IMPLEMENTATION OF THE GUIDELINE FOR SAFE DISPOSAL OF UNFIT MEDICINES: A CASE OF REGIONAL REFERRAL AND REGIONAL HOSPITALS AND REGULATORY AUTHORITIES IN DAR ES SALAAM

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By

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science (Project Management, Monitoring and Evaluation in Health) of Muhimbili University of Health and Allied sciences

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CERTIFICATION

The undersigned certifies that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled *"**Implementation of the Guideline For Safe Disposal of Unfit Medicines: A Case of Regional Referral and Regional Hospitals and Regulatory Authorities in Dar es Salaam"*** in fulfilment of the requirements for the degree of Master of science of Muhimbili University of Health and Allied Sciences.

Dr George Ruhago
(Supervisor)

Date:

DECLARATION AND COPYRIGHT

I, **BERITHA GODFREY KYABULA**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature_____ Date _____

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First I would like to thank the almighty God for the guidance, protection and provision throughout these years

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DEDICATION

I dedicate this work to my precious family, thank you so much for your support, prayers and your endless love towards me. I love you so much

ABSTRACT

Background: Unfit medicines includes expired, improperly sealed, damaged, unexpired but improperly stored, improperly labelled, counterfeit, substandard and adulterated, prohibited and unauthorized. To prevent accumulation and unsafe/ improper disposal of unfit medicines in Tanzania, Tanzania medicines and Medical Devices Authority (TMDA) formulated the guideline for safe disposal of unfit medicines. However, studies done after the introduction of the guideline in Tanzania has shown that unsafe/ improper disposal of unfit medicines is still rampant.

The aim of the study: To assess how hospitals in Dar es Salaam implement the guideline for safe disposal of unfit medicines and regulatory authorities (Local Government Authorities (LGA'S) and TMDA) ensure adherence to the guideline.

Materials and Methods: This study was conducted in Dar es Salaam region. A total of 18 participants were interviewed, a study design was a descriptive cross-sectional study using a mixed-method approach both qualitative (in-depth interview) and quantitative (observational). Quantitative data were analysed by Microsoft excel and qualitative data by thematic analysis.

Results: The findings of this study revealed that in handling unfit medicines before disposal; hospitals register them in the book for unfit medicines, segregate from usable medicines, separate according to dosage forms, keep in the separate area for storage of unfit medicines and label them properly. And before disposal, they request for disposal from hospital management and others from respective authority (TMDA). The study also explored various disposal methods such as incineration, returning to the supplier, and outsourcing and based on TMDA guideline. Moreover, the study revealed inspection, supportive supervision, provision of education and dissemination of the guideline as measures applied by TMDA and LGA'S in ensuring adherence to the guideline.

Conclusions: The study has shown non-adherence to some of the procedures in the guideline for safe disposal of unfit medicine and measures used by regulatory authorities in ensuring adherence to the guideline.

Recommendations: Enough budgets should be allocated to regulatory authorities to ensure effective implementation of their roles in ensuring adherence to the guidelines, enough space for storage of unfit medicines and continuous education to hospitals on the importance of implementing the TMDA guideline and the impact of improper disposal of unfit medicines.

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ABBREVIATION

ARVS	**-**	Antiretroviral drugs
DMO	**-**	District Medical Officer
DHIS2	-	District Health Information Software 2
HIV	**-**	Human Immunodeficiency Virus
LGA	**-**	Local Government Authority
MOHCDGEC	-	Ministry of Health, Community Development, Gender, Elderly and Children
MUHAS	**-**	Muhimbili University of Health and Allied Sciences
NEMC	**-**	National Environment Management Council
NGO	-	Non-government Organisation
PORALG	**-**	President's Office Regional Administration and Local Government
RMO	**-**	Regional Medical Officer
TMDA	**-**	Tanzania medicines and Medical Devices Authority
FEFO	**-**	First- Expiry- First Out
WHO	-	World Health Organization.
USA	**-**	United state of America

DEFINITION OF TERMS

Disposal: The process of rendering the unfit medicinal products for the duration of its biological and chemical activity such that it is harmless.

Institution: Community pharmacies, Health facilities such as hospitals, health centres and dispensaries

Medicines / Pharmaceutical product / Drug: 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.

Safe disposal: Disposal through medium and high incineration, immobilization, fast-flowing watercourse, chemical decomposition, sewer, return to donor or manufacturer, engineered and open uncontrolled non-engineered landfill depending on the type and formulation of the medicines.

Store personnel: Personnel responsible for the supervision of the hospital medicines stores as the main responsibility daily.

Unsafe/improper disposal: Disposal in the toilet/ sink, street /municipal dustbin and burning in open containers

Unwanted pharmaceuticals/ pharmaceutical waste: Medicines which have expired, damaged, have contaminated items, have items instituted for recall and prohibited.

CHAPTER ONE

1. INTRODUCTION

1.1 BACKGROUND

Unfit medicines include expired, improperly sealed, damaged, unexpired but improperly stored, improperly labelled, counterfeit, substandard and adulterated, prohibited and unauthorized(1,2). Among the reasons for unfit medicines is the problem in the supply chain such as poor selection and quantification due to lack of proven data and techniques leading to overstocking, poor storage conditions such as direct storage of medicines on the floor, lack of systematic arrangement of stock, presence of dust and pests, inadequate protection from direct sunlight and lack of monitoring of the temperature to prevent degradation of medicines together with issuing of medicines without using First Expiry First Out (FEFO) (3,4)

Globally, the most common methods used for disposing of medications by individuals or households are disposal in the toilet or sink, rubbish bin, burning and returning to the pharmacy(5). Most of these methods are also commonly used by health facilities, communities and pharmacies in African countries including Tanzania except returning to the pharmacy which is fewer practices in most Africa countries(5–11)

Disposal of unfit medicines through toilet or sink and the rubbish bin is reported to be among the route through which pharmaceuticals enter into environment together with excretion via faeces and urine, agriculture, and industries. Once disposed of through the sink or toilet or landfilling, pharmaceuticals reach municipal water or effluent treatment plant of municipalities and groundwater through leachate from the landfilling. The effluent treatment plant is reported not to completely remove the medicines and hence allow some medicines to pass and reach homes through municipality based water supply(12–14).

In almost seventy-one countries worldwide pharmaceutical substances have been found in the environment where more than hundred different pharmaceutical substances have been found in several European countries and United State of America (USA) in the aquatic environment (surface waters, groundwater and/or tap/drinking water) and most regions of the Pacific, Africa, and Eastern Europe less or equal than thirty pharmaceuticals have been detected. With the most commonly found therapeutic groups were antibiotics, analgesics, and hormones(15)

To ensure safe disposal of unfit medicines, World Health Organization (WHO) formulated the guideline for safe disposal of unwanted pharmaceuticals in and after emergencies in 1999 to assist with safe disposal of unused pharmaceuticals based on a report on the safe disposal of unwanted and unusable drugs in Mostar, which had accumulated during the war in Bosnia and Herzegovina due to inappropriate donation (16,17).

Tanzania also through Tanzania medicines and Medical Devices Authority (TMDA) formulated the guideline for safe disposal of unfit medicines in 2009 based on WHO guideline which was then updated in 2018 to guide medicines dealers on the handling of unfit medicines before the disposal and during disposal after seeing disposal of unfit medicines not being done systematically and professionally(1,2). This guideline gives TMDA a mandate to supervise the destruction of all unfit medicines in the country to ensure safe disposal, and up to 2013, TMDA supervised disposal of unfit medicines worth around TZS 4,941,259,131 (18).

According to the TMDA guideline for safe disposal of unfit medicines, the following are procedures for handling and disposal of unfit medicines; Procedures for handling unfit medicines and procedures for disposal of unfit medicines.

Procedures for handling unfit medicines; Once the medicines become unfit, all premises should store unfit medicines by putting in place a register for unfit medicines, kept separately medicines which fall under controlled drugs, antineoplastic, antibiotics and any other hazardous medicines, keep unfit medicines into different categories by dosage forms, demarcate an area for keeping unfit medicines which shall be labelled conspicuously in red ink with words “ unfit for intended use" or "hazifai Kwa matumizi" and maintain safe custody of unfit medicines in registered premises until they are disposed of.

Procedures for disposal of unfit medicines; before the disposal, the institution should seek the approval from the TMDA, and once the approval is issued, the TMDA will do the sorting and verification to verify the products. Once the verification and sorting are complete, TMDA shall order the applicant to liaise with National Environment Management Council (NEMC) or any other institution responsible for environment management on the proposed mode of destruction and issuance of disposal permit.

Upon issuance of disposal permit, the applicant shall submit the permit to TMDA and shall liaise with Local government Authority (LGA) or any other institution approved by NEMC for disposal site, cost and date of destruction(2).

The destruction exercise shall be supervised by the Health Officer, Environmental Officer, Policeman and Drug Inspector. Then after completion of the destruction, a drug disposal form shall be duly filled in and signed by the supervisors and owner/owner's representative then the form shall be sent to TMDA headquarter offices and then TMDA will issue a certificate of destruction of unfit medicines to the corresponding institution(2).

Since the introduction of this guideline in Tanzania, two studies have been done to assess the practices and challenges encountered in the managing disposal of unfit medicines and found that the most common methods used for disposal of unfit medicines were putting into the street dustbin or pouring into the sink(6), crushing and burying at the dumpsite, burning at the dumpsite and incineration(7).

So, this study aimed at evaluating the process implementation of the guideline for safe disposal of unfit medicines involving health service providers, TMDA and LGA's to get an in-depth understanding of guideline implementation.

