

**ASSESSMENT OF IMPLEMENTATION STATUS AND CHALLENGES
OF PHARMACEUTICAL REVERSE LOGISTICS: THE CASE OF
SELECTED PUBLIC HOSPITALS IN ADDIS ABABA, ETHIOPIA**



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**ADDIS ABABA UNIVERSITY
ADDIS ABABA, ETHIOPIA
SEPT, 2021**

Assessment of Implementation status and challenges of pharmaceutical reverse logistics: The case of selected public hospitals in Addis Ababa, Ethiopia

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A Thesis submitted to the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy in partial fulfillment of the requirements for the Degree of Master of Science in Health Supply Chain Management

Addis Ababa University

Addis Ababa, Ethiopia

Sept, 2021

ADDIS ABABA UNIVERSITY
SCHOOL OF GRADUATE STUDIES

This is to certify that the MSc Thesis prepared by Zerihun Zekariyas entitled: *“Assessment of Implementation status and challenges of pharmaceutical reverse logistics: The case of selected public hospitals in Addis Ababa, Ethiopia”* and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Health Supply Chain Management complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Approved by the Examining Committee

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Advisor: Tariku Jabena (PhD) _____ Signature _____ Date _____

Head of Department

DEDICATION

I boldly dedicate this thesis to my forever beloved wife

Maye (Mihret Milkias)

Then,

To my guardian grannies

Gashe and Etiye (gospel warriors)

To my real Mom

Meselech

To my childhood role-models

Tsadiku Eka and Yenealem Getachew

And finally,

to the loving memory of my lost Dad

Zekariyas Eka

You all made me the person where I am today.

I love you all especially my best half-*Maye*

I saw you in Proverbs 31:10-31

ACKNOWLEDGEMENT

Above all, I would like to thank God Almighty then my gratitude goes to my Advisor Tariku Jabena (PhD) for his supervision during my research proposal work and to Mr. Dawit Teshome from AAU School of Pharmacy for his humble facilitation. I am also grateful to all health workers who supported me during data collection in the public hospitals.

The last but not least, may I appreciate Addis Ababa Regional Health Bureau for sponsoring my study and Addis Ababa University for funding my research work.

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ACRONYMS

AACAHB	Addis Ababa City Administration Health Bureau
AAPHREMD	Addis Ababa Public Health Research and Emergency Management Directorate
ARV	Antiretroviral
CCO	Chief Clinical Officer
CEO	Chief Executive Officer
DSM	Drug Supply Management
EFDA	Ethiopian Food and Drug Authority
EFY	Ethiopian Fiscal Year
EPSA	Ethiopian Pharmaceutical Supply Agency
FEFO	First Expired First Out
FMOH	Federal Ministry of Health
HF	Health Facility
HSDP	Health Sector Transformation Plan
IFRR	Internal Facility Report and Resupply Form
LIAT	Logistics Indicator Assessment Tool
PH	Public Hospitals
PRL	Pharmaceutical Reverse Logistics
RL	Reverse Logistics
RLA	Reverse Logistics Association
RRF	Request and Requisition Form
SPHMMC	Saint Paul Hospital Millennium Medical College
SPSH	Saint Peter Specialized Hospital
TASH	Tikur Anbesa Specialized Hospital
TBGH	Tirunesh Beijing General Hospital
USAID	United States Agency for International Development
WHO	World Health Organization
Y12HMC	Yekatit 12 Hospital Medical College
ZMH	Zewuditu Memorial Hospital

ABSTRACT

Ethiopia procures more than 16-billion-birr worth of pharmaceuticals and medical supplies per year to more than 4000 public health facilities across the country but with very little consideration for reverse logistics. In Ethiopia, the average wastage rate of medicines is 3.9%. In spite of the efforts that the Ethiopian Ministry of Health and the Ethiopian Pharmaceutical Supply Agency have put in place to ensure efficiency in supply chain, and availability of medicines at all times, however, significant quantities of pharmaceuticals have been expiring in facility pharmacy stores and have been causing a challenge in supply chain system. The objective of the study is to assess the implementation status and challenges of pharmaceutical reverse logistics in the case of selected public hospitals in Addis Ababa, Ethiopia. Therefore, a descriptive cross-sectional study design and qualitative study was employed in six public hospitals in which 12 are key informant interviews. The quantitative data was collected through questionnaires, data abstraction formats and checklist and analyzed using SPSS version 20 and Microsoft Excel 2016. The qualitative data was collected through in-depth interview with the heads of the hospitals, pharmacy directorates and pharmacy case team leaders and analyzed using thematic analysis. The results were presented using, graphs, percentages, mean scores, standard deviations and written texts. Majority of the respondents 47% agree that there is unclear reverse logistics practice in their respective hospitals. Overstocks are common at the hospital level, most hospitals 66% experience overstocks, 28% rarely experiences overstock and 6% experience no overstock. Redistribution has the highest grand mean score as compared to other reverse logistics activities such as recycling, recalling and disposal during the study period. Moreover, there is data invisibility to trace and track the implementation status of reverse logistics. This all, in turn made the public hospitals to turn their face from the practical implementation of reverse logistics. Reverse logistics management should get attention in the pharmaceuticals supply system of the country for the proper management of unused medications for disposal and usable for redistribution. It is recommended to give training for pharmacy professionals on proper quantification of pharmaceuticals and attention must be given to the whole picture of reverse logistics rather than sticking only to waste management. Otherwise, the negative impact of reverse logistics may end up in financial loss to health sector and environmental unfriendliness.

Key Words: *Supply Chain Management, Reverse Logistics, Hospital Reverse Logistics, Pharmaceuticals, Redistribution*

CHAPTER ONE

INTRODUCTION

1.1 Background

Nowadays, the global economic system is so much wasteful of labor, capital and resources. Since consumption is so central to many economies of recent forms of globalization, the effects therefore are seen all over the world. Thus, a huge amount of discarded and consumed products has expanded radically when having reached its user needs (Pereira, 2012).

In the supply chain management cycle, Reverse Logistics is crucial in considering the logistics backflow for any reasonable returns. It can happen either when the product is needed for recycling, remanufacturing, and reusing. Thus, reverse logistics is the process of moving products from the final destination back to the supplier while in the case of hospitals, it means reversing expired, damaged and excess medicines back to the storehouse for redistribution, disposal and proper storage (Kabir, 2013).

The Ethiopian health supply chain system has experienced the fast growing of donor-driven distribution systems and mostly using “push” replenishment systems. Hospitals “pull” bimonthly to ramp-up to four months of stock from their sole federal or hub warehouses which are scattered geographically throughout the country. All regional warehouse supplies pharmaceuticals to hospitals and health centers in the corresponding geographical regional border (PFSA, 2013). In 2015, the Ethiopian pharmaceutical market was estimated to be valued at \$450M and it is expected to grow at 15% to reach an estimated value of USD 0.9 billion by 2020 (Aida, 2018).

It is known that pharmaceuticals are supplied either by pull or push system. A “Pull system” is when order is placed by the respective facility after decision is made on number of quantities to resupply. This system seeks the service delivery points to order pharmaceuticals based on their average consumption data of the hospital/health center during the review period. In this case, health facilities initiate the request. On contrary, the Push system is where the decision on quantities is determined by the supplier who fulfills the resupply facilities (USAID, 2011). In this case, the central level is the one who decides what commodities to push down and when to redistribute. This is the system that is being implemented by a parallel supply chain to ensure the availability of medicines in the health facilities all the time. Thus, it is very crucial to consider the proper ways of managing the stock imbalances in the public hospitals with a focus on expired medicines, overstocks and under stocks which in turn helps to proper management of pharmaceuticals. (Chirwa, 2015)

Therefore, Pharmaceutical Reverse Logistics (PRL) becomes a key to the health supply chain system to manage unused medicines due to either expiration or damages or oversupply to improve efficiency in the supply chain. In most African countries, pharmaceutical reverse logistics has a little focus and is a new concept to many hospitals too. However, at a health facility level, it is common to share either stock out or overstock medicines within or in neighboring district health facilities (Chirwa, 2015).

Therefore, pharmaceutical reverse logistics is the practice of returning or disposing medicines according to the procedures and activities according to the guidelines stipulated in Reverse logistics management guideline for pharmaceuticals and medical device. Thus, it is acceptable when the health facilities perform all the PRL activities and in turn the implementation status is approved (FMOH, 2021).

In Ethiopia, the average wastage rate of medicines is 3.9% ranging from 1.53% to 11.2 % (FMOH, 2021). The pharmaceutical industry and health facilities have a young concept on reverse logistics in developing countries including Ethiopia and this can be clear to know as the Food and Drug Authority or Ministry of Health have no separate directive on Reverse Logistics except Healthcare Waste Management Directive except the on-going guideline being finalized at FMOH.

However, there is a standard operating manual, such as Integrated Pharmaceuticals Logistics System (IPLS) which mentions the upper-level facilities provides feedback to the lower facilities. Then facilities are encouraged to stock transfer items to other facilities if they have excess and borrow if they are being stock out. Thus, the stock imbalances are properly managed without loss (PFSA, 2015).

Reverse Logistics considers issues of management of expired and overstocks. As to Rogers *et al*, (2010), reverse logistics includes but is not limited to processes of planning, implementing, cost-effective flow of raw materials, in-process inventory, finished goods and from the point of consumption to the point of origin either for reuse or proper disposal. If the implementation of Reverse Logistics system is applied to hospitals, it would properly manage the overstocks by redistribution for returning a value, and to manage overstocks and expiries by properly disposing them in order to keep the safety of the environment. (Chirwa, 2015)

Even though the practices of pharmaceutical reverse logistics are an issue in different public hospitals, they are expected to fulfill the minimum standard stipulated by the Ethiopian federal ministry of health. All the reverse logistics activities, processes and procedures should be maintained at each hospital level in order to be considered as acceptable or not.

Therefore, this study has gone through how public hospitals manage reverse logistics of pharmaceuticals, and their implementation status and challenges.

1.2 Statement of the Problem

Nowadays, more attention is not given to reverse logistics, especially in developing countries. However, reverse logistics in the pharmaceutical industry is particularly important from an environmental, economic and regulatory points of view (Kumar T. and S. Saravanan, 2016). Improper management of returned drugs can have a negative impact on the health of the people, economy and the environment in the long term. Thus, improved and proper reverse logistical chain must be introduced and implemented to the pharmaceutical supply chain system (Kwateng et.al, 2014).

In the forward logistics, Ethiopia procures 16-billion-birr worth of Pharmaceuticals and medical supplies per year to more than 4000 public health facilities across the country but considering little about reverse logistics. (EPSA, 2019). An assessment done in January 2014 in Malawi (Chirwa, 2015) revealed that an amount worth \$1,286,868.21 was lost through expiry in 29 districts among 30 health commodities assessed. In Ethiopia, a study conducted in selected public health facilities in the Oromia region, the monetary value of wasted medicines in 2015-2016 was 500,522.09 Ethiopian Birr, while in the same period all surveyed health facilities received medicines worth 6,635,910.97 Ethiopian Birr, resulting in wastage rate of 7.5%. This indicates that proper reverse logistics should be implemented to handle the wastages (Gebremariam, 2017).

