
   b) Mke

3. Umri (miaka)
   a) 18-24
   b) 25-31
   c) 32-38
   d) Zaidi ya 39

4. Uzoefu katika usimamizi na kutoa dawa (miaka)
    a) Chini ya mwaka 1
    b) 1- 5
    c) 6- 10
    d) 11- 15
    e) Zaidi ya miaka 15

5. Je, umewahi kuhudhuria mafunzo endelevu yoyote yahusuyo dawa uteketezaji wa dawa zisizofaa kwa matumizi ya binadamu?
    a) Ndiyo (nenda swali linalofuata)
    b) Hapana

6. Je, ni mara ngapi umehudhuria mafunzo kama hayo katika kipindi cha miaka miwili iliyopita?
    a) Mara moja
    b) Mara mbili
    c) Mara tatu
    d) Zaidi ya mara tatu

7. Vipi ilishawahi kutokea kuwa dawa zinaisha muda wa matumizi kabla ya kutumika katika kituo chako?

    a) Ndiyo (kama ndiyo nenda swali linalofuata)
    b) Hapana

8. Kwa uzoefu wako unafikiri ni vitu/sababu gani zinachangia au kusababisha dawa kuisha muda wa matumizi (expiries) bila kutumika ilihali huwa dawa hazitoshelezi katika maeneo mengi nchini? Taja.

    ……
    ……
    …….

9. Eleza jinsi unavyosimamia na kutunza dawa hizo zisizofaa kwa matumizi kabla ya kuzitekeza….……
……
……
……
…….

10. Aina ya vitabu vilivyopo katika famasi yako ambavyo hutumika kama rejea wakati wa kutoa huduma na usimamizi wa ujumla dawa ndani ya stoo ya dawa.

    a) Mwongozo wa utoaji sahihi wa dawa
    b) Mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi ya binadamu
    c) Mwongozo wa usambazaji sahii wa dawa
    d) Vingine (taja)……..

11. Kama unacho kitabu cha Mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi kutoka Mamlaka ya Chakula na Dawa (TFDA); Je ulishausoma na kutambua njia mbalimbali zilizoainishwa za utunzaji na usimamizi wa dawa zisizofaa kwa matumizi kabla ya kuziteketeza?

    a) Ndiyo (kama ndiyo jibu swali linalofuata)
    b) Hapana

12. Vipi mwongozo huo una manufaa kwako na unafaa katika mfumo mzima wa utunzaji na uteketezaji wa usimamizi wa dawa zisizofaa kwa matumizi?

    a. Ndiyo
    b. Hapana (kama hapana); Taja mapungufu ambayo unafikiri yamo ndani ya mwongozo huo yanayoweza kukwamisha zoezi zima la utunzanji, usimamizi na uteketezaji wa dawa zisizofaa kwa matumizi ya binadamu.
    ……
    ……
    ……

13. Kwa kawaida mnateketeza mara ngapi dawa zisizofaa kwa matumizi ya binadamu?
    a) Mara moja kwa mwaka
    b) Mara mbili kwa mwaka
    c) Kila baada ya miaka miwili
    d) Kila baada ya miaka 3
    e) Kila baada ya miaka 4
    f) Kila baada ya miaka 5
    g) Kila inapobidi (hakuna kipindi maalumu)

14. Kwa mara ya mwisho ni lini mlifanya zoezi la kutekeza dawa? Taja mwezi na mwaka……

15. Taja njia mnazotumia kuteketeza dawa pale zinapokuwa hazifai tena kwa matumizi ya binadamu.

……...
……
……
…….

16. Unafikiri ni athari zipi zinaweza kutokea iwapo dawa zisizofaa kwa matumizi ya binadamu zitachelewa kuteketezwa au zitaketezwa kwa njia zisizo salama (mfano kutupa kwenye dampo la mtaa)? Zitaje.

    ..……
    ……
    …….....
    .....
    .....

17. Kwa maoni yako unafikiri ni vitu gani vingine vinakwamisha mfumo mzima wa uteketezaji wa dawa zisizofaa kwa matumizi ya binadamu katika kituo chako?