1.2 PROBLEM STATEMENT

A good implementation of the guideline for safe disposal of unfit medicines which involves implementing procedures for handling unfit medicines and procedures for disposal of unfit medicines prevents accumulation and unsafe disposal of unfit medicines (1,2). However studies done to assess practices and challenges encountered in the managing disposal of unfit medicines after the introduction of the guideline has shown that the practice of unsafe disposal of unfit medicines is still practised, whereby 72.4% of public health facilities dispose of unfit medicines through crushing and burying while 31.0% through burning. On the other hand, 41.4% of both private hospitals and medicines outlets dispose through street dustbins or pouring into the sink (6,7).

According to WHO guideline for safe disposal of unwanted pharmaceuticals in and after emergencies, improper/unsafe disposal can contaminate water, kill bacteria necessary for the treatment of sewage, and release of toxic pollutants into the air (16).

However, the studies done in Tanzania did not involve regulatory authorities (TMDA and LGA'S) to get their views regarding guideline implementation and still little is known on how health facilities follow the procedures for disposal as stipulated in the TMDA guideline for safe disposal of unfit medicines (6,7). So, this study aimed at evaluating the process implementation of the guideline for safe disposal of unfit medicines involving hospitals, TMDA and LGA's to get an in-depth understanding of guideline implementation.

1.3 CONCEPTUAL FRAMEWORK

This conceptual framework shows that good implementation of the guideline for safe disposal of unfit medicines ensures safe disposal of unfit medicines and good implementation of the guideline for safe disposal of unfit medicine involves following the procedures stipulated in the guideline in handling unfit medicines before disposal and during disposal.

The implementation of the guideline for safe disposal of unfit medicines is influenced by the availability of the guideline in the health facilities, inspection, supervision but also training on the implementation of the guideline.

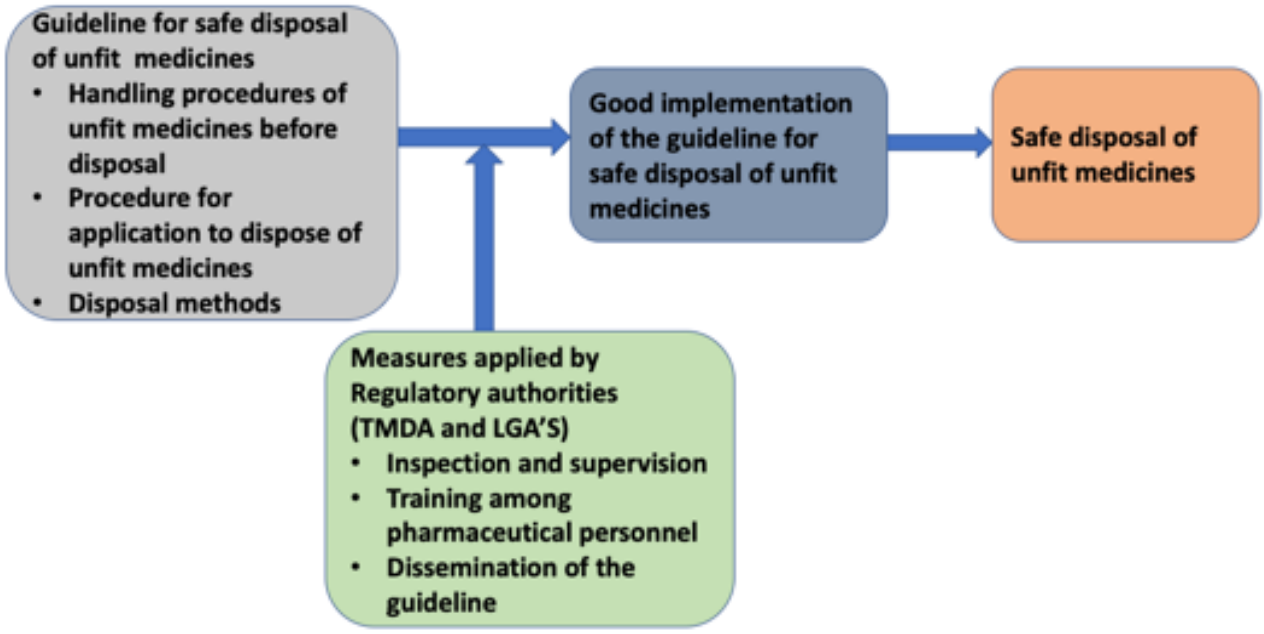

Figure 1: Conceptual framework

1.4 STUDY RATIONALE

The findings of this study provided valuable information to TMDA who are the enforcers of the implementation of this guideline and other stakeholders involved in the disposal of unfit medicines such as President's Office, Regional Administration and Local Government (PORALG), Ministry of Health, community development, Gender, Elderly and Children (MOHCDGEC) and the ministry responsible for the environment to improve the implementation of this guideline. But it will add more literature on the implementation of the guideline for safe disposal of unfit medicines

1.5 RESEARCH QUESTIONS

1.5.1 MAIN QUESTION

How do hospitals in Dar es Salaam region implement the guideline for safe disposal of unfit medicines and the regulatory authorities (TMDA and LGA's) ensure its adherence?

1.5.2 SUB QUESTIONS:

1. How do hospitals in Dar es Salaam region handle unfit medicines before disposal?
2. To what extent do hospitals in Dar es Salaam adhere to a procedure for application to dispose of unfit medicines?
3. What measures are applied by TMDA and LGA's to ensure adherence to the guideline for safe disposal of unfit medicines?
4. What types of disposal methods are practised by hospitals in Dar es Salaam in the disposal of unfit medicines?

1.6 OBJECTIVES OF STUDY

1.6.1 BROAD OBJECTIVE

To assess the implementation of the guidelines for safe disposal of unfit medicines by hospitals in Dar es Salaam region and how regulatory authorities (TMDA and LGA's) ensure its adherence.

1.6.2 SPECIFIC OBJECTIVES

1. To assess the handling procedures of unfit medicines before disposal at hospitals in Dar es Salaam.
2. To assess the extent to which hospitals in Dar es Salaam adhere to a procedure for application to dispose of unfit medicines.
3. To assess measures applied by TMDA and LGA's to ensure adherence to the guideline.
4. To explore types of disposal methods which are practised by hospitals in Dar es Salaam to dispose of unfit medicines?

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Disposal of unfit medicines has been reported in different parts of the world as a public health challenge (5). These challenges differ from one setting to another due to various factors including law enforcement status, knowledge among pharmaceutical personnel and existing disposal infrastructures. Proper disposal of unfit medicine has a significant contribution and protections to public health(16). Therefore, guidelines on the proper way of managing disposal are of paramount importance to be implemented and adhered. Globally health facilities and medicines outlets are required to implement the guideline to ensure proper disposal of unfit medicine. But, due to the stated challenges, there have been discrepancies in adhering to this guideline.

This following section discusses the implementation of the guideline as guided by the specific study objectives.

2.2 Handling procedures of unfit medicines before disposal

2.2.1 Globally

In Yemen, a study done on assessment of medical waste management in main hospitals has shown that both in government and private hospitals, pharmaceutical waste (expired drugs) are not segregated from the other hospital waste (liquid waste, blood waste, human tissue remains), both are collected in the same waste bag(19).

In Nepal, a study done on pharmaceutical waste management in private pharmacies of Kaski district has shown that most of the pharmacies (95.8%) has waste collecting container but few (28.6%) use system of colour coding and labelling for the segregation of waste(20)

2.2.2 Africa

In Nigeria, a study done on assessment of disposal practices of expired and unwanted medications among community pharmacies has shown that a majority of pharmacies are ensuring proper separation and storage of the expired medicines (8), This is the similar to South Africa where 75% of pharmacies comply with the separation of expired medicine for disposal and 78% store the expired medicine in a locked place away from the view of the public (21).

In Kenya, a study done on the handling of pharmaceutical waste in community pharmacies in Nairobi has shown that community pharmacies store their pharmaceutical waste in waste containers such as cartons, paper bags, dustbin or boxes and half of them keep these waste containers in a segregated room while 43% have no place to keep the pharmaceutical waste (22)

Also in Egypt, a study done on management of hazardous pharmaceutical waste generated from healthcare facilities has shown that hazardous pharmaceutical waste generated from health care facilities are collected in yellow bags, stored in special red or yellow containers and stored in the area specified for infectious hospital waste (23)

2.2.3 Tanzania

In Tanzania, a study done on managing the disposal of unwanted pharmaceuticals at public health facilities in Dar es Salaam has shown that few procedures for handling unfit medicines before disposal are known and practised by store personnel's at public health facilities in Dar es Salaam, which are separation of unfit medicines from usable stock, listing the medicines in a register, packing them into boxes and labelling them, and keeping them in a separate area. But a physical check of the stores revealed unfit medicines are poorly handled before disposal as some of the unfit medicines are left unpacked into boxes or separated from the usable medicines and not properly labelled (7)

Also, a study done on disposal practice of unfit medicines at non-governmental hospitals and private medicines outlets in Mwanza region has shown that few health facilities (10%) are maintaining the register book for recording unfit medicines (6)

2.3 A procedure for application to disposal of unfit medicines.

2.3.1 Globally

According to WHO guideline for safe disposal of unwanted pharmaceuticals in and after emergencies, approval for disposal of unfit medicines should be sought from appropriate Authority before disposal of unfit medicines(16).

Globally no study has been done to assess the extent to which health facilities or community pharmacies follow a procedure for application to disposal of unfit medicines.