In Ethiopia, per the Ministry of Health, the government budget has not been able to meet the pharmaceutical needs of the country, though the sector has been receiving various supports in various health conditions like from GF, USAID, UNFPA and GAVI. In this regard, it is reasonable to put in place proper forward and reverse logistics for the sector to enhance efficiency and safe utilization of pharmaceuticals. There are many problems in public hospitals and health centers are

either suffering from limited or excess number of pharmaceuticals and the hospital management has not given enough attention to fully reverse logistics.

Most recently, FMOH is working on reverse logistics management guidelines for pharmaceuticals and medical devices which is the first in its history (FMOH, 2021).

Even though Ethiopia is a developing country with tremendous investment and growth, there is a huge wastage of health commodities leading to loss of life. In addition to poor implementation of disposal and wastage according to the Healthcare Waste Management Directive, Ethiopia has no guideline for reverse logistics for health commodities (EFMHACA, 2005).

The current health supply chain system does not pay much attention to reverse logistics and there are unsatisfactory regulations for the management of expired, damaged medicines as well as disposal procedures, and none for management of stock imbalances. The only sort of regulation related to reverse logistics outlines disposal of goods, old vehicles and supplies (PPA, 2009). This has forced hospitals to makeshift procedures for disposal of medicines because there is no standard way of doing it. Besides, as to the knowledge of the student, little or no research was done in Ethiopia to examine the implementation status and challenges of reverse logistics of pharmaceuticals.

There is also no proper system to integrate or implement a system called 'relocation' or 'redistribution' of products (pharmaceuticals) before expiry or damage or even for proper disposal. This common practice is implemented in African countries like Malawi (Chirwa, 2015). Therefore, these problems are calling for a swift resolution. Thus, this study uses the concept of reverse logistics as an approach to address these aforementioned problems practiced in the public hospitals.

1.3 Research Questions

1. How does PRL look like in selected Public Hospitals in terms of RL activities?
2. How does PRL look like in selected Public Hospitals in terms of RL processes?
3. In what status is the PRL Implementation in selected Public Hospitals?
4. What possible challenges are there to implement PRL in selected Public Hospitals?

1.4 Objective of the study

1.4.1. General objective

The general objective of the study is to assess the Implementation status and challenges of pharmaceutical reverse logistics in the case of selected public hospitals in A.A.

1.4.2. Specific objectives

- To examine how PRL looks like in selected Public Hospitals in terms of RL activities
- To examine how PRL looks like in selected Public Hospitals in terms of RL processes
- To evaluate the Pharmaceuticals Reverse Logistics Implementation status in selected public hospitals
- To identify Challenges involved in implementing Pharmaceutical Reverse Logistics in selected public hospitals

1.5 Scope of the study

Reverse Logistics is a concept that covers activities such as reuse, recondition, resell, refurbish, remanufacture, repair, recycle etc. (Rogers and Tibben-Lembke,1999). However, this study only focuses on redistribution, recall, recycle, disposal of return pharmaceuticals in public hospitals.

This study is designed to assess the implementation status and challenges of pharmaceutical reverse logistics in public hospitals. Thus, this study was undertaken on some of the public hospitals in Addis Ababa which includes 3 hospitals under AARHB (Tirunesh Beijing Hospital, Yekatit 12 hospital Medical College and Zewditu Memorial Hospital and 3 hospitals from FMOH (TASH, St. Paul and Saint Peter Hospital). The study only focused on public hospital's current

practice of the subject matter and the challenges faced. The data was gathered from responsible bodies in the hospitals who had a direct and indirect work relationship with pharmaceuticals.

1.6 Significance of the Study

Reverse logistics have been found to play an important role in almost any firm including the health sector. The findings of this study will benefit all bodies of the case study public hospitals in Addis Ababa and other health facilities in the country by providing them with a deeper understanding of the positive impacts of reverse logistics on the health facilities' performance. Again, it will help the facilities to take it as an opportunity to make a difference in their supply chain. It also aids policymakers in decision-making process when coming up with legislation that promote the adoption of best reverse logistics practices in health facilities as well as the pharmaceutical industry. Additionally, as per the Federal Ministry of Health plan, Ethiopia has targeted HSDP V (2008-2012 EFY) was to increase the availability of essential pharmaceuticals from 65% to 100% (FMOH, 2015). Thus, it will be a good contribution to its targeted evaluation. However, this can be achieved especially, by careful implementation of stock redistribution and proper wastage disposal. Therefore, this study will benefit the think-tankers of the sector to consider the wise use of pharmaceutical inventory management in congruence with proper reverse logistics management.

Furthermore, this study also will initiate interest for further research on this topic by academicians on the knowledge gaps and future studies can draw ideas from it to improve the problems in the sector.

1.7 Limitation of the Study

The use of the term 'redistribution of pharmaceuticals' as one type of reverse logistics had been vague to data providers with the concept of 'transfer of pharmaceuticals.' However, a customized definition of redistribution was given and it was used as one part of reverse logistics activity within

the hospitals and among other hospitals. The other limitation was the intention of limiting the study to only pharmaceuticals but not medical equipment and medical supplies because a higher problem is seen in the previous one and the latter one has a slightly different approach. The small number of sample size of the hospitals is another limitation.

1.8 Operational definition of Terms

Hospital Reverse Logistics is the reversing of damaged, excess medicines and expired pharmaceuticals back to the warehouse/quarantine for proper storage, redistribution and disposal. **Pharmaceuticals** can be defined as any mixture of substances used in the diagnosis, prevention, treatment of a disease in humans. However, the term ‘pharmaceuticals’ is used interchangeably with the terms ‘medicines’ or ‘products’ where necessary (FMOH, 2021).

Redistribution can be defined as the process of movement of medicines from a certain point of consumption (Health facility) back to point of origin (supplier) or the movement of pharmaceuticals from one hospital to another hospital after returning to the main store (FMOH, 2021).

1.9 Organization of the Study

Chapter 1 presents a background and the underlying logic of this study and the importance of researching this topic. The chapter ends up with limitations of the study and operational definitions. **Chapter 2** provides an in-depth theoretical background of previous research in the field. The theoretical concepts and conceptual frameworks are also identified in the same chapter. **Chapter 3** presents the methodological design of the data collection and the methods used for analyzing the data and the methods used to present the data. **Chapter 4** present an overall analysis of the results of the study and interpret the findings of the collected data. **Chapter 5** provide a summary of the findings, conclusions, recommendations, and suggestions for further study.

CHAPTER TWO

RELATED LITERATURE REVIEW

2.1 Concepts and Definitions of Reverse Logistics?

The conception of Reverse logistics dates from a long time ago even though the designation of the term is difficult to name exactly. However, Reverse logistics is emerging as a crucial issue nowadays. Surprisingly, the scope of reverse logistics throughout the 1980s was limited to the movement of material against the primary flow. Then through time, more advanced definitions began to emerge. Thus, Rogers and Tibben-Lembke (1999) defined reverse logistics as “the process of planning, implementing and controlling the efficient, cost-effective flow of raw materials, in-process inventory, finished goods and related information from the point of consumption to the point of origin for the purpose of recapturing value, or proper disposal”. However, this definition is still somewhat limited since many products are returned to a point of recovery and not their origin (De Brito and Dekker 2002).

More recently, it is having some different definitions. For example, The Reverse Logistics Association (RLA) refers to the term reverse logistics as being the ultimate goal to optimize the market after the activity, it is associated with a product/ service in saving money and environmental resources (RLA, 2009).

Moreover, nowadays, reverse logistics is attracting attention while many organizations are looking for different ways of competition with demands more than just the product but the environmental relevance of the product as well. Thus, there are many driving forces for implementing reverse logistics like, competition and business motives, concerns with the environmental situations and indeed customer satisfaction (Kabir, 2013).

2.2 Reverse Logistics Practices and Policy

The practices and policies of RL is very important for healthcare workers in understanding how to manage the products and properly dispose of them to prevent negative impacts to humans and the environment if not handled in proper manner. Thus, healthcare workers ought to have the knowledge of the right procedures and understanding of guidelines to manage waste in their respective health facilities. (Chirwa, 2015)

The Ethiopian Drug and Food Authority has a clear directive for healthcare wastage management. The directive is good in its approach and takes into consideration of minimizing the wastage for pharmaceuticals. It defines the intention of minimizing the need for disposal. Good practice of waste minimization within the health facility is monitored and evaluated according to the availability and implementation of waste minimization plan, reuse and recycling practices. (EFMHACA, 2005)

2.3 Process and Activities for implementing Reverse Logistics

According to the reverse logistics management guideline for pharmaceuticals and medical devices, the reverse logistics process usually involves returns, recalls, repairs, repackaging for restock or resale, recycling and disposal (FMOH, 2021). This paper gives an emphasis on return, recall, and redistribution and disposal activities.

2.3.1 Recall

Recall is a process for withdrawing or removing a medicine, and/or medical device product from the pharmaceutical distribution chain due to multiple reasons such as complaints of serious adverse reactions to the product, defects in the product, and/ or concerns that the product is or may be counterfeit. The recall process might be initiated by the manufacturer, wholesaler or the EFDA

(FMOH, 2021). The way organizations manage the returns by following the four key steps involved in return processes. Accordingly, these processes are; local screening, collection, sorting, and disposition (Chirwa, 2015).

Local Screening

Local screening is mostly performed immediately on collection of returned products. For example, in hospitals, health commodities which are damaged or expired are checked, collected, and counted for the purpose of accountability and transparency before the next steps.

Collection

Then, the products are collected to enter the reverse supply chain after being screened. This step is similar to “handling”, in which the unused and wasted products are transported to the specified location within the respective facility. Then after the products should follow the next steps such as handling and transporting for disposal purpose.

Sorting

This is the act of collecting similar sorts together in order to effectively categorize each thing. Some of the key benefits include: focusing on handling returns and cycle times will improve, resulting in better asset recovery. However, sorting is a crucial step in reverse logistics as it will assist employees in making decisions on what ultimately happens with the returns.

2.3.2 Redistribution

Redistribution is one way of reverse logistics in which pharmaceutical products are redistributed to the nearby health facilities or within the facility for the purpose of maintaining either stock balances or giving to the needy health facility in order to cover their stock out. Therefore, if we consider this as a backflow thus it is reverse logistics.

2.3.3 Recycling

Recycling is one type of RL activities of pharmaceuticals that can be converted into reusable materials without causing major pollution to the environment. These materials can serve as raw materials for other manufacturing companies (FMOH, 2021). The agreement should be placed between source facility and manufacturer/ collecting body/ disposal site/ to collect recyclable materials. The above reverse logistics process and activities can also be applied to hospitals in the recycling of unused health commodities by customizing to suit into the needed setup.

2.3.4 Disposition

These activities might help in eliminating the pharmaceutical wastes from hospitals. Pharmaceutical wastes and residues may have a hazardous impact on the well-being of humans. This, in turn, may bring antibiotics resistance and hormonal changes. (Jonjić & Vitale, 2014). The Ethiopian Food and Drug Authority recommends all health institutions shall only use disposal referral system of licensed disposal firms, respective medicines suppliers or central disposal sites. And hospitals shall submit applications for disposal of unfit for use pharmaceuticals to central disposal sites, licensed disposal firms, or respective suppliers and shall report to the appropriate organ in charge (FMHACA, 2011).