    ……
    ……
    ……
    ……

18. Unafikiri unahitaji mafunzo ya kila mara yahusuyo uteketezaji wa dawa zisizofaa ili kuimarisha ujuzi wa usimamizi na utunzaji dawa katika kituo chako cha kazi?

    a) Ndiyo
    b) Hapa

Kama ni “ndiyo’ taja maeneo/aina ya mafunzo ambayo unahitaji kupata fursa kama hiyo.…….

    …….....
    .....
    .....

19. Je ungependa kuishauri Serikali mambo/hatua gani za kuchukua hususan Mamlaka ya Chakula na Dawa (TFDA) juu ya tatizo la kulundikna dawa zisizofaa kwa matumizi ya binadamu (mfano dawa zilizoisha muda wa matumizi katika vituo vya afya na hospitali)

    ……
    ……
    ……
    ……
    ……
    ……..

Ahsante kwa ushirikiano

APPENDEX 3

FACILITY INDICATORS REPORTING FORM

DISTRICT……NAME OF THE FACILITY……

NAME OF INVESTIGATOR……DATE……

S/N	**HANDLING OF UNWANTED STOCK AT THE FACILITY INDICATORS**		
1.0	**Description of Indicators**	**YES**	**NO**
1.1	Is there a maintained register book for recording unwanted stock?		
1.2	Are unwanted medicines segregated from the usable stock?		
1.3	Is there a separate area to keep the unwanted stock?		
1.4	Presence of adequate security measures to avoid pilferage (e.g. Grilled gate and windows) for the store		
1.5	Presence of previous disposal records		
2.0	**Unwanted items in stock**		
2.1	Number of unwanted items in stock		

APPENDEX 4

HEALTH FACILITY INDICATORS CONSOLIDATION FORM

DISTRICT…….DATE……

S/N	Facility name	No. of expired items in stock	Main store room-adequate (YES/NO)	Register for unwanted stock (YES/NO)	Unwanted medicines segregated (YES/NO)	Separate area for unwanted stock (YES/NO)	Adequate security avoid pilferage (YES/NO)	Presence of previous disposal records (YES/NO)

APPENDEX 5

CONSENT FORM *(English version)*

CONSENT TO PARTICIPATE IN A SURVEY STUDY TO ASSESS KNOWLEDGE AND DISPOSAL PRACTICES OF UNWANTED PHARMACEUTICALS AT HEALTH FACILITIES IN DAR ES SALAAM REGION.

Greetings!

My name is Damas Matiko from Muhimbili University of Health and Allied Sciences. I am conducting a survey study on the problem of unwanted pharmaceuticals (such as expiries) in public health facilities found in Dar es Salaam region.

Purpose of the Study

The study will examine knowledge, currently used medicines disposal practices and finally identify challenges encountered in the safe disposal of unwanted pharmaceuticals in Tanzania.

Participation

If you agree to join the study, you will be required to answer all the questions that will be asked by the investigator in form of interview.

Confidentiality

All information that will be collected from you will be treated confidential and will not be used for any other purpose other than this study.

Risks

We do not expect that any harm will happen to you because of joining in this study.

Rights to Withdraw and Alternatives

Taking part in this study is completely your choice. If you choose not to participate in the study or if you decide to stop participating in the study you will continue to be treated normally. You can stop participating in this study at any time, even if you have already given your consent and if for any reason you would wish to come back into the study after withdrawal, we will be ready to accept you to continue with the study. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Benefits

Taking part in this study you will contribute towards alleviating the problem of poor handling and improper disposal of unwanted pharmaceuticals. Your information and others participating in the study will collectively be used by policy makers in addressing this problem hence protecting the health of Tanzanians. You will receive the new information about this study upon completion.

Who to Contact

If you ever have questions about this study, you should contact the following:

Mr. Damas Matiko (Principal Investigator)
School of Pharmacy,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65001, Dar es Salaam.
Mobile phone: 0715/0754 820463 OR

Dr G. A. Kagashe (Study Supervisor)
School of Pharmacy,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65013, Dar es Salaam.
Mobile : 0713 310511

Also, if you will have questions about your rights as a participant, you may call Prof. M. Aboud, Chairman of the College Research and Publications Committee,
P.O. Box 65001, Dar es Salaam. Tel: 2150302-6.