2.3.2 Africa

In Nigeria, all expired drugs should be reported to the National Agency for Food and Drug Administration and Control (NAFDAC). According to the study done on the assessment of disposal practices of expired and unused medications among community pharmacies in Nigeria, it has shown that 23.4% of community pharmacies complied fully to the guideline meaning they adhered to the application procedure for disposal of unfit medicine from the NAFDAC (8).

2.3.3 Tanzania

According to TMDA guideline for safe disposal of unfit medicines, anyone who intends to dispose of unfit medicines should request in writing to Director General of TMDA(1,2). Although studies done to assess the practices and challenges encountered in the managing disposal of unfit medicines in Tanzania provided information on the records of past disposal of unfit medicines by TMDA but didn't give information on the extent to which hospitals adhered to the application procedure for disposal of unfit medicines(6,7)

2.4 Measures which are applied by TMDA and LGA's to ensure adherence to the guideline.

Little is known on how drug authorities and LGA's are ensuring adherence to the guideline although many studies have recommended what should be done to ensure adherence to the guideline.

2.4.1 Globally

In Kuwait, a study done on practice, awareness and opinion of pharmacists toward disposal of unwanted medications have recommended that education campaign should be provided to the pharmacists to increase awareness of the disposal guideline and hence high compliance to the guideline(24).

2.4.2 Africa

In Kenya, a study done on the handling of pharmaceutical waste in community pharmacies in Nairobi has recommended training should be provided to pharmacy staff on the guideline of handling of unfit medicines by the body responsible for handling the disposal of unfit medicines to ensure adherence to the guideline and guideline should be available in regulatory authorities website to ease access (22)

In Nigeria, a study done on the assessment of disposal practices of expired and unused medications among community pharmacies has recommended strengthening of protocols and adequate law enforcement to ensure adherence to the guideline (8)

2.4.3 Tanzania

In Tanzania, studies done to assess practices and challenges encountered in the managing disposal of unfit medicines have recommended that TMDA should do regular supervision, distribute the guideline for safe disposal of unfit medicines, regular training**,** facilitate the availability of large commercially-run incinerators through private investments to ensure safe disposal of unfit medicines (6,7)

2.5 Disposal methods practised in the disposal of unfit medicines.

2.5.1 Globally

In South and South-East Asian region, a study done on improper management of pharmaceutical waste has shown that pharmaceutical waste generated from households, community pharmacies and hospital pharmacies are disposed of mostly through toilet/ sink and trash/bin, where liquid pharmaceutical wastes are disposed through toilet/sink and solid dosage forms through trash/bin(25)

In Kuwait, a study done on practice, awareness and opinion toward disposal of unwanted medications of pharmacists from governments and specialized polyclinics have shown that the main method of disposing of unwanted medications is through the trash, where 73% of pharmacists reported disposing of unwanted medications through throwing in the trash and 16% reported disposing of according to the guideline of Ministry of Health, Kuwait(24).

In India, a study done on minimizing pharmaceutical waste has shown that most of the leftover/expired drugs were returned to the distributors irrespective of dosage forms however many of the respondent were not clear on how the pharmaceutical distributors dispose of drugs, moreover this study reported that when there is a less quantity of these medicines, they are trashed especially the one in solid dosage forms (28).

2.5.2 Africa

In Nigeria, a study done on assessment of disposal practices of expired and unused medications among community pharmacies has shown that the major methods of disposing of unfit medicines by pharmacies are through the rubbish bin, by returning to drug wholesalers/ distributors and through the National Agency for Food and Drug Administration and Control (NAFDAC), where 23.4% of community pharmacies are complying fully to the guideline, 22.1% complying partially to the guideline and 54.5% do not comply to the guideline (8).

In Ghana, a study done on assessment of pharmaceutical waste management at selected hospitals and homes has shown that hospitals are disposing pharmaceutical waste through burying or dumping on landfill/ dumpsite, and among the five studied hospitals, four hospitals are burning in incinerator below the recommended temperature and no segregation of pharmaceutical waste with other hospital waste is done during disposal through incineration(26)

Also in Kenya, a study done on the handling of pharmaceutical waste in community pharmacies in Nairobi has shown that pharmacies are disposing of pharmaceutical waste through municipal waste, informal waste collectors and burning(22)

Nonetheless, a study done in Ethiopia has reported that health facilities dispose of expired and damaged medications based on disposal guidelines provided by Ethiopian Food Medicine and Healthcare Administration and Control Authority (FMHACA) (27)

2.5.3 Tanzania

In Tanzania, a study done on disposal practice of unfit medicines in non-governmental hospitals and private medicines outlets in Mwanza region has shown that 41.4% of non-governmental hospitals and private medicines outlet are disposing unwanted pharmaceuticals through street dustbin or pouring into the sink(6). Another study done on managing the disposal of unwanted pharmaceuticals at public health facilities in Dar es Salaam has shown that 72.4% of the public health facilities are disposing of unwanted pharmaceuticals through crushing and burying, 31.0% burning and 37.9% incineration(7)

CHAPTER THREE

3.0 METHODOLOGY

3.1 INTRODUCTION

This chapter describes the study design, study area, study population, sampling procedure, sample size, data collection methods, data analysis and ethical consideration.

3.2 Study Design

The study was a descriptive cross-sectional study with a mixed-method approach of qualitative (in-depth interview) and quantitative (observational) which was used in assessing the implementation of the guideline for safe disposal of unfit medicines involving hospitals, TMDA and LGA'S in Dar es Salaam.

3.3 Study Area

The study was conducted in Dar es Salaam Region, which has five districts, Kinondoni, Ubungo, Ilala, Temeke and Kigamboni. This region was among the regions where improper disposal of unfit medicines was reported (7)**,** This region has a large number of hospitals (52 operating hospitals of which 13 are public and 39 are private) compared to other regions in Tanzania, a large number of patients whereby in 2019, 121,996 were inpatients and 7,986,813 outpatients as per District Health Information Software 2 (DHIS2) data but also due to high consumption of medicines due to its large number of patients.

3.4 Study population

The study population was pharmacists in charge and store personnel from hospitals, drug inspectors from TMDA eastern zone and district pharmacists from LGA'S.

3.4.1 Inclusion criteria

- Pharmacists in charge, store personnel, drug inspectors, and district pharmacists who have been designated to that position for at least one year.

3.4.2 Exclusion criteria

- Pharmacists in charge, store personnel, drug inspectors and district pharmacists who were on leave during data collection and those who were not willing to participate in the study.

3.5 Sampling procedures

Hospitals were selected conveniently due to easy accessibility and the limited time of research, whereby public and private hospitals in the level of regional referral and regional

respectively were included in the study, and from each pharmacist-in-charge and store personnel who met the inclusion criteria and voluntarily consented was interviewed.

There were 3 public hospitals in the level of regional referral and 5 private hospitals in the level of regional, all 3 public hospitals and 4 private hospitals were involved in the study. 6 hospitals had pharmacist in charges and store personnel except for 1 hospital which had the only pharmacist in charge.

For TMDA and LGA's the participants (drug inspectors and district pharmacists) were purposively sampled based on their knowledge on the area of study and their experience, The TMDA eastern zone had 26 drug inspectors and LGA'S had 5 district pharmacists

3.6 Sample size

A total of 18 participants were involved in the study, whereby 10 were from hospitals (5 pharmacists in charge and 5 store personnel), 4 from LGA'S (district pharmacists) and 4 from TMDA (drug inspectors). For each population, the sample size was reached after saturation of information.

Two pharmacists in charge of the hospitals were excluded from the study as they were on leave during data collection and one store personnel who was not willing to participate in the study.

3.7 Pre-testing of the data collection tools.

A pre-test of the data collection tools (interview guides and checklist) was done before commencing of data collection to check whether the tools were able to collect the intended information, so this was done in one of the hospitals involving both the store personnel and pharmacist in charge and regulatory authorities involving three participants. In the in-depth interview, the pre-test revealed that some questions were not well formulated and in the checklist, some questions were not measurable. Therefore, these tools were modified according to the results of the test by reforming, adding, and removing some questions and this hospital and participants from both hospital and regulatory authorities were not included in the study. Furthermore, the checklist and interview questions used for data collection in the hospitals were adapted from previous quantitative studies done on assessing the disposal practice of unfit medicines and modified for use in the in-depth interview (6,7).

3.8 Data collection procedures.

Data were collected by the researcher herself whereby the researcher asked for an appointment with the participants before conducting the study, during data collection the researcher introduced herself and explained the title of the study, the purpose of the study and methods of data collection and then the consent forms were given to participants before starting the data collection and only those who gave their informed consent were interviewed. In the hospital's data were collected both quantitatively and qualitatively, whereby qualitative data were collected first through in-depth interview with the pharmacists in charge and store personnel by using an interview guide and the audiotape was used to record the conversation. The in-depth interview was then followed by a collection of quantitative data which was collected through observation by using a checklist.

In-depth interview was used to get in-depth information on how hospitals handle unfit medicines before disposal, a procedure for application followed before disposal of unfit medicines and to explore various disposal methods practised during disposal of unfit medicines while a checklist was used to observe the handling procedures before disposal, application forms and disposal form or certificate for destruction to verify information collected through the in-depth interview.

In TMDA and LGA'S data were collected only qualitatively through an in-depth interview by using an interview guide different from the one used in hospitals to get in-depth information on different measures used by regulatory authorities in ensuring adherence to the guideline.

3.9 Data management

Checklists and transcripts were given codes to facilitate data analysis. Both audio files and transcripts were stored both in the computer and online to prevent loss of data but also checklists and consent forms were stored in the file and placed where only the researcher has access to.