Reports indicated that, absence of regular tracking and reporting of wasted products at PFSA and delayed disposal of waste products leading to accumulation in-store and space occupation. PFSA does not have the mechanism, infrastructure, and system to handle pharmaceutical waste disposal on time in addition to the shortage of resources for waste disposal (PFSA, 2016). Therefore, pharmaceutical returns require regulatory management; secure handling for controlled drugs, airtight security, risk assessment and innovation. Thus, the best procedures and practices of pharmaceutical reverse logistics should continue its influence in addressing the environmental affairs and concerns of medication disposal (Tompkins, 2010).

Therefore, the above processes and activities are expected to be maintained in order to say the pharmaceutical reverse logistics is practiced.

2.4 Reverse Logistic Practice in Hospitals

In Ethiopia, there is no full reverse logistics practice as stipulated in other countries and as per the new document being finalized by FMOH. However, part of it is practiced such as disposal and to some extent recall. Just as with other organizations, waste elimination and product recalls are of increasing issue to hospital pharmacies. A study conducted in Manchester Royal Infirmary Pharmacy assessed the practices of reverse logistics focusing on returned stock to storeroom, stocks being returned from the hospital wards, and other departments. And found that there is a tremendous loss of money that could have been saved by returning and reusing the products (Ritchie et al., 2020).

The study conducted in Ethiopia on few selected public health facilities shows the huge amount of wasted medicines indicating the health facilities are losing the money and in turn destroys the country's economy. Therefore, it is a big loss because of damage, expiration of medicines or absence of clearly stipulated procedures for the proper management of reverse logistics. Thus, the managing practice of expired and damaged pharmaceuticals seeks serious monitoring ensuring the proper handling before leaving the control area so that to ensure and secure sustainable supply chain management. (Gebremariam, 2017).

Clear and timely information is crucial in addressing the implementation of pharmaceuticals. For example, hospitals are expected to record and report LMIS (Logistics Management Information System) such as RRF, IFRR, SSA, bin card and stock card (PFSA, 2015). This will be easy to trace and track the in and out of pharmaceuticals for effective forward and reverse management.

The reverse logistics processes and activities shows the product flow and information flow between supplier and health facilities and in between the facility. The back flow of products in the pipeline shows the reversing of pharmaceuticals either to supplier or to health facilities for reuse, recycle, redistribution or disposal (FMOH, 2021).

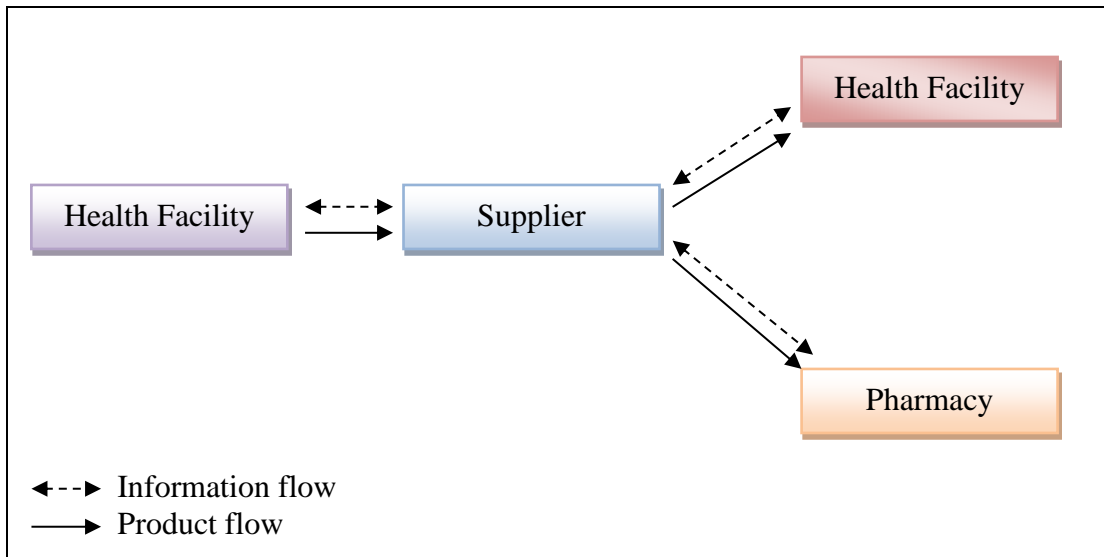


Figure 1. Reverse Logistic Process: Information and Product flow (FMOH, 2021)

Therefore, hospitals should follow the above procedures and processes in order to maintain their proper practices pharmaceutical reverse logistics. As a result, the implementation status is said to be accepted in line with all the activities to be followed.

2.5 Challenges of Reverse Logistics

There are few studies conducted in the area of RL focusing on the major barriers of reverse logistics. The challenge for RL is not only the tiresome procedures it takes but also the negligence of government bodies. This problem emanates from not knowing the economic, customer handling management and environmental benefits of implementing RL. To address this, a study on the benefits of RL done in the UK concludes by arguing that the National Health Service benefits from proper implementation of reverse logistics processes which requires changes to certain practices and procedures and increased staff training (Ritchie et al., 2020).

Challenges related to the process and activities of RL are tremendous. The activities such as redistribution, recycling, reuse and disposal are not well implemented in a hospital setting. Besides, the exact magnitude of the problem of unused pharmaceuticals is not well documented in Ethiopia. This is due to the absence of reverse logistics policy, lack of capacity building in the pharmaceutical supply chain system.

The most crucial thing to be considered is the wastage of pharmaceuticals in public hospitals. In Ethiopia, according to the assessment, 81.1% of the public hospitals reported wastage of medicines worth 57,374,603.59 birrs by value in 2018/2019. The study also confirmed that 25% of the available medical devices were nonfunctional. The reasons for wastage of products are supplying near expiry medicines, poor inventory management, and lack of communication among stakeholders within and outside of the hospital and lack of stock rotation or exchange policy (FMOH, 2021).

India has faced challenges for pharmaceutical implementing reverse logistics and the researchers found the following five reasons that hindered RL implementation (Sharma et.al, 2011).

2.5.1 Lack of awareness about Reverse Logistics

The rise to increase in the volume of product returns in the form of reverse logistics has brought a dramatic increase in high return rate and tremendous wastage rate. Thus, for the economic benefit, reverse logistics is implemented by using recovery of the returned products for reuse, redistributing, recycling for adding value chain to the product. Lack of awareness of the benefits of reverse logistics is a major challenge for its implementation. (Sharma et.al, 2011).

2.5.2 Management Inattention

Most companies have practiced reverse logistics primarily because of pressure from environmental agencies or government regulation, not for economic profit. Thus, this led the management is

taking less interest in thinking about nonprofit issues. This is because the company's focus is on forward logistics but not on backward logistics (Sharma et.al, 2011).

2.5.3. Financial constraints

For reverse logistics to be in practice and implemented, companies or health facilities require allocation of funds. (Sharma et.al, 2011).

2.5.4. Inadequate Technological Systems and Training

The training of personnel related to the reverse logistics is also very important for efficiently managing reverse logistics. Information technology is very important for end-to-end control and transparency along with reverse chain (Sharma et.al, 2011).

2.5.5. Policies

Policy and guidelines are very crucial in the course of implementing reverse logistics. They govern the institution and bring customer satisfaction if and only if acted as it is stipulated. Companies do not want their "junk" to deteriorate their existing quality. Thus, they are obliged to develop policies that make ease of handling returns and to recover much monetary value from those returns (Sharma et.al. 2011).

In summary, the practices and procedures of RL is an emerging concept especially in health facilities setup. However, not implementing it might bring a serious loss of economy and the environment.

CONCEPTUAL FRAMEWORK

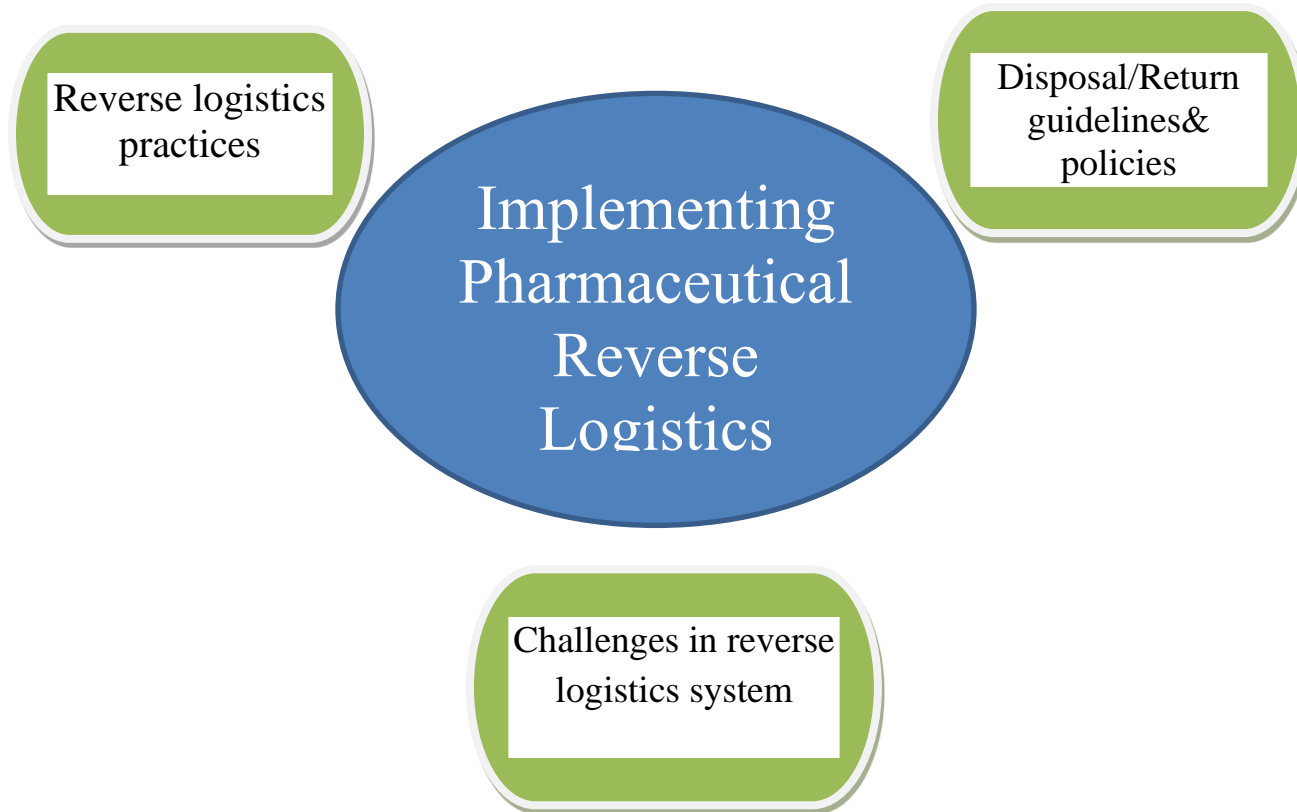


Figure 2: Conceptual framework (Own survey, 2020)

In this study, the implementation status of reverse logistics (RL) can be described in three dimensions as Reverse logistics practices and Expires, Disposal guidelines & policies and challenges of reverse logistics system. These factors are taken to assess the challenges and the implementation of the reverse logistics. The first factor will see why and how the pharmaceuticals are expired and overstocked. This helps to know the status of the extent of products expired and overstocked and manage them in the hospitals. The second factor is disposal guidelines and policies. This is to evaluate if there are clearly stipulated guidelines and policies on the ground to be easily implemented in the hospitals that can smoothen the reverse logistics system. The third and last one is the challenges of reverse logistics system which will look for the availability of the system and how it is implemented facing related challenges. Therefore, the study will also see individual challenges under each dimension of reverse logistics.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Description of the Study Area

Ethiopia has an established pharmaceutical supply chain system which functions in all over the country. Hospitals and health centers are among the places where logistics activities took place. The public hospitals are observed to have a high burden of pharmaceuticals in rendering medical services. There are 11 public hospitals in Addis Ababa city performing tremendous health and health related works. All of them receive pharmaceuticals from PFSA however suffer from implementing reverse logistics. This study was conducted in 6 hospitals in Addis Ababa, 3 under AARHB (Tirunesh Beijing Hospital, Yekatit 12 Hospital Medical College and Zewditu Memorial Hospital) and 3 hospitals from FMOH (TASH (University Hospital), St. Peter and St. Paul Hospital). The detailed descriptions of the study area are given below.