Signature

Do you agree to participate? *Write the word 'Yes' if you agree.……..*

I, _____ have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of investigator _____

Date of signed consent _____

APPENDEX 6

CONSENT FORM *(Swahili version)*

FOMU YA KUKUBALI KUJIUNGA KWA HIARI KATIKA UTAFITI KUHUSU UFAHAMU NA NJIA ZINAZOTUMIKA KATIKA UTUNZAJI NA UTEKETEZAJI WA DAWA ZISIZOFAA KWA MATUMIZI YA BINADAMU KATIKA HOSPITALI, VITUO VYA AFYA NA ZAHANATI MBALIMBALI ZA UMMA MKOANI DAR ES SALAAM

Salamu!

Mimi naitwa Damas Matiko kutoka Chuo Kikuu cha Sayansi za Afya Muhimbili. Ninafanya utafiti kuhusu uelewa na changamoto za mfumo uliyopo wa utunzaji na uteketezaji wa dawa zisizofaa kwa matumizi ya binadamu katika hospitali na vituo vya afya vya umma, mkoani Dar es Salaam.

Malengo ya utafiti:

Utafiti huu umelenga kuangalia uelewa wa wataalam wa afya juu ya utunzaji na usimamizi, njia zinazotumika kuteketeza dawa zisizofaa kwa matumizi ya binadamu na kuainisha changamoto za mfumo wa uteketezaji salama wa dawa hizo nchini.

Ushiriki katika utafiti

Kwa kushiriki katika utafiti huu utatakiwa kujibu kwa kujaza maswali yaliyopo utakayokuwa unaulizwa na mtafiti.

Usiri

Taarifa zote zitakazopatikana kutoka kwako zitakuwa ni siri na hazitatumika sehemu nyingine isipokuwa katika utafiti huu tu.

Madhara

Hatutegemei kitu chochote kibaya kutokea kwa kushiriki katika utafiti huu.

Kukubali kwa hiari kushiriki kwenye utafiti:

Ushiriki kwenye utafiti huu ni kwa hiari. Unaombwa kukubali kwa hiari. Endapo utaamua kutoshiriki au endapo utaamua kujiondoa katika utafiti utaendelea kubaki na haki zako za msingi kama kawaida. Unaweza kujiondoa katika utafiti wakati wowote, na pale utakapotaka kujiunga tena utapokelewa kuendelea na utafiti. Kukataa kujiunga ama kujitoa katika utafiti hakutasababisha adhabu au kupoteza haki yako ya msingi.

Faida za utafiti

Ukikubali kujiunga na utafiti utakuwa mmojawapo wa wale watakaofanikisha kuboresha utoaji wa taarifa za madhara yatokanato na dawa sehemu yoyote Tanzania.

Utasaidia kuwawezesha watunga sera na wataalamu wa afya kufanya maamuzi yenye faida kwa umma mzima. Utapatiwa taarifa zozote mpya zitakazopatikana kupitia utafiti huu. Hatutegemei utaingia gharama zozote kwa kushiriki kwenye utafiti huu.

Mawasiliano

Kama una swali lolote kuhusu utafiti huu tafadhali wasiliana na:

Bw. Damas Matiko (Mtafiti Mkuu)
Chuo Kikuu cha Sayansi za Afya ,Muhimbili,
S.L.P 65013, Dar es salaam
Simu ya mkononi : 0715/0754 820463, au

Dk G. A. Kagashe (msimamizi wa utafiti)
Chuo Kikuu cha Sayansi za Afya ,Muhimbili,
S.L.P 65013, Dar es salaam
Simu Na: 0713 310511

Kama utakuwa na suala lolote kuhusu haki yako kama mshiriki katika utafiti huu wasiliana na Prof. M. Aboud, Mwenyekiti wa Kamati ya Utafiti na Uchapishaji, Chuo kikuu cha Afya na Sayansi ya Tibai, S.L.P 65001, Dar es Salaam.
Simu Na : 2150302-6.

Sahihi kwa wanaokubali

Je, unakubali? Andika ndio kama umekubali……

Mimi ……nimeisoma fomu hii na kuelewa lengo la utafiti huu na maswali yangu yamejibiwa na sasa nakubali kwa hiari kujiunga na utafiti huu.

Sahihi ya mshiriki…….....
Sahihi ya mtafiti……

Tarehe ya kusaini……