3.10 Data analysis

Qualitative data were analysed by thematic analysis whereby recordings were transcribed into text in Swahili language and then translated in English. This was followed by coding, then codes were merged into themes, the themes were then named, reviewed, and described to produce meanings according to research questions. Then meanings extracted from themes were then presented in the text.

Quantitative data were checked for completeness, correctness every day and after completion of data collection, because the quantitative data were small, they were analysed by Microsoft excel and presented in a column chart.

3.11 Reliability and Validity

To ensure quantitative data are reliable and valid, the checklist was adapted from the similar previous studies conducted (6,7) and pre-testing of the checklist was done before data collection commenced.

3.12 Trustworthiness of the findings

To ensure the findings of this study are credible, transferable, confirmable and dependable (29,30), this study used various data collection methods especially in hospitals i.e. in-depth interview by using an interview guide and observation by using a checklist, but also it involved a wide range of participants such as pharmacists in charge and store personnel from hospitals and district pharmacist and drug inspectors from regulatory authorities so that information given can be verified against others, Furthermore, the study used probing to elicit detailed information during the in-depth interview and provide a detailed description of the methodology.

3.13 Ethical issues

The ethical clearance was obtained from MUHAS Ethical Review Committee of Research and publication, and the permission to conduct the study in the hospitals was approved by the medical officers in charge for public hospitals, managing directors for private hospitals, Director-general-TMDA headquarters for conducting the study in TMDA eastern zone and councils' directors and District Medical officers for LGA'S.

But also, before commencing of data collection, the written consent/ permission was sought from the participants and only those who gave their informed consent was allowed to participate in the study.

3.14 Confidentiality

To ensure confidentiality the names of the participants were not required during the interview or captured during the audio recording but also the transcripts were given codes to hide the identity of the participants involved in the study.

3.15 Dissemination of the results

The study report will be disseminated to the regulatory authorities (TMDA eastern zone and LGA'S) and to the implementers of the guideline, which for the case of this study will be hospitals involved in the study.

CHAPTER FOUR

RESULTS AND FINDINGS

4.0 INTRODUCTION

This chapter describes the findings of the study based on study objectives which were; handling procedures of unfit medicines before disposal, a procedure for application to disposal of unfit medicines, measures applied by TMDA and LGA'S in ensuring adherence to the guideline and types of disposal methods which are practised in the disposal of unfit medicines.

4.1 Socio-demographic characteristics of the respondents

The respondents were 18 in total whereby male (11) and female (7), their age ranges from 29 years to 50 years. The respondent had experience ranging from 1 year to 10 years.

4.2 Handling procedures of unfit medicines before disposal

In assessing handling procedures of unfit medicines before disposal compared to the TMDA guideline for safe disposal of unfit medicine, both in-depth interview and observation by using checklist were used. The checklist was used to verify what has been said in the in-depth interview compared to what was being practised.

The results from the checklist revealed that 7 (100%) of the visited hospitals segregate the unfit medicines from the usable medicines, 6 (86%) maintained a register book for unfit medicines, 3 (43%) separate the unfit medicines according to dosage forms, 5 (71%) have a separate area to keep the unfit medicine, 3 (43%) have adequate security measures to avoid pilferage and 3 (43%) label properly expired not for sale in red ink as shown in figure 2 below;

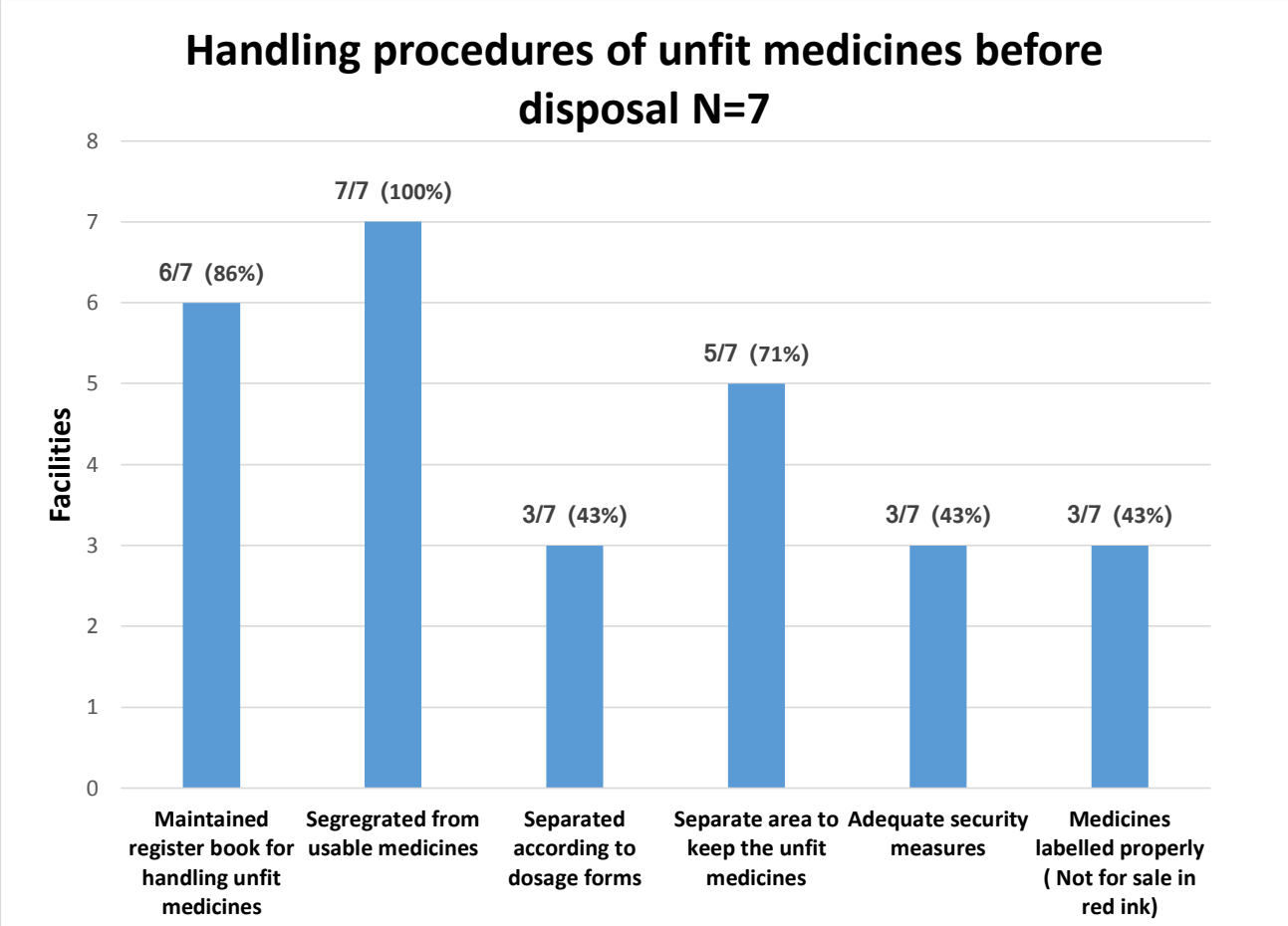

Figure 2: Handling procedures of unfit medicines before disposal

The results from the in-depth interview revealed procedures for handling unfit medicines before disposal as the broad theme with its sub-themes which were; registering in the book for unfit medicines, segregating from usable medicines, separating according to dosage forms, keeping in the separate area for storage of unfit medicines and labelling properly.

4.2.1 Segregating from the usable medicines

The findings revealed that when medicines get expired, they are removed from the shelves to separate them from the usable medicines

As one respondent reported.

> *"The first thing you are supposed to remove them from the shelves and find for them the isolation area" (Hospital 6A)*

And another respondent added

"First you remove them from the shelves; you record them with the name of the medicine, batch number, manufacturing date, expiring date, quantity and value" (Hospital 4B).

4.2.2 Registering in the book for unfit medicines

The findings revealed that when medicines expire, they are removed from the ledger of fit medicines and recorded in the ledger/book for unfit medicines; this ledger is known as a suspensory ledger in public hospitals.

As one respondent reported.

> *"We remove them from the ledger for medicines that are fit for use and register them in the ledger for medicines that are not fit for use" (Hospital 2B).*

And another respondent reported

"*We register unfit medicine in the suspensory ledger, with the name of expired medicine, its quantity and additionally with the value of the expired drug" (Hospital 4A)*

And another one had this to say

"*They are recorded with details such as batch number, expiry date, quantity and its formulation" (Hospital 1A)*

4.2.3 Separating according to dosage forms

The findings of this study revealed that once the medicines become unfit, during storage they are separated according to dosage forms.

As one respondent reported.

"We do sort the expired drugs according to their type and dosage form, for example, tablets and capsules they stay in one place, injectable in one place, we don't mix them to ease disposal" (Hospital 7A)

And another respondent added

> *"We pack based on type of medicine particularly dosage form, injectable will be packed separately, tablets separately, supplies separately but apart from that controlled drugs also they might be injectable but we can't mix with other injectable" (Hospital 4B)*

And another one had this to say

> *"When medicines get expired, we remove them from the shelves and we keep them separately like syrups we put them separate from tablets" (Hospital 3B)*

4.2.4 Labelling properly

The findings of the study revealed that once medicines become unfit they are removed from the shelves and put in the boxes labelled with the mark indicating that they are unfit for use with two hospitals (hospital 6 and 4) labelling also with information such as the name of the medicine, batch number, quantity and form of the medicine.

As one respondent reported.