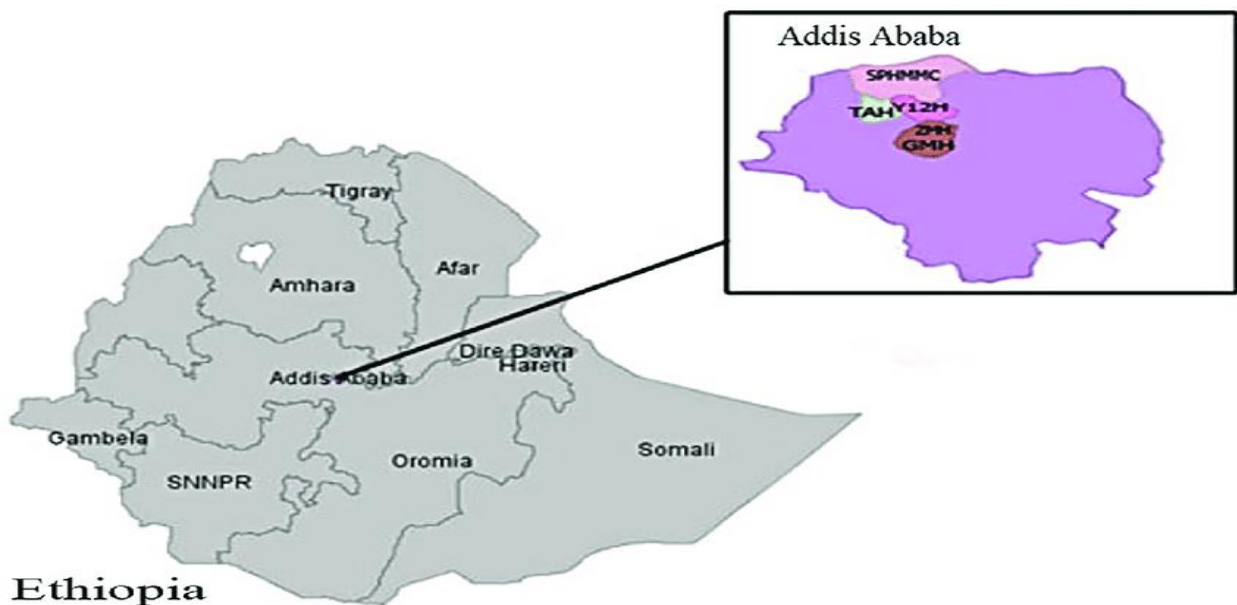


Figure 3: Map of Ethiopia showing all Regional States and Addis Ababa City Administrations including Public Hospitals (**Source:** Map of Addis Ababa, Ethiopia, accessed from www.google.com on July 30, 2020).

Zewditu Memorial Hospital (ZMH)

Zewditu Memorial Hospital is found in Addis Ababa, Ethiopia. It was built, owned and operated by the Seventh-day Adventist Church, but was nationalized during the Derg regime in about 1976. The hospital is named after Empress Zewditu, the cousin and predecessor on the throne of Emperor Haile Selassie. Today it is operated under the management of Addis Ababa health bureau providing comprehensive medical services and is among the leading hospitals in the treatment of ART patients.

Tirunesh Beijing General Hospital (TBGH)

Tirunesh Beijing General Hospital is one of the hospitals under the Addis Ababa City Administration Health Bureau that has been giving routine health services for the city community and other referral cases from different regional states of Ethiopia. It is situated in Akaki Kality sub-city near to the Debrezeit road. It was built by the Chinese government after the Beijing Olympics, in which Tirunesh Dibaba won two gold medals in 10000m and 5000 meters' race so that the hospital is named after the Athlete, Tirunesh Dibaba. It provides both outpatient and inpatient services. It has 100 beds for the inpatient services (Medical, Pediatrics, Obs/Gyn, Neonatal, and Surgical) and the OPD services.

Yekatit 12 Specialized Hospital

Yekatit 12 specialized Hospital Medical College (Y12HMC) is found in Addis Ababa the capital city of Ethiopia. The hospital is serving more than in all six major departments and other units since 1923. The hospital provides various services such as OPD, surgery, family planning, ART, laboratory, pharmacy, ANC and deliver dental and neonatal care.

Tikur Anbessa Specialized Teaching Hospital (TASH)

TASH is a government-owned large referral teaching hospital under the administration of Addis Ababa University, located in Addis Ababa, Ethiopia. The hospital has been operating since 1972, currently providing diagnostic and treatment services with 700 beds (AAU, 2020).

Saint Paul Hospital (SPH)

St. Paul's Hospital Millennium Medical College is located in Addis Ababa, Ethiopia. It is the second-largest specialized hospital established in 1968. It is governed by a board under the Federal Ministry of Health (FMOH). The hospital has more than 2800 clinical and non-clinical staff members that provide medical specialty services to patients who are referred from all over the country.

Saint Peter Specialized Hospital (SPSH)

The study was carried out in St, peter specialized hospital Addis Ababa Ethiopia. St Peter, was established in 1953 and its mission is to become the center of excellence a model TB specialized hospital in east Africa. Its objectives are to integrate internal medicine with pediatrics services and to improve research, training and health services. St. Peter offers a host of services including laboratory, dental, maternal health, neonatal care, voluntary counseling and testing, health facility-based medical care psycho-social support, information, education and communication, as well as HIV/AIDS research.

3.2 Research Approach

Based on the objectives of the research, three research approaches can be used: Quantitative, Qualitative and Mixed-Research Approaches. Again, from their prototypical versions of view, there are three mixed methods, namely: convergent parallel, explanatory sequential parallel and exploratory sequential parallel. Therefore, this study used a Sequential Parallel mixed-research method to guide the process of data collection, data analyses and interpretation of the findings. This approach ensures the triangulation and validation of information gained from all

the data providers during the course of data collection and analyzes different types of objectives.

The mixed methods research design creates a wider picture by giving the depth and insightful information through inclusion of narratives and dialogues (Leedy and Ormrod, 2010 and Creswell, 2015).

3.3 Study design and period

A facility-based cross-sectional survey supplemented by a qualitative study was conducted in selected public hospitals in Addis Ababa city to assess the implementation status and challenges of pharmaceuticals reverse logistics. The data collection was carried out from March 08 to April 08, 2021. Both qualitative and quantitative methods were used. The qualitative study involved key informant interviews while quantitative study used a cross-sectional study design which was conducted by using semi-structured self-administered questionnaire, data abstraction formats and a checklist.

3.4 Source and study population

Source population

According to each public hospital's structure, there are main 6 case teams under pharmacy directorate, drug supply management unit, Drug Therapeutics Committee and other different dispensing units. Thus, all the public hospitals found in Addis Ababa, all pharmacy professionals and documents used for medicines wastage registrations (disposal report), redistributions (stock transfer receipt) were source of information.

Study population

The study population for this research is all pharmacy directorates, drug supply managers, Drug and Therapeutics committee members, pharmacy store managers, disposal focal person, and all pharmacy dispensing heads who involve directly or indirectly in pharmaceutical logistics

practices at the selected public hospitals. And also, all records of medicines wastage/ disposal report, redistribution (stock transfer receipt) of the year 2012 EFY-2013EFY in the sampled public hospitals.

Unit of Analysis

The unit of analysis for this study were both public hospitals in Addis Ababa which are engaged in rendering health service under federal ministry of health and professionals working under pharmacy directorate.

3.4 Inclusion and exclusion criteria

Inclusion criteria:

- Public hospitals that were in operation for the last 5 years because they gave enough information on certain reverse logistics practices.
- Staff who were available and volunteer during the study period
- Medicines stock status and record with price in the year 2012-2013EFY. This helps in determining the value of budget medicines wasted.

Exclusion criteria:

- Medicines recorded with no price indication
- Medicines whose stock status is unknown
- Wasted medicines recorded as free prices such as program and donation medicines

3.5 Sample size determination

The sample of public hospitals was calculated by using the Logistics Indicators Assessment Tool (LIAT) (USAID | DELIVER PROJECT, 2008) which recommends a minimum of 15% of the targeted health facilities can be included in the survey. Assuming 6 (more than half) hospitals to be a representative sample, the researcher took 55 % of the source population, then sample size can be calculated as $(11 * 55 / 100 = 6.05)$. Accordingly, 6 public hospitals were selected out of 11 public hospitals which were more than 5 years in operation in which 3 hospitals from AARHB and 3 hospitals from the FMOH. First, hospitals were stratified into

Federal and Regional based on their administrative level. Then, the proportionate number of hospitals from the federal and regional level were selected by using simple random sampling techniques (Annex 3).

3.6 Sampling techniques

a) Quantitative Study

For the quantitative part of the study, health professionals engaging in the Drug and Therapeutics Committee (DTC) and other pharmaceutical supply management activities of the hospital. Thus, they are nearly 42 pharmacists who have a closer knowledge on pharmaceuticals logistics. For the document review, the LMIS, disposal reports and stock redistribution reports were assessed to check the wasted/returned stocks of 10 randomly selected samples of pharmaceuticals as experienced in 2012-2013 EFY in all study hospitals. This information is needed to verify either the hospital is expired with pharmaceuticals or overstocked at certain point and how it was managed in reversing manner.

b) Qualitative Study: Basically, there can be four broad techniques used to select a sample for a qualitative study, namely: quota sampling, purposive sampling and convenient sampling, and judgmental sampling technique. Thus, this study used a combination of convenience and purposive sampling technique. Pharmacy directorate, DTC members and case team leaders in the hospitals were purposively selected as key informants because they were supposed to be information-rich in policy-related issues.

3.7 Data collection and Management

Data collection

Structured Questionnaires: Semi-structured questionnaire was designed to gather mainly quantitative data pertaining to employee's demographic and socio-economic characteristics, RL practices, challenges they faced, etc. In PRL challenges section, each item was scored on a 5-point Likert scale ranging from 1 is strongly disagree to 5 is strongly agree.

- a) **Data abstraction:** Used to collect 10 medicines to examine the reason of their expiry and amount wasted and this data is collected from store manager.
- b) **Checklist:** 14 operational standard criteria of PRL were asked from pharmacy directorate (annex 5).
- c) **Key Informant Interview:** interviews and discussions were conducted with CEO, pharmacy directorate, DSM unit leader DTC members. The key informant interview was intended to complement with the survey questionnaire results. The interview was done by the researcher.

3.8 Data quality and analysis

Data quality assurance

The quantitative data collection tool was pretested prior to the data collection (1 hospital). Then, the collected data was summarized on the same day of the data collection. The qualitative data was conducted after the interview guide was tested for its face and content validity by health supply chain management students at AAU. The questions were prepared in English language and translated into Amharic and it was used for the interview. A digital voice recorder was used and transcription took place after the information was received. For the qualitative study the confidentiality was assured of hospitals and health workers. Personal identifiers were removed and the result was presented aggregately. Interviewees were coded as (DTC1, DTC2, ... & pharm1, pharm2, ...)

Data entry and analysis

The collected data were manually checked, coded for completeness before being entered into the computer. The quantitative data were entered and analyzed by using SPSS version 20 and Microsoft Excel 2016. The analysis was performed in aggregate and presented with (frequency, mean, standard deviation, graph and percentages). The qualitative data responses

were subcategorized under main themes and sub-themes, then respondents' information was analyzed thematically.

3.9 Validity and Reliability

The validity of a study was assured by a pilot study conducted and results were examined by the researcher. The purpose of a pilot study is to identify possible flaws in the measurement procedures such as ambiguous instructions and inadequate time limit of the intended study. A questionnaire, data abstract and checklist were expected to be tested to ensure the clarity that was done before the before the start of the main study.

Reliability test was performed so that the study was given the same results if similar study is repeated. Thus, a Cronbach's Alpha was used to ensure the reliability of the LIKERT study part showed as follows:

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.757	.766	17

The Cronbach's Alpha is >0.7 and acceptable and above the standard threshold, thus the questionnaire was reliable.

3.10 Ethical Consideration

Ethical clearance was obtained from the Ethics Review Committee of the School of Pharmacy, AAU, Addis Ababa public health research and emergency management directorate, St. Peter Specialized Hospital. Verbal consent from all respondents was obtained before enrolling them as the respondents of the study. During the consent process, the respondents were provided with information regarding the purpose of the study, why and how they were selected as the respondents. All respondents were also told that they can withdraw at any time during the interview process. Participants were also assured about the confidentiality of the information that was obtained during the study time.

CHAPTER FOUR

RESULT AND DISCUSSION

Result

This chapter consists of the analyzed data and the findings which were collected using an interview, checklist, data abstraction format and a semi-structured questionnaire. Data analysis was done in line with the objectives of the study which was to assess the Implementation Status and Challenges of Pharmaceutical Reverse Logistics in public hospitals in Addis Ababa. Thus, this section will present both quantitative and qualitative finding respectively. A total of six public hospitals were surveyed. The minimum year since the facilities became operational was 9 years and the maximum were more than 50 years.

4.1 Quantitative Findings

4.1.1 Response Rate

Based on the calculated sample of 6 public hospitals, there are 6 to 8 case teams under pharmacy directorate and averagely there are nearly 42 pharmacists who have a closer knowledge on pharmaceuticals logistics. Therefore, a total of 42 self-administered questionnaires were distributed to health professionals from different roles within pharmacy department (drug supply manager, Drug Therapeutics Committee, store manager, disposal focal person, purchaser, dispensing unit leaders, and pharmacy directors). But only 35 questionnaires were returned and 32 are qualified for analysis after checking for data error which makes 76 % of response rate.

According to Mugenda and Mugenda (1999) the response rate of 50% is adequate for analysis and reporting; a rate of 60% is good and a response rate of 70% and over is excellent. Based on this assertion, the response rate was considered to be excellent (Mugenda and Mugenda, 1999).

4.1.2 Socio-Demographic Characteristics of Study Participants

Among 32 respondents participated for quantitative study, the majority are male 23 (71.9%) and 9(28.3%) are female. Majority of respondents age were 21-30; 16(50%). 15(46.9%) were between 31 to 40 years of age & 1(3.1%) was between age greater than 51. In terms of marital status, 17(53.1%) of respondents were single and 15(46.9) were married. When educational level is described. pharmacists holding masters were 5(15.6%), pharmacists holding degree and diploma were 26(81.3%) and 1(3.1%) were medical doctors, health officers, nurses or laboratory technologists. Again, most of the respondents were working in dispensing units 20 (62.3%); management position 2(6.3%). The majority of respondents 16(50%) had 4- 6 years of work experience, 6(18%) had 7-9 years of experience as shown in (Table 1).

Table 1. Background information of respondents in public hospitals, Addis Ababa, Ethiopia, 2021. (N=32)

Variables		Frequency	Percentage
Gender	Male	23	71.9
	Female	9	28.1
Age	21-30	16	50.0
	31-40	15	46.9
	41-50	0	0
	Greater than 51	1	3.1
Educational level	Pharmacist (MSc.)	5	15.6
	Pharmacist (BSc.)	23	71.9
	Diploma in pharmacy	3	9.4
	Others*	1	3.1
	Management Staff	0	0
Department	Dispensing units	20	62.3
	Hospital wards	0	0
	Management	2	6.3
Work Experience	≤ 1year	1	3.1
	1-3 years	5	15.6
	4-6 years	16	50.0
	7-9 years	6	18.8
	≥10 years	4	12.5

*Either Health officer/nurse/doctor/ laboratory technologist

Survey Result, 2021

4.1.3 Reverse Logistics Practices at the Hospitals in terms of RL activities

Respondents who were asked whether their respective hospitals practiced reverse logistics, responded that majority of them 14(47%) agree that there is no proper reverse logistics practice. However, 9(30%) practice reverse logistics and 7(23%) do not have a clear set out guideline to experiences reverse logistics. When asked to write the procedures of reverse logistics, most of them were new or naïve to the concept. However, there are a few pharmacists who clearly described the procedures according to the customized practices to the facilities. Generally, they know that expired pharmaceuticals are collected for disposal purpose and overstocked are redistributed within the facility or to the nearby. For example, some of the hospitals usually use their own method of reversing products since there is no clearly stipulated guideline for pharmaceutical reverse logistics. They register to be disposed or redistributed drugs, then selected and sorted, then after they are quarantined in a separate store and at last disposed as per the stipulated guideline or redistributed to other health facilities or sometimes transferred to the needy and nearby health facilities.

Some experienced respondents clearly stated the procedures of reverse logistics as it is a process of recording expired, obsolete or overstocked pharmaceuticals from store, wards and dispensing units and then quarantined for a time. In the meantime, the disposal committee in collaboration with EFDA disposes the products if they are no longer used. However, the products expected to be overstocked will be redistributed to other health facilities. Surprisingly, some of the responses differ from one hospital to the other, as well as differ between individual respondents from same hospital. Therefore, the student-researcher has seen that reverse logistics is not properly practiced amongst some hospitals.

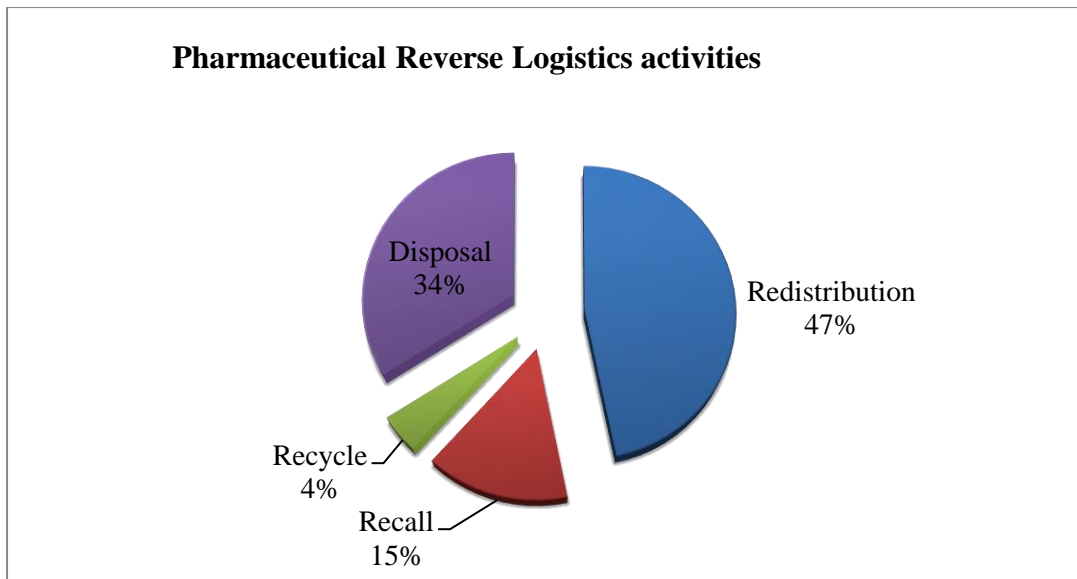


Figure 4. *Pharmaceutical RL activities practiced in the public hospitals*

Respondents were provided with four pharmaceuticals reverse logistics activities to indicate which are practiced in their hospital. Among the activities, 22(47%) practice redistribution, 16(34%) practice disposal, 7(15%) and 2(4%) practice recall and recycle respectively. Therefore, most health facilities rely on redistribution activities to practice pharmaceuticals reverse logistics and least practice is related to recycling.

4.1.4 Management of overstocks at the hospitals

Reasons for overstock

Regarding the experience of overstocks at the facility level, most hospitals 21(66%) experience overstocks, 9(28%) rarely experiences overstocks and 2(6%) experience no overstock. The same respondents confirmed that mostly they experience overstock every month.

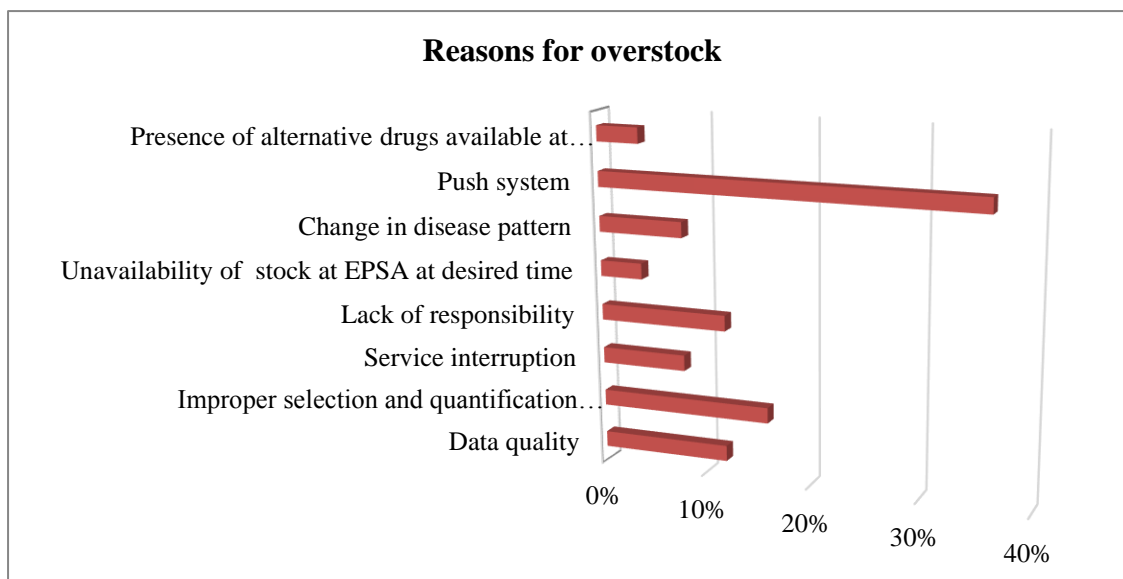


Figure 5. *Reasons for overstock at hospital level*

Majority of the hospitals blame either the international donors or EPSA for pushing system of pharmaceuticals to their respective hospitals. Donors supply excess items, EPSA dumps near expiries without the request of hospitals and even other specialized hospitals pushes unwanted pharmaceuticals to the nearby hospitals. Then improper selection, quantification and procurement play the second role for the reason of overstocking. This problem is related to lack of experts in quantifying with proper forecasting, committing corruption among procurement committees and some enigmatic procedures, unplanned purchasing order etc. Other reasons for overstock are lack of data quality, i.e., lack of tracing and tracking of data between providers and receivers, data invisibility between dispensing units and store managers and responsibility, i.e., mismanagement of pharmaceuticals, carelessness change in disease pattern, service interruption and stock out of pharmaceuticals from the supplier-EPSA (Figure 6).