"*You have to label them that they are unfit for use with red mark together with a list that shows the brand, quantity and the form of the medicine" (Hospital 6A)*

And another respondent added

> "*During the process of storing these medicines, we pack them in boxes then we label the boxes with those descriptions I mentioned such as the name of the medicine, batch number and quantity" (Hospital 4B)*

4.2.5 Keeping in the separate area for keeping the unfit medicines

The findings of the study revealed that five hospitals have a separate room/ area for keeping the unfit medicines once they have been removed from the usable medicines.

As one respondent reported.

> *"We have a storage area with the internal auditor where we are sending them; I don't keep any expired medicines in the store" (Hospital 6B)*

And another respondent reported

"*We remove them from the position of the medicines which are fit for use and then we put them in the position for unfit medicines'' (Hospital 2B)*

4.3 Procedure for application to dispose of unfit medicines

In assessing the extent to which hospitals adhere to request in writing to TMDA before disposing of the unfit medicines, the in-depth interview was used to assess the application procedure but also the checklist was used to observe the application forms for the past disposal.

The results from the checklist revealed that only one hospital had the application form to TMDA for past disposal. And the results from the in-depth interview revealed application procedure to dispose of unfit medicines as a broad theme with its sub-themes which were; requesting from the hospital management and requesting from the respective authority (TMDA).

4.3.1 Requesting from the hospital management

The findings of this study revealed that, both hospitals before disposing of unfit medicines they first request for approval from hospital management, whereby for private hospitals they request from internal auditor while public hospitals they request from facility medical officer in charge and ministry of health as one respondent reported:

"*We are writing the letter to the hospital internal auditor to inform him about the expired medicines then he will come and check them then we put them in the boxes and take them there in the incinerator where they are burning the medicines" (Hospital 3B)*

4.3.1 Requesting from the respective authority (TMDA)

The findings of this study revealed that after requesting the approval from the hospital management hospital 2, 4 and 6 request again for disposal from TMDA as one respondent reported:

"We are writing to the internal auditor, the internal auditor will send a list to TMDA to get permission, and then we will have to pay depending on the quantity of medicines" (Hospital 6B)

And another one had this to say:

"When I have expired medicines, the first thing I do is to quantifying them and put its value then I will notify the medical officer in charge of the hospital who will then notify the ministry, the ministry has a department of stock verification who came and inspected, condemned them and put their labels then they said they are taking to the general secretary of the ministry of finance to get the finance" (Hospital 2A)

4.4 Measures applied by TMDA and LGA's to ensure adherence to the guideline

In assessing measures which are applied by TMDA and LGA'S to ensure adherence to the guideline, an in-depth interview was used with the drug inspectors from the TMDA and the district pharmacists from LGA'S.

The findings from the in-depth interview revealed measures applied by TMDA and LGA's as the broad theme with its sub-themes which were a provision of education, inspection, supportive supervision, penalties such as fines and dissemination of the guideline.

4.4.1 Provision of education

Provision of education was reported as a measure used by both TMDA and LGA'S to create awareness or sensitize on issues relating to the implementation of the guideline for safe disposal of unfit medicines, including the handling of unfit medicines before disposal and application for disposal to ensure adherence to the guideline, this measure was reported to be done through formal meeting and on job training during supervision and inspection.

4.4.1.1 Formal meeting

The formal meeting was reported by both TMDA and LGA'S as a means for the provision of education and awareness on different guidelines including the guideline for safe disposal of unfit medicines, as TMDA respondents mentioned, it helps them to disseminate the information to the local government authorities and then from LGA'S to the facilities.

"We have been reaching hospitals and passing through facilities to providing education, but also we have been preparing meetings or training with professionals in the municipals where these hospitals and facilities are to train them

" (TMDA 9D)

And respondent from Local government added

> *"The large information we get through the meetings; these meetings are the major way we use for the provision of education, for example, one month ago we had a meeting with owners of "Maduka ya Dawa Muhimu" in the meeting we discussed the handling of expired medicines" (LGA'S 11)*

4.4.1.2 On job training

The findings of this study also revealed that education on the implementation of the guideline is mostly provided through on job training during inspection or supervision to sensitize on different procedures in the guideline.

As one respondent reported

> *"Due to limited budget for formal training, during our visits/supervision to health facilities, we normally provide on job training, based on the issues arising during the supervision" (LGA 12)*

And another respondent added

"*We have been doing inspection and provision of education when passing through these areas together with the inspection we have been doing facilitation whereby we explain to them and remind them about the procedures and guidelines" (TMDA 9E)*

4.4.2 Supportive supervision and inspection

The findings revealed that supportive supervision and inspection are methods used to ensure adherence to the guideline with the frequency of supervision varies from every month, every quarter and based on complain or when there is a special need.

As one respondent reported

"*Mostly we are creating awareness through supportive supervision in all health facilities both public and private, and following them up closely for those who have problems" (LGA'S 12)*

And another one reported

"*We have been doing an inspection in these hospitals and one of the things that we look at in our inspection it's the way unfit products are handled whether it's expired or damaged, its one of the requirement in our inspections to check handling of expired items" (TMDA 9D)*

And another one had this to say

"*We do an inspection, from my experience every quarter a facility has to be inspected, whenever possible a facility has to be visited not less than four times in a year" (LGA 10P)*

4.4.3 Fines

The findings also revealed that during supervision and inspection, when the facility is found with unfit medicines such as counterfeit or substandard or expired medicines which are not segregated from the usable medicines, the medicines will be confiscated and the owner will pay 25% of the cost of those medicines as a fine.

As one respondent reported

"When we find the expired medicines in the shelf according to the law, we confiscate them, and the owner has to pay 25% of the cost of those medicines for the destruction of those medicines" (TMDA 9F)

And another one had this to say

"When doing supervision in these facilities with TMDA or pharmacy council, when we find the expired medicines in the shelves, the authority follows the procedures which are; they write them then take them to TMDA and charge a fine of 25% of the cost of those medicines "(LGA 11P).

4.4.4 Dissemination of the guideline

Dissemination of the guidelines through the website has also been reported as a method used to ensure availability and accessibility of the guidelines to ensure adherence to the guidelines as one respondent reported

"We have a unit for public education and we have been helping each other as stakeholders in sharing guidelines through the website for both the current version and former version, they have to attach them in the website" (TMDA 9C)

And another one had this to say

"*Most of our guidelines we put them in the TMDA website so that every stakeholder can access them through our website" (TMDA 9D)*

4.5 Types of disposal methods which are practised by hospitals in the disposal of unfit medicines

In assessing disposal methods practised by hospitals in discarding unfit medicines both the in-depth interview and observation through checklist was employed. In an in-depth interview, participants were asked how do they dispose of unfit medicine in their hospitals and in observation the checklist was used to observe the certificate of destruction or disposal form issued by TMDA as a proof of disposal based on TMDA guideline.

The results from the checklist revealed that hospital 6 had the disposal form for the past disposal as a proof for disposal of unfit medicines based on TMDA guideline. The results from the in-depth interview revealed disposal methods as a broad theme with its sub-themes which were returning to the supplier, incineration, outsourcing and based on TMDA guideline.

4.5.1 Returning to the supplier

Returning to the supplier was reported by hospital 6 and 2 as a type of disposal method which was practised in the disposal of unfit medicines as one respondent reported.

"*When procuring medicines, we have a condition with the supplier that if medicines are not moving or if they have expired, they are supposed to be replaced and so they are going to replace" (Hospital 6B)*

And another one added.

"*We don't use waste disposal services but there was a certain time when we had so much ARVS expired due to change in HIV regimen and a certain NGO which sponsor HIV came and took them" (Hospital 2B)*

Returning to the supplier was also reported by hospital 6, 5 and 7 to be used when the medicines are nearly to expire. As one respondent reported.

"*When we are doing tendering for supplying the medicines we enter in an agreement with the suppliers, first we don't take medicines which expire below six months and when we take them, in case it's nearly to expire, we notify them three months before so that they can exchange for us" (Hospital 6A)*

And another one added.

"When we take medicines from suppliers, most of these suppliers they allow the exchange of short expiry medicines with the one with the long expiry date, so we inform them when we see three or four months have remained for the medicine to expire, then they will just check in their list how much order do they have, then they will take them and distribute to other places and bring others with a long expiry date" (Hospital 5B)

4.5.2 Incineration

This method was also reported by hospital number 3 as a method which can be used for disposal of unfit medicines even when there is no permit for disposal from TMDA as one respondent reported.

"*We remove the expired medicines from the shelves and put them in the boxes thereafter we take them there in the incinerator where they are burning the medicines and so we dispose of them there" (Hospital 3B)*

Furthermore, disposal through the incinerator was also reported by hospital number 2 as the method which can be used for disposal of unfit medicine when there is a special permit as one participant reported.

"*We don't use incinerator to dispose of, maybe when we get a special permit especially for those medicines which are environmentally friendly" (Hospital 2B)*

And another participant added.

> *"The decision on which method of destruction can be used for disposal of unfit medicines is made by TMDA and the institute of the environment depending on the formulation of the medicine and the type of the medicine, we have the incinerator here so there are others which they can propose to be burnt here and others through landfill" (Hospital 2A)*

However, this method has also been reported by hospital number 1 and 5 as the method which cannot be used for disposal of unfit medicines, as one participant reported.

"*We have the incinerator for disposing of other things but not medicines because you cannot dispose of them in the incinerator may be the boxes of the medicines, which we do dispose of through the incinerator" (Hospital 5B)*

And another one added.

"*We cannot dispose of the unfit medicines through the incinerator, as I know Incinerating the medicines is not allowed" (Hospital 1A)*

4.5.3 Outsourcing

Outsourcing to other facility was revealed as a method of disposal used by hospital number 6 especially when the hospital has less quantity of expired medicines. However, the participant didn't know the methods which are used for the disposal of those unfit medicines in that hospital.