Management of overstocks

The same respondents when asked to explain if how to manage overstocks at their respective hospitals described several solutions. Amongst them, majority agree in redistributing pharmaceuticals to the near-by hospitals or any health facilities. They explained transferring to other facilities before the pharmaceutical arrival is the best way of preventing overstock since the same product is at hand. Still others confirmed that posting overstocks on social media

groups so that other facilities would see and take it, updating doctors to prescribe the near expiries and promoting drugs in wards through clinical pharmacists was also mentioned as a method of managing overstocks.

Majority of the respondents claim that they are reacting to overstock mostly on monthly basis and other react within every two months. However, there are also hospitals who react to overstock within two weeks. As was observed, respondents who never seen any guidelines on overstocks management are 72% and those who acknowledge the availability of guidelines which is customized are 28%. Though, they were not able to describe the procedures clearly.

4.1.5 Management of expiries at the hospitals

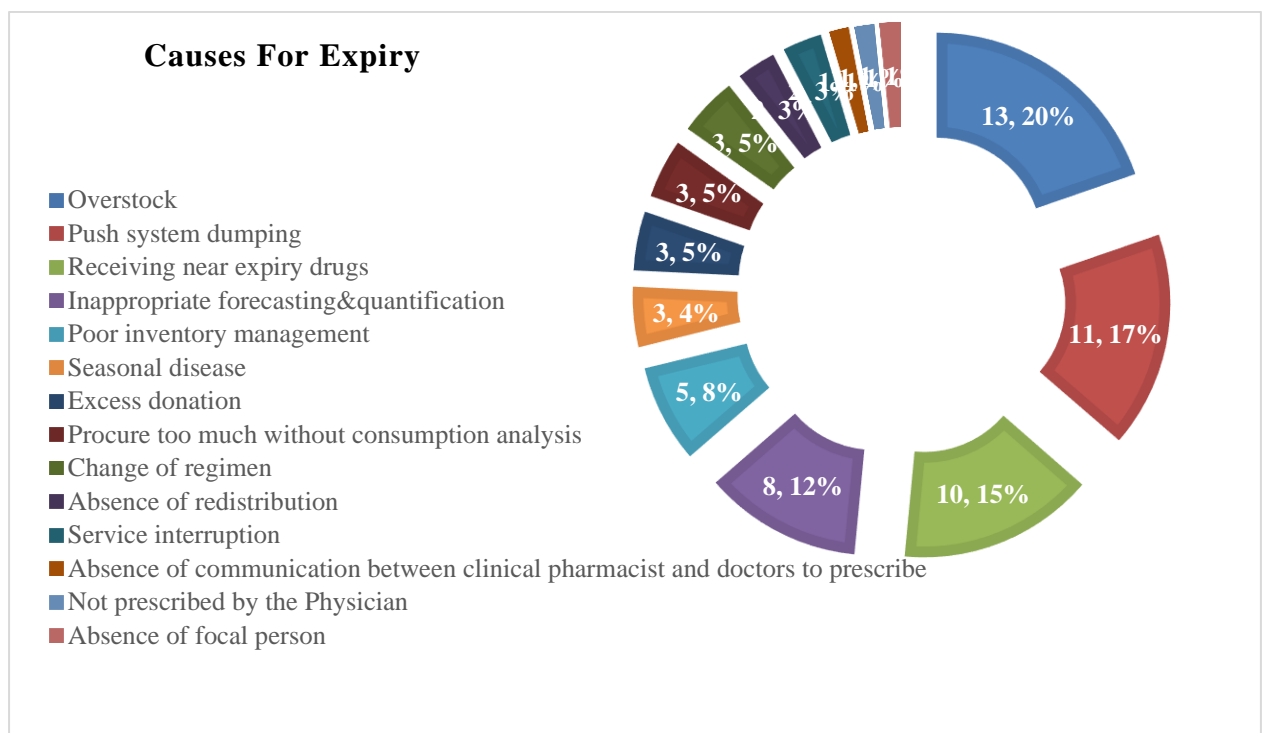


Figure 6. Causes for expiry in public hospitals

In this study all the surveyed hospitals showed that they experience drug expiries due to several causes. To put in decreasing order of causes, the most frequent cause is overstock 13(20%) and then 11(17%) is the push system dumping by suppliers, 10 (15%) is due to receiving near expiry drugs and 8(12%) are due to inappropriate forecasting, quantification and procurement. Here,

the problem is related to forecasting inaccuracies, not relying on morbidity data to quantify and vague procurement processes. Added to that, poor inventory management has also caused expiry 5(8%). Further, there are also causes of expiry mentioned by the respondents such as seasonal disease, change of regimen, absence of redistribution, excess donation, procure too much without consumption analysis, service interruption, absence of communication between clinical pharmacist and doctors to prescribe, not prescribed by the physician, and absence of focal person.

Respondents described many techniques such as proper disposal as per the guideline of EFDA, redistributing before expiring, promotes near expiry drugs, sorting, recording separately, procure long expiry date, using FEFO and quantification order etc.

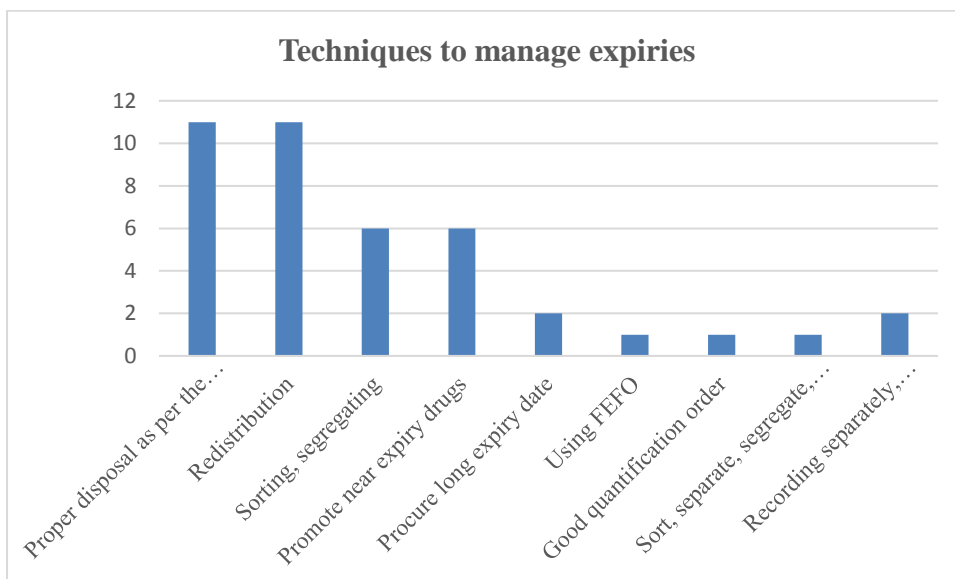


Figure 7. Techniques to manage expiries in the public hospitals

Majority of the hospitals react to expiries once a month and some other facilities react at any time during personal investigation. Moreover, 50% of respondents confirmed that their respective facilities have reference guideline clearly stipulated on management of expiries, 41% confirmed that they have no clear guideline and 9% do not know either they have the expiry management guideline.

Among the top ten wasted medicines the top four by value were Capecitabine 500mg (28%) followed by Thiopental Sodium 0.5g and Bleomycin 15mg/ml (14%) and Nifedipine(13%) (Figure 9).

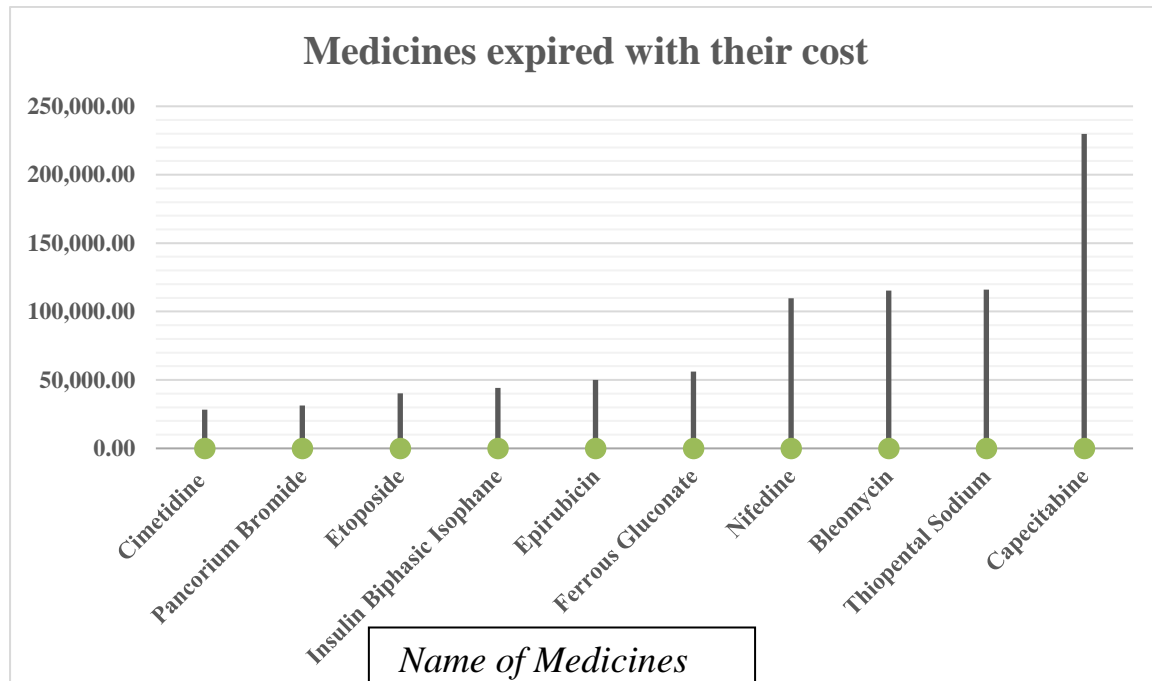


Figure 8. Top ten medicines wasted (in value) in sampled hospitals from April 2020 – July 2021

Out of randomly selected sixty wasted medicines from six hospitals were used to know the reason for the wastage in connection with reverse logistics. Almost all are reported as expired which is one part of reverse logistics activities. From each hospital, ten medicines were selected randomly to know their strength, dosage form, reason for wastage, amount wasted and cost in ETB. Amongst those hospitals, from July 8, 2020 – April 08, 2021, the wastage amount in money is 4,343.21 ETB to 409,366.37 ETB from lowest to highest respectively.