As one respondent reported.

"*Since I came here, we have not done disposal of medicines through TMDA, but we have done once through outsourcing to hospital X" (Hospital 6A)*

4.5.4 Through TMDA

Disposal of unfit medicines based on TMDA guideline was also reported as a method practised for disposal of unfit medicines, with hospital number 6 already done through it and expecting to be used by hospital number 1, 2 and 4 as one respondent reported.

"*Actually when medicines get expired we prepare the list which we submit to the management, the management gives it to the internal auditor who will come and cross-check and take the medicines, after that the internal auditor will submit the list to TMDA whereby we will then pay and the TMDA will destroy the medicines*"*(Hospital 6B)*

Another one reported

"*In this management that we have right now we have never done disposal of medicines but we are expecting to follow all the procedures of TMDA when disposing of the medicines which have special supervision and procedures on how to destroy based on the nature of the medicine" (Hospital 4B)*

CHAPTER FIVE

DISCUSSION

5.0 INTRODUCTION

This chapter discusses the study findings compared to other studies guided by the study objectives which were handling procedures of unfit medicines before disposal, a procedure for application to disposal of unfit medicine, measured applied by TMDA and LGA'S in ensuring adherence to the guideline and types of disposal methods which are practised in the disposal of unfit medicines.

The findings of this study revealed the most common type of unfit medicines in the hospitals were expired medicines with the cause of getting expired being the change in the treatment regimen, overestimation in ordering, the slow movement of medicines, prescribing practise, change of disease frequency, lack of data during ordering, donation and a low number of patients.

5.1 Handling procedures of unfit medicines before disposal

The findings of this study from in-depth interview revealed that most hospitals register unfit medicines into books for unfit medicines, segregate them from usable medicines, separate according to dosage forms, keep in the separate area for keeping the unfit medicines and label them properly in storing them before disposal. These procedures look to concur with the TMDA Guideline. However, during physical observation by using a checklist, some discrepancy from the TMDA guideline was discovered, from which only one procedure was practised by all hospitals: separating unfit medicines from usable medicines.

The findings of this study are similar to the findings of the studies done in Tanzania which reported inadequate adherence to procedures for handling unfit medicines before disposal by hospitals (6,7). From these findings it shows that both pharmacists in charge and store personnel are aware of the procedures to be followed during storage of unfit medicines but are not practising, this might be attributed to inadequate supervision and inspection as reported by previous studies (6,7) but also lack of enough space for storage of these medicines in these facilities.

5.2 Procedure for application to disposal of unfit medicine

In assessing the extent to which hospitals adhere to the procedure for application to disposal of unfit medicine which is requesting in writing to TMDA before disposing of the unfit medicines, the results from in-depth interview revealed hospitals request first for disposal from hospital management followed with requesting from respective authority or disposal. In general, the reported results from in-depth shows that, most hospitals follow the required procedure of writing a request to TMDA before disposal of unfit medicines.

However, the findings of this study through observation have shown that only one hospital had the application form for the past disposal of unfit medicines, which shows only one hospital adheres to the TMDA procedure for application before disposal of unfit medicines which is requesting in writing to TMDA. However, the findings from the checklist are attributed by most hospitals not disposing of unfit medicines which were reported to be associated with hospitals not having a large quantity of unfit medicines for disposal due to purchasing of a small quantity of medicines, practising of good inventory management and the agreement for exchange that they have with suppliers especially for private hospitals.

5.3 Measured applied by TMDA and LGA'S in ensuring adherence to the guideline

In assessing measures which are applied by regulatory authorities (TMDA and LGA'S) to ensure adherence to the guideline, the following measures were observed: provision of education through formal meetings and on job training, inspection and supportive supervision, penalties such as fines and dissemination of the guideline.

Provision of education was also recommended by a study done in Kuwait to be used to increase awareness to the disposal guideline and hence adherence to the guideline (24). Inspection and supportive supervision is in line to other similar reported studies done in Tanzania which recommended this measure as a measure that should be used by regulatory authorities for safe disposal of the unfit medicines (6,7). Penalties such as fines were recommended in a study done in Nigeria that adequate law enforcement can be used to ensure adherence to the guideline(8).

Dissemination of the guideline agrees with the study done on disposal practices for unused medications around the world which reported that availability of the official guideline influences safe disposal of unfit medicines (5).

From the findings of this study, it shows that regulatory authorities have measures in place to ensure adherence to the guideline however some of these measures such as the provision of education, inspection and supervision are limited by the availability of enough budget which might lead to inadequate implementation of these measures.

5.4 Types of disposal methods which are practised by hospitals in the disposal of unfit medicines

The findings of this study reported various methods which are used by hospitals in disposing of unfit medicines which were incineration, returning to the supplier, outsourcing and TMDA. Returning to the supplier was also reported by a study done in Nigeria on the assessment of disposal practices of expired and unused medications among community pharmacies which reported returning to drug wholesalers/ distributors as a method which is used by the pharmacies in the disposal of unfit medicines (8,). It is also similar to a study done on minimizing pharmaceutical waste in India which has shown leftover/ expired drugs were returned to the distributors (28). However, this study was not able to confirm this method from the supplier.

Incineration was also reported in Tanzania as a method used for disposal of unfit medicines by public health facilities in Dar es Salaam region(7). Nonetheless, disposal of unfit medicines based on TMDA guideline for safe disposal of unfit medicines was also reported by a study done in Nigeria on the assessment of disposal practices of expired and unused medications among community pharmacies which have shown that pharmacies are disposing of their expired and unused medicines through the National Agency for Food and Drug Administration and Control (NAFDAC) (8). This is also similar to study done in Ethiopia which reported that health facilities dispose of expired and damaged medications based on disposal guidelines provided by Ethiopian Food Medicine and Healthcare Administration and Control Authority (FMHACA)(27).

According to the TMDA guideline for safe disposal of unfit medicine, National Environment Management Council (NEMC) or any other institution responsible for environment management is responsible for proposing mode of destruction and then issuing of disposal permit (2). But this study shows that disposal through incineration, returning to the supplier, outsourcing is practised even without the permission from the respective authority which is against the TMDA guideline for safe disposal of unfit medicines.

The findings of this study have also shown that the participants from the hospital which dispose of through the incineration after having a permit were aware of the impact of incineration to the environment if not done appropriately while those that are done without the permit are not aware of its impact to the environment. So, education should continue to be provided to the hospitals by the regulatory authorities on the importance of disposing of unfit medicines based on TMDA guideline and the impact of improper disposal to the environment and public health.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

This chapter includes the conclusion, recommendations, and study limitations

5.1 CONCLUSION

This study was conducted to evaluate the process implementation of the guideline for safe disposal of unfit medicines which involved hospitals, TMDA eastern zone and LGA'S in Dar es Salaam. In the hospitals, this study assessed handling procedures of unfit medicines before disposal, adherence to the procedure for application to dispose of unfit medicines, types of disposal methods practised by the hospitals in the disposal of unfit medicines, and in regulatory authorities it assessed the measures applied by TMDA and LGA's in ensuring adherence to the guideline.

The findings of this study reveal non-adherence to some of the procedures for handling unfit medicines before disposal and requesting in writing to TMDA before disposal of unfit medicines hospitals as some hospital disposes of without the approval from TMDA. And in exploring various methods which are used by hospitals in disposing of unfit medicines, incineration, returning to the supplier, outsourcing, and based on TMDA guideline were the methods reported with some practised without the permit from TMDA. Moreover, the study reveals that TMDA and LGA'S do the inspection, supportive supervision, provision of education and dissemination of the guideline in ensuring adherence to the guideline.

5.2 RECOMMENDATIONS

This section discusses the recommendations based on the findings of the study

- There should be a continuing education to the hospitals on the disposal based on TMDA guideline and the impact of improper disposal on the environment and public health.
- Hospitals should create enough space for storage of unfit medicines to promote proper storage of unfit medicines before disposal.
- Enough budget should be allocated to regulatory authorities to help effective implementation of their roles in ensuring adherence to the guideline.

5.3 STUDY LIMITATIONS

- Due to the time limit, this study did not involve other types of hospitals, community pharmacies and other health facilities such as health centres and dispensaries.
- Although the study was able to prove disposal of unfit medicines based on TMDA guideline through observing certificate for destruction or disposal form from TMDA, it was not able to prove disposal of unfit medicines through other methods which were reported by the respondents such as returning of unfit medicines to the supplier.
- The study was not able to explore methods used for disposal of unfit medicines by the suppliers after they have been returned to them.