Total value of budget medicines wasted in all hospitals in the new fiscal year from July 8, 2020 – April 08, 2021 (ETB) is five million six hundred eighty thousand four hundred sixty-eight birr and thirty-one cents (5,680,468.31ETB) while one of the hospital’s reports is missing. This time duration is chosen till the data collection and seeking for full information of the pharmaceuticals.

Among five hospitals that provided enough information on the wastage registration and disposed medicines lists, in 2012 EFY, hospital 5 has encountered the wastage amount of birr 1, 983,616.72, hospital 3 lost birr 1,869,363.52 and hospital 2 has lost birr 1,399,756.93 and Hospital 1 and 4 have no significant loss of medicines wastage in the fiscal year. However, Hospital 6 was excluded from the above presentation since it has not provided ample information provided. (Figure 10)

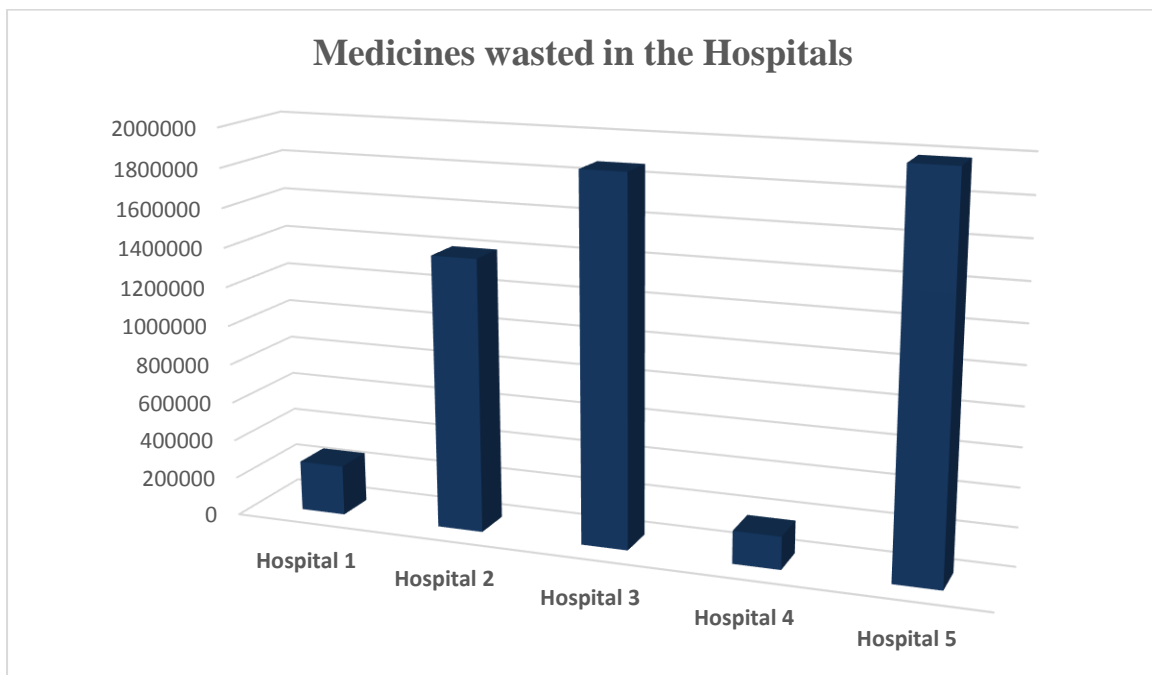


Figure 9. Monetary value of wasted medicines in each hospital from July 2020-April 2021

4.1.6 Policy and Guidelines

Among the study participants, 28(87.5%) completely confirmed that the hospitals have no any reverse logistics policy and guideline, 3(9.37%) moderately agree that the facility has either customized or some manuals to implement pharmaceuticals reverse logistics and only one respondent do not know if there is a policy governing reverse logistics for pharmaceuticals. On the contrary, 24(75%) confirmed that they have disposal guideline of pharmaceuticals and 8(25%) claim that they do not have.

4.1.7 Challenges of Pharmaceuticals Reverse Logistics

The study began by assessing reverse logistics activities such as redistribution, recall, recycle, disposal and general challenges of reverse logistics practices. The findings were as is indicated in Table 2.

Table 2. Challenges on Reverse Logistics Activities in Public Hospital, Addis Ababa, Ethiopia, 2021.

Descriptive Statistics			
	N	Mean	Std. Deviation
Redistribution			
There is clear standard for redistribution of pharmaceuticals	32	2.5000	1.19137
Redistribution of pharmaceuticals has a vague concept	32	3.0313	1.03127
Poor implementation of SSA* to identify which items are redistributable	32	2.4375	1.01401
Grand Mean		2.6563	1.07883
Recall			
Lack of knowledge about the procedures of recalling	32	2.5000	1.13592
There is technical support from EFDA, EPSA and disposal firms	32	2.1563	.98732
Never received a recall initiation from manufacturers or regulatory authority	32	2.2188	1.09939
Grand Mean		2.2917	1.07421
Recycle			
There is a well-documented policy for recycling	32	2.5313	1.34367
Unavailability of responsible body for segregation, collection, storing & recording	32	2.5938	1.24069
Lack of definite rules and regulations on managing returned products	32	2.3750	.94186
Grand Mean		2.5000	1.17540
Disposal			
There is simple procedure and guideline for disposal	32	2.9375	1.24272
We use traditional ways of disposing the unwanted pharmaceuticals	32	3.0000	1.48106
We do have an easy access to incinerate the wasted products	32	1.8125	.96512
Grand Mean		2.5833	1.22963
Other Challenges			
Lack of appropriate technology	32	2.2188	1.00753
The reverse logistics policy is not included on the annual plan	32	2.1875	.96512

Transportation problem (moving products back to supplier or disposal sites)	32	2.5313	1.19094
Absence of internal and external follow up and inspection	32	2.3125	1.09065
Most of the time the products are unfriendly to the environment	32	2.4375	1.13415
Grand Mean		2.3375	1.07767
Valid N (listwise)	32		

*SSA= Stock Status Analysis

Note: Strongly Disagree (SD) =1, Disagree(D)=2, Neutral(N) =3, Agree(A) =4, Strongly Agree (SA)=5.

Survey Result, 2021

Health professionals involved in the Drug Therapeutics Committee, dispensary units and medicines supply management activities were asked about challenges of pharmaceuticals RL activities using 5 points Likert scale; *Strongly Disagree (SD) =1, Disagree(D)=2, Neutral(N) =3, Agree(A) =4, Strongly Agree (SA)=5*. The challenges were sub-categorized into redistribution, recall, recycle, disposal and other multi challenges.

Redistribution: The challenges related to redistribution are unclear standards for redistribution of pharmaceuticals, the vague concept of redistribution of pharmaceuticals and the poor implementation of Stock Status Analysis (SSA) to identify which items are redistributable. They have the highest grand mean score and thus indicated the most common challenge perceived by health professionals (2.6563 ± 1.07883) (mean \pm SD). This implies that, the main challenge for redistribution is poor implementation of stock status and timely analysis should be implemented.

Recall: The challenges related with recall are lack of knowledge about the procedures of recalling, absence of technical support from EFDA, EPSA and disposal firms, and never or rarely received a recall initiation from manufacturers or regulatory authority. The grand mean score and standard deviation are (2.2917 ± 1.07421).

Recycle: The challenges related with recycle are absence of well-documented policy for recycling, unavailability of responsible body for segregation, collection, storing and recording, lack of definite rules and regulations on managing returned products. The grand mean and standard deviation are (2.5 ± 1.1754) respectively.

Disposal: The challenges related with disposal are procedure and guideline for disposal, use traditional ways of disposing the unwanted pharmaceuticals, and having an easy access to incinerate the wasted products. Thus, the ($M=1.8125$) indicated there is no easy access to disposal incineration.

Other Challenges: There are also other challenges that can be mentioned such as lack of appropriate technology (2.2188 ± 1.00753), no inclusion of reverse logistics activities in the annual plan ($2.1875 \pm .96512$), transportation problem (moving products back to supplier or disposal sites) (2.5313 ± 1.19094), absence of internal and external follow up and inspection (0.3125 ± 1.09065) and the products unfriendliness to the surrounding environment (2.4375 ± 1.13415). And the grand total mean score and standard deviation for other challenges counts for 2.3375 ± 1.07767 (mean \pm SD) (Table 2)

Therefore, generally we can infer from the finding that pharmaceutical reverse logistics activities face challenges as majority of the respondents were indicated as (M=2) which is disagreement the practice and statuses.

Table 3. Assessment of operational standards for the implementation Status of Reverse Logistics of Pharmaceuticals in the public hospitals, Addis Ababa, Ethiopia, 2021. (Source, FMOH, 2021)

Description	Hospital 1		Hospital 2		Hospital 3		Hospital 4		Hospital 5		Hospital 6	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Properly select, quantify, and order/procure/acquire only pharmaceuticals	✓		✓		✓		✓		✓		✓	
Conduct SSA* & identify stocks that can't be used every two months	✓		✓		✓			✓	✓		✓	
Notify about unused stock in the facility to responsible bodies for further action	✓		✓		✓		✓		✓		✓	
Try to exchange or lend products unable to be used &to another health facility	✓		✓		✓		✓		✓		✓	
Report to supplier to reverse the products	✓		✓		✓			✓		✓	✓	
Sign mutual written agreement (for reimbursed / disposed product)		✓		✓		✓		✓	✓		✓	
Sort products to be returned	✓		✓			✓	✓			✓	✓	
Prepare/arrange and properly pack for return	✓		✓			✓	✓			✓	✓	
Fill necessary data of reversed products in standard issuing formats/ vouchers		✓		✓	✓			✓		✓	✓	
Transportation mechanism to ensure manufacturers storage condition		✓	✓		✓		✓			✓	✓	
Reverse to respective supplier, refurbishment center, and manufacturer	✓			✓		✓		✓	✓		✓	
Receive verification documents for products that are returned to supplier	✓			✓		✓		✓	✓		✓	
Mechanism to sort & collect recyclable plastic container		✓		✓	✓			✓	✓			✓
Report on how much cost saved/revenue generated by doing reverse logistics	✓			✓		✓		✓		✓	✓	

*SSA=Stock Status Analysis

Survey result 2021

Survey of operations standard of reverse logistics in connection with the wastage disposal lists, redistribution (transfers) records and reverse product issuing voucher were also conducted using a checklist (Table 3). Percentage fulfillment of the reverse logistics operations by hospitals was calculated by multiplying the number of “yes” by 100% and dividing with the total number of reverse logistics operations standards considered. Even though there is no desirable or acceptable range for health facilities, however, if the hospitals that fulfilled at least 60% of the operations standard of reverse logistics is defined in the checklist. Using such criteria, only 2 hospitals had fulfilled the desirable operations standard of reverse logistics; one hospital 93% and the other one 71%, while the remaining 3 hospitals had only fulfilled 57% and 1 hospital fulfilled 43% of reverse logistics operations standard.