REFERENCES

1. Tanzania Food and Drug Authority. Guidelines for safe disposal of unfit medicines and cosmetic products. 2009;(April):18.
2. Tanzania Food and Drug Authority. Guidelines for recall, handling and disposal of unfit medicines and cosmetics. Nippon Ronen Igakkai Zasshi Japanese J Geriatr. 2018;55(June):16.
3. Gebremariam ET, Gebregeorgise DT, Fenta TG. Factors contributing to medicines wastage in public health facilities of South West Shoa Zone, Oromia Regional State, Ethiopia: A qualitative study. J Pharm Policy Pract. 2019;12(1):1–7.
4. Nakyanzi JK, Kitutu FE, Oria H, Kamba PF. Expiry of medicines in supply outlets in Uganda. Bulletin of the World Health Organization. 2010.
5. Tong AYC, Peake BM, Braund R. Disposal practises for unused medications around the world. Environment International. 2011.
6. Mwita S, Ngonela G, Katabalo D. Disposal Practice of Unfit Medicines in Nongovernmental Hospitals and Private Medicine Outlets Located in Mwanza, Tanzania. J Environ Public Health. 2019;2019.
7. Matiko Damas. Managing disposal of unwanted pharmaceuticals at health facilities in Tanzania. A case of Dar es Salaam region public health facilities. 2011;11(2):10–4.
8. Michael I, Ogbonna B, Sunday N, Anetoh M, Matthew O. Assessment of disposal practices of expired and unused medications among community pharmacies in Anambra State southeast Nigeria: A mixed study design. J Pharm Policy Pract. 2019;12(1):1–10.
9. Qusai N. Al-Shahed, Anhar Assali, Ruba Najjar. Safe Disposal of Medicines in Palestine. J Pharm Pharmacol. 2016;
10. Sivasankaran P, Mohammed EB, Ganesan N, Durai R. Storage and Safe Disposal of Unwanted/Unused and Expired Medicines: A Descriptive Cross-Sectional Survey among Indian Rural Population. J Young Pharm. 2018;
11. Manojlović J, Jovanović V, Georgiev AM, Tesink JG, Arsić T, Marinković V. Pharmaceutical waste management in pharmacies at the primary level of health care in Serbia situation analysis. Indian J Pharm Educ Res. 2015;
12. Musson SE, Townsend TG. Pharmaceutical compound content of municipal solid waste. J Hazard Mater. 2009;
13. Daughton CG, Ruhoy IS. Environmental footprint of pharmaceuticals: The significance of factors beyond direct excretion to sewers. Environmental Toxicology

and Chemistry. 2009.

14. Metzger JW. Drugs in Municipal Landfills and Landfill Leachates. In: Pharmaceuticals in the Environment. 2004.
15. Weber F-A, Carius A, Grüttner G, Silke H, Ebert I, Hein A, et al. Pharmaceuticals in the environment – The global perspective: Occurrence, effects, and potential cooperative action under SAICM. Umwelt Bundesamt. 2014;
16. Societies RC, Federation IP. Safe disposal of unwanted pharmaceuticals in and after emergencies. Rev Panam Salud Publica/Pan Am J Public Heal. 2000;7(3):205–8.
17. Berckmans P, Dawans V, Schmets G, Vandenbergh D, Autier P. Inappropriate drug-donation practices in Bosnia and Herzegovina, 1992 to 1996. New England Journal of Medicine. 1997.
18. Years TEN, Regulating OF, Attained M. Mamlaka ya chakula na dawa. 2018;3(2):5–6.
19. Al-Emad AA. Assessment of medical waste management in the main hospitals in Yemen. East Mediterr Heal J. 2011;
20. Paudel E, Choi E, Shrestha N. Pharmaceutical Waste Management in Private Pharmacies of Kaski District, Nepal. 2019;4(August).
21. Clack V. The safe disposal of medicines – What is happening in South African hospitals? 2009;(July):40–1.
22. Njenga MJ. Community Pharmacies in Nairobi, Kenya. 2012;
23. Hussein R, Selim D. Management of Hazardous Pharmaceutical Waste Generated from Health Care Facilities. J High Inst Public Heal. 2008;38(Proceedings):49–65.
24. Abahussain E, Waheedi M, Koshy S. Practice, awareness and opinion of pharmacists toward disposal of unwanted medications in Kuwait. Saudi Pharm J. 2012;
25. Nilufer Yeasmin Nipa, Shamim Ahmed, Md.Shahariar, Mashiqur Rahman BH and MBU. Improper Management of Pharmaceutical Waste in South and South-East Asian Regions. J Environ Stud. 2017;
26. Sasu S, Kümmerer K, Kranert M. Assessment of pharmaceutical waste management at selected hospitals and homes in Ghana. Waste Manag Res. 2012;
27. Ebrahim AJ, Teni FS, Yimenu DK. Unused and Expired Medications: Are They a Threat? A Facility-Based Cross-Sectional Study. J Prim Care Community Heal. 2019;
28. Aditya S, Rattan A. Minimizing pharmaceutical waste: The role of the pharmacist. J Young Pharm. 2014;

29. Krefting L. Rigor in qualitative research: the assessment of trustworthiness. The American journal of occupational therapy. : official publication of the American Occupational Therapy Association. 1991.
30. Anney VN. Ensuring the quality of the findings of qualitative research: looking at trustworthiness criteria. J Emerg Trends Educ Res Policy Stud. 2014;

APPENDICES

Appendix I: Informed Consent (English Version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

DIRECTORATE OF RESEARCH AND PUBLICATIONS

ID no: ……

Introduction

Greetings!

My name is Beritha Godfrey Kyabula a student of Master of Science in Project Management, monitoring and evaluation in health at Muhimbili University of Health and Allied Sciences (MUHAS).

Purpose of the Study:

To evaluate the implementation of the guideline for the safe disposal of unfit medicine.

Methods of the study:

An in-depth interview will be conducted and the interviewer will record and may write your responses, and then followed by observation by using the checklist.

Participation:

If you agree to participate in the study you will be required to answer all questions asked by the interviewer

Confidentiality:

To ensure confidentiality your name will not be associated with the research findings in any way, and your identity as a participant will be known only to the researchers.

The expected benefits:

There are no direct benefits for your participation, however, the information you provide will help the hospitals, TMDA and LGA'S to improve the implementation of the guideline for safe disposal of unfit medicines and hence safe disposal of unfit medicines.

Risk:

No harm is expected as a result of participation in the study.

Right to withdraw:

You should be aware that you are free to decide not to participate or to withdraw at any time without affecting your relationship with the researcher.

Whom to contact:

In case of any question or query concerning this study, please contact

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And If you have any question about your rights as participants you may contact

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Signature:

I……have read the contents of this form and understood it, my questions have been adequately answered, I agree to participate in this study.

Signature of Participant……Date…….

Researcher's Signature……. Date……

Appendix II: Fomu ya kujiunga kwa hiari katika utafiti

Namba ya utambulisho: ….……

Utangulizi

Salamu!

Mimi naitwa Beritha Godfrey Kyabula ni mwanafunzi wa shahada ya uzamili katika ufuatiliaji na tathmini ya usimamizi wa mradi katika chuo kikuu cha Afya na sayansi Shirikishi, Muhimbili

Malengo ya Utafiti:

Utekelezaji wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi katika hospitali za Dar es Salaam.

Njia za utafiti:

Utafiti huu utahusisha mahojiano na mahojiano hayo yatarekodiwa na kuandikwa, na baada ya mahojiano uchunguzi utafanyika kwa kutumia orodha maalumu.

Ushiriki:

Iwapo utashiriki katika utafiti huu utatakiwa kujibu maswali yote utakayoulizwa na mtafiti

Usiri:

Ili kuzingatia usiri jina lako halitokea katika matokeo ya utafiti huu na utambulisho wako utafahamika kwa mtafiti tu.

Faida za utafiti:

Hakuna faida ya moja kwa moja utakayoipata katika utafiti huu ila taarifa zitakazopatikana katika utafiti huu zitawasaidia mamlaka ya dawa na vifaa tiba na tawala na serikali za mitaa kuboresha utekelezaji wa mwongozo wa uteketezaji wa dawa zisizofaa kwa matumizi.

Madhara ya utafiti:

Hakuna madhara yatakayokupata kutokana na ushiriki wako katika huu utafiti

Kukubali kwa hiari kushiriki katika utafiti:

Ushiriki katika utafiti huu ni hiari na una haki ya kushiriki ama kutokushiriki na haitaharibu mahusiano baina yako na mtafiti

Mawasiliano:

Kama una swali lolote kuhusu utafiti huu, Tafadhali wasiliana na

Mtafiti Mkuu
Beritha G Kyabula
Chuo kikuu cha Afya na sayansi Shirikishi, Muhimbili
S.L.P. 65001,
Dar es salaam
Simu ya Mkononi: 0762432763,
Barua Pepe: berithagkyabula@gmail.com
Au
Msimamizi wa Utafiti
Dr George Ruhago
Chuo kikuu cha Afya na Sayansi Shirikishi, Muhimbili
S.L.P. 65001,
Dar es salaam
Simu ya Mkononi: 0769 772772,
Barua Pepe: ruhagogm@gmail.com

Na kama utakuwa na swali lolote kuhusu haki yako kama mshiriki katika utafiti huu wasiliana na

Dr Bruno Sungunya
Mwenyekiti wa Kamati ya Utafiti na Uchapishaji
Chuo kikuu cha Afya na Sayansi Shirikishi, Muhimbili
S.L.P 65001
Dar es Salaam
Tanzania
Tel +2552150302-6.

Sahihi kwa wanaokubali:

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

Sahihi ya mshiriki……Tarehe…….

Sahihi ya Mtafiti……. Tarehe……

APPENDIX III: CHECKLIST

CODE OF THE HOSPITAL……...

S/NO	DESCRIPTION OF INDICATOR	YES	NO
A: Handling procedures of unfit medicine before disposal			
1	Is there a maintained register book for recording unfit medicines?		
2	Are unfit medicines segregated from usable medicines? (observe)		
3	Are unfit medicines separated according to dosage forms and kept in containers according to dosage forms?		
4	Is there a separate area to keep the unfit medicines?		
5	Presence of adequate security measures to avoid pilferage (e.g. Grilled gate and windows) for the area to store unfit medicines		
6	Are unfit medicines labelled properly? (“Not for sale in red ink)		
B: Procedure for application to dispose of unfit medicines			
8	Is there a copy of application form for the past disposal unfit medicines? (observe)		
C: Types of disposal methods which are practised by hospitals to dispose of unfit medicines			
10	Presence of previous disposal records (certification of destruction document/disposal form) Check Date of issue……..		

APPENDIX IV: INTERVIEW GUIDE FOR HOSPITALS (ENGLISH VERSION)

ID no……

Type of the hospital: …….

Qualification…….

Sex…….

Experience…….

A: General overview of unfit medicine

1. What are unfit medicines?
    i. Does it happen that your medicines in the stock become unfit?
2. What are the most common medicines which become unfit in your hospital?
3. What are the causes of your medicines becoming unfit?

B: Handling of unfit medicines before disposal

4. How do you handle such unfit medicines before terminal disposal?
    i. Probe if there is a register for unfit medicines
    ii. Probe if there is a storage area for unfit medicines

C: **Procedure for application to dispose of unfit medicines**

5. What procedures do you follow before disposal of unfit medicines?
    i. Do you request for disposal before disposing of unfit medicines?
    ii. Where do you request for disposal before disposing of unfit medicines?
    iii. What procedures do you follow while requesting for disposal of unfit medicines?

C: Disposal methods practised by hospitals

6. How do you dispose of unfit medicines at your hospital?

i. Have you ever dispose of unfit medicines?
ii. When was the last time you disposed of unfit medicines?
iii. How often do you dispose of your unfit medicines?
iv. What methods do you use in the disposal of unfit medicines?

7. What else would you like to share about unfit medicines?

Thank you for participating in this study.

APPENDIX V: MWONGOZO WA MAHOJIANO KWA HOSPITALI (SWAHILI VERSION)

Fomu Namba……

Aina ya Hospitali: …….

Taaluma…….

Jinsia…….

Uzoefu…….

A: Mtazamo wa ujumla kuhusu dawa zisizofaa kwa matumizi

1. Nini maana ya dawa zisizofaa kwa matumizi?
    i. Vipi ilishawahi kutokea kuwa dawa zinaisha muda wa matumizi au kuharibika kabla ya kutumika katika kituo chako?
2. Je ni dawa zipi mara nyingi hutokea hazifaa kwa matumizi katika hospitali yenu?
3. Je ni sababu zipi zinazopelekea dawa zenu zisifae kwa matumizi?

B: Utunzaji wa dawa zisizofaa kwa matumizi

4. Eleza Jinsi unavyosimamia na kutunza dawa hizo zisizofaa kwa matumizi kabla ya kuziteketeza?
    i. Uliza kama kuna rejesta maalum ya kuandikishia dawa zisizofaa kwa matumizi
    ii. Uliza kama kuna sehemu maalumu ya kuhifadhi dawa zisizofaa kwa matumizi

C: Hatua ya maombi ya kuteketeza dawa zisizofaa kwa matumizi

5. Ni hatua gani mnafuata kabla ya kuziteketeza dawa zisizofaa kwa matumizi?
    i. Je huwa mnaomba kibali cha kuteketeza dawa zisizofaa kwa matumizi kabla ya kuziteketeza?
    ii. Ni wapi huwa mnaomba kibali cha kuteketeza dawa zisizofaa kwa matumizi kabla ya kuziteketeza?
    iii. Ni hatua gani mlifuata wakati wa kuomba kibali cha kuteketeza dawa zisizofaa kwa matumizi kabla ya kuziteketeza

D: Njia za uteketezaji wa dawa zisizofaa kwa matumizi zinazotumiwa na hospitali

6. Je ni jinsi gani huwa mnateketeza dawa pale zinapokuwa hazifai tena kwa matumizi ya binadamu?
    i. Je umewahi kuteketeza dawa zisizofaa kwa matumizi?
    ii. Je ni lini ilikua mara ya mwisho kuteketeza dawa zisizofaa kwa matumizi?

iii. Je ni mara ngapi huwa unateketeza dawa zisizofaa kwa matumizi?

iv. Ni njia gani huwa mnatumia kuziteketeza?

7. Je kitu gani kingine ungependa kutushirikisha kuhusu dawa zisizofaa kwa matumizi?

Asante kwa kushiriki katika utafiti huu.

APPENDIX VI: INTERVIEW GUIDE FOR TMDA AND LGA'S

ID no……

Qualification…….

Sex…….

Experience…….

A: Measures applied by TMDA and LGA'S to ensure adherence to the guideline for safe disposal to unfit medicines

1. How do hospitals in Dar es Salaam implement the guideline for safe disposal of unfit medicines?
    i. Do they apply for disposal of unfit medicines?
    ii. How often do they apply for disposal of unfit medicines?
    iii. What types of hospitals are mostly applying for disposal of unfit medicines?
    iv. What procedures in the guidelines for disposal of unfit medicines are mostly implemented by the hospitals in Dar es Salaam Region?
2. What factors influence the implementation of the guideline for safe disposal of unfit medicines by Hospitals?
    i. Probe about factors which influence the good implementation of the guideline
    ii. Probe about factors which influence the poor implementation of the guideline
3. As regulatory authorities, how do you ensure adherence to the guideline for safe disposal of unfit medicines by the hospitals in Dar es Salaam region?
    i. Probe if training is provided on safe disposal and impacts of unsafe disposal to pharmaceutical personnel, how is it provided and how often?
    ii. Probe if inspection and supervision is done on implementation of the guideline for safe disposal of unfit medicines, how is it done and how often
    iii. Probe about the dissemination of the guideline to hospitals
4. What else would you like to share about the implementation of the guideline for safe disposal of unfit medicines by the hospitals in Dar es Salaam region?

Thank you for participating in this study.

APPENDIX VII: MWONGOZO WA MAHOJIANO KWA MAMLAKA YA DAWA NA VIFAA TIBA NA TAASISI ZA SERIKALI ZA MITAA (SWAHILI VERSION)

FOMU NAMBA:

Fomu Namba……

Taaluma…….

Jinsia…….

Uzoefu…….

A: Hatua zinazochukuliwa na mamlaka ya dawa na vifaa tiba na taasisi za serikali za mitaa kuhakikisha utekelezaji wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi

1. Ni jinsi gani hospitali za Dar es Salaam zinatekeleza mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi ?
    i. Je huwa wanaleta maombi kwa ajili ya kuteketeza dawa zisizofaa kwa matumizi?
    ii. Je ni mara ngapi huwa wanaleta maombi kwa ajili ya kuteketeza dawa zisizofaa kwa matumizi?
    iii. Je maombi yanatoka hasa katika aina zipi za hospitali?
    iv. Ni hatua zipi katika mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi zinafatwa zaidi katika hospitali za Mkoa wa Dar es Salaam?
2. Ni vitu gani vinachochea utekelezaji wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi katika hospitali za mkoa wa Dar es Salaam?
    i. Peleleza vitu vinavyopelekea utekelezaji bora wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi katika hospitali za mkoa wa Dar es Salaam
    ii. Peleleza vitu vinavyopelekea utekelezaji mbovu wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi katika hospitali za mkoa wa Dar es Salaam
3. Kama mamlaka za kisheria, Ni jinsi gani mnahakikisha utekelezaji sahihi wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi katika hospitali za mkoa wa Dar es Salaam?
    i. Uliza kama huwa wanatoa mafunzo kuhusu uteketezaji salama na matokeo ya uteketezaji mbovu kwa wanataaluma wa famasi, Jinsi gani wanatoa na mara ngapi?

ii. Uliza kama huwa wanafanya ukaguzi na usimamizi wa utekelezaji wa mwongozo wa uteketezaji wa dawa zisizofaa kwa matumizi. Jinsi gani wanafanya na mara ngapi?

iii. Uliza kuhusu usambazaji wa mwongozo katika hospitali.

4. Je kitu gani kingine ungependa kutushirikisha kuhusu utekelezaji wa mwongozo wa uteketezaji salama wa dawa zisizofaa kwa matumizi katika hospitali za mkoa wa Dar es Salaam?

Asante kwa kushiriki katika utafiti huu

Table 1: Thematic framework (from codes to themes)

Codes	**Sub-themes**	**Themes**
Record them in its book, put them in the ledger for properties that are not fit for use, put them in the suspensory ledger	Register in the book for unfit medicines	**Handling procedures of unfit medicines before disposal**
Remove them from the shelves, separate from other medicines	Segregate from usable medicines	
Sort them for example tablets, capsules they stay in one place, injectable in one place, pack them based on the type of medicine particularly dosage form, injectable will be packed separately, tablets separately, supplies separately but apart from that controlled drugs also they might be injectable but we can't mix with other injectable, put them separately if there are a	Separated according to dosage forms and kept in containers according to dosage forms	

small amount of syrups we put them separate with maybe tablets"		
Keep in the isolation area, put them in the position for unfit medicines, we take them to the place that we store them, its a store like that we have separated for storing damaged medicines	Keep in the separate area for keeping the unfit medicines	
We have one box we will write expired medicines, label them that they are unfit for use with a red mark, we pack them in boxes then we label the boxes with those descriptions I mentioned such as the name of the medicine, batch number, quantity	label properly (“Not for sale in red ink)	
Internal Auditor TMDA the medical officer in charge Ministry of Health	Request from hospital management Request from respective authority (TMDA)	**Procedures for application before disposal**
Outsourcing Burning in the incinerator TMDA Returning to the supplier	Disposal methods	**Disposal practise by the hospitals**
Never experience, only once	Frequency of disposal	
On job training, formal meetings	Provision of education	**Measures applied by TMDA and LGA’S in ensuring adherence to the guideline**
Routine supervision, routine inspection, inspection based on complaining	Supervision and inspection	