Therefore, pharmaceutical reverse logistics is the practice of returning or disposing medicines according to the procedures and activities according to the guidelines stipulated in reverse logistics management guideline for pharmaceuticals and medical device. Thus, the pharmaceutical reverse logistics practice and implementation is acceptable when the health facilities perform all the PRL activities and in turn the implementation status is approved.

4. 2 Qualitative Findings

In-depth interviews were held with DTC members, Pharmacy Directors, DSM unit leaders, Inpatient ward heads and coordinators of dispensaries in the hospitals. Totally 12 interviews were undertaken; 7 were from Federal hospitals and 5 from the regional administration health bureau. Among them 8 were males and 4 were females. The majority of them were in the age group between 31 to 40 years with 5 Master degrees and 7 bachelor's degrees. The majority of their work experience ranged from 7 to 9 years. The responses were controlled by anonyms identifiers. Therefore, three main themes from these in-depth interviews were identified.

In-depth interviews were conducted to gather information about the current practices, implementation status and challenges of reverse logistics in their hospitals, implementation status and challenges on service provision and suggestions for improving hospital reverse logistics. Added to that, explorative questions were asked to know more about reverse logistics since its implementation status is very poor.

Practices of Pharmaceutical Reverse Logistics

Most key informant interviewees more or less expressed similar views regarding the reverse logistics practice of pharmaceuticals. The most of them agree that they do not have a clear-cut practice of reverse logistics at the facility level. Even the concept is at the young stage, though the hospitals are facing many challenges due to the absence of sound reverse logistics practices.

However, there are hospitals that very rarely practice reverse logistics but only disposal.

Except for some respondent, majority agree with the that reverse logistics at the hospital level has a young concept and there is no very favorable condition to practice it. Even they say that there is no focal person to handle the issue except a disposal focal person who only deals with incinerating the disposed of items.

One respondent said that:

“The practice of reverse logistics is somewhat ambiguous at the hospital level because there is no guideline to practice it in a good manner. However, we seldom return products which are damaged, expired or out-of-usage for disposal purpose.” (Pharm.01)

The other respondent added that:

“Even though we are supposed to practice reverse logistics, we do not have enough manpower who is expert in the area and we are naïve to implement all the expected procedures.” (Pharm.10)

Asked if their hospitals are reversing unused medicines from inpatients wards which are left from hospitalized patients, almost all interviewees were said in one word *“we have never practiced reversing the leftover medicine from the patient side (hospital ward)” (Pharm, 6)*

Generally, the issue of practices and procedures of pharmaceutical reverse logistics has a negative impression among the key informants except one interviewee argued that it is being practiced in the whole set-up. He mentions that returning expired pharmaceuticals from dispensing units for disposal purposes and quarantining them in an isolated place. His argument is shallow and cannot fully represent what really reverse logistics is.

Implementation status of Pharmaceutical Reverse Logistics

There are multiple responses about the implementation status of pharmaceuticals reverse logistics. Even though the practice is known little, the implementation is yet to be done among all the health facilities. In agreement with this idea, one of the respondents said:

“In our hospital, the implementation status of reverse logistics is somewhat good. For example, we manage expired drugs to be placed in quarantine place until it is disposed accordingly to procedure and overstocked items are shared to other facilities.” (Pharm, 09)

Sometimes it is very devastating to leave pharmaceuticals without implementing proper procedures as per the guidelines of EFDA, Thus, respondent says:

“The status is poor or no sometimes. As per the guideline stipulated in wastage disposal (EFDA), we follow procedures and try to collect them in our hospital quarantine. But there is no further action taken....” (Pharm, 07)

Respondents who were asked for the implementation status in relation to the drug management cycle, answered as follows:

“...Quantifying, procuring, storing and selecting pharmaceuticals require big expertise and potential. Doing them might help us in many ways but there is a huge problem in implementing it. Look, we do have 5 stores in total, so we do not have the problem of storage rooms but as I said we have the problem in completing the remaining task, which can only be run by our own executives and EFDA officials.” (Pharm 01)

The other respondent for the same question said:

“...By information-based quantification, well-practiced policies, well-equipped Management Information System, following good procurement policies, preparing enough space for storage and standardized storage.” (Pharm, 04)

Another respondent added that the drug supply management cycles should be out in place in order to assure good implementation of reverse logistics:

“...all the drug management cycles are important in order to assure an uninterrupted supply chain. However, failure to follow the rules will result in damage, expiry and an interruption in the sustainable provision of pharmaceuticals. Therefore, each stage of the cycle should be handled by well-experienced practitioners.” (Pharm, 11)

Some senior hospitals take prior caution by implementing customized and facility-based practices so that they would not end up in excess overstock and mitigate the bad consequences of reverse logistics. One of the key informants explained as:

“By applying the proper APTS, redistribution, duty-time-night inspection on unavailable drugs, we use software to see the missing or overstock in other departments which is very helpful in creating data visibility. We again use transfer-in and out. That is transferring the overstock within the facility and out of the facility.”

“...As the hospital has no defined catchment area, it is forced to use all its resources on a situational basis. Therefore, we only rely on our consumption data method to procure the pharmaceuticals. Then, we are unable to stick to a certain method of quantification and reduce the wastage in reverse.” (Pharm, 9)

Some hospitals do not pay heed to for unused medicines to be disposed. Then a respondent from one of the federal hospitals said:

“My hospital has forgot to dispose the unused medicines from their compound and it took a large space. For example, I can mention some expired drugs which are left here for more than 7 years...” (pharm 07).

Challenges of Reverse Logistics

As mentioned by interviewees, there are tremendous challenges that hinders the implementation of RL such as financial problems, management inattention, lack of information technology, policy issues, etc. In agreement with this idea, one of the respondents said:

“Frankly speaking, the implementation is at its young stage. We sometimes dispose of by ourselves just by following the procedures in the EFDA wastage guideline. We ask them to help us but they do not respond.” (DTC member 02)

Added to the above statement, other respondent said:

“There is no well-functioning strategy produced, however, it is good as compared to the previous practices and still, there are things that should be improved such as by making a guideline at the facility level.” (Pharm.01)

Another respondent also agrees with the above idea saying: *“There is no fully clear-cut policy regarding reverse logistics and we do have difficulties in the disposal process.” (Pharm 02)*

The Ethiopian Food and Drug Authority (EFDA) is one of the entities which play a crucial role in managing the pharmaceuticals in regulating the process from entry to exit. However, the respondents accuse the authority of not addressing the issue at hand in order to alleviate the challenges. One of the DTC members explains the challenge as:

“I think EFDA itself, has a shorthand to improve things related to disposal, management of overstocks, stock out, etc. Except enforcing the laws, it never tries to help the facility by providing every necessary procedure. Added to that, they do not allow the procedures are breached. Therefore, we store the unused pharmaceuticals in the compound quarantined for several years. Finally, there is inadequate number incinerators, high cost in private disposal firms, mismanagement with the Chief Executive Officer and Chief Clinical Officer, this all contribute to the big challenge in reversing the products.” (DTC member, 04)

The challenges for the poor implementation status of reverse logistics have resulted in many bad consequences. One key informant said that

“We do not have a sorting place because we have not to experience de-junking. However, if we fail to dispose on a timely basis, it is clear that it would not be friendly for the environment. The strategy should be developed, redistribution should be encouraged, assign one focal pharmacist as a data collector on the issue and overseer to all hospitals who is expert on this work. This helps to improve the problem we speak about. It would be good if there is a structure starting from the top institutions to the bottom in order to be transparent and accountable.

Generally, if the thing is to be done, we should give aggressive attention that would change the issue for real.” (DTC member 05)

Other key informants added for the above issue in relation to the green legacy and economy,

“The absence of proper RL exposes the environment to pollution plus exposes the drugs for illegal use and wastage of the economy. Therefore, reverse logistics shall be supported by a legal framework in the health care system to enhance confidence for decision-makers and to reduce wastage.” (DTC member, 02)

In addition to that, respondents agree that flexibility of the executing bodies is crucial in line with bureaucratic issues.

“It is crystal clear that mismanagement of RL might bring tremendous damage not only in monetary value but also affects the green supply chain concept and will end up causing them in an unfriendly environment in addition to the health problem inside the facility or outside. The written procedures of managing reverse logistics should be implemented without any precondition.” (DTC member 03)

The challenges of pharmaceutical reverse logistics are not only the problem of EFDA, EPSA, disposal firms and health facilities but also the system from the suppliers; this can be seen in the push system either by EPSA or donor agencies. Added to that, the immediate pharmacy directorate who is responsible for the first action of reverse logistics has no ability to take immediate action but has to go through a long process to execute.

“The first and the most challenging thing that hinders the implementation of reverse logistics is the push system of pharmaceuticals. Then after, it is expected to be reversed for either case, nobody is responsible to receive back then we face the insufficiency of storing areas. The other challenge is the lack of the authority of the pharmacy directorate to directly take swift action

such problems. They have to follow the procedures to execute the matter that makes the process tedious. The last could be the false reports for the sake of work performance.” (Pharm 12, Pharm 6)

Therefore, the aforementioned problems due to improper and poor implementation of reversing pharmaceuticals have might bring a huge damage in the supply system. As a result, respondents confirmed that all responsible bodies especially hospital management body must address the issue. This problem is elaborated by one respondent as:

“If not handled, it has a tremendous hazard within the facility and nearby environment. No access to get immediate and main suppliers to facilitate the reverse logistics, no adequate disposal options, the problem of lacking quarantining, no standard on donor policy, the hospital should follow strict donor policy, should see consumption data, the problem of the supplier to damp, the CEO and CCO should work closely to the lower pharmacy professionals, etc.” (Pharm 08, DTC, 04, Pharm 01)

Generally, all the respondents agree with the poor implementation status and existence of challenges of pharmaceutical reverse logistics. They report that there is no access to get immediate and main suppliers to facilitate the reverse logistics, no adequate disposal options, the problem of lacking pharmaceuticals quarantining, no standard guideline on donor policy. Other key informants added that hospitals should follow strict donor policy, should see their medicines consumption data. They also advise Chief Executive Officer and Chief Clinical Officer should work close to the lower pharmacy professionals in order to alleviate the challenges of reverse logistics and to reverse the tremendous hazards within the hospital and nearby environment. It is not encouraging to do reverse logistics because some suppliers even refuse to accept the returned products.

Being a hospital pharmacist and from my experience, I can boldly say that the implementation status of pharmaceutical reverse logistics is at its young stage though part of it, for example, disposal of wasted and expired are a bit practiced in some hospitals. Therefore, attention is needed implementing all RL activities and processes. To do so, effective managerial execution, timely follow-up and other hospital's experiences should be adopted.

Discussion

The quantitative and qualitative findings are discussed and triangulated. Both findings indicated related outcomes, even though there are some divergences due to respondents' personal experiences and their understanding of defining reverse logistics.

Ethiopia has many unworked things to deal with the logistics area including reverse logistics in the health sectors. And, it has not been well implemented in the health facilities yet. Therefore, there is almost no clear guideline and directive for implementing pharmaceutical reverse logistics except the Healthcare Wastage Management Directive. This present study focused on the determination of practices, implementation status and challenges pharmaceuticals reverse logistics using mixed data collection methods and tried to show a clear picture of reverse logistics in public hospitals found in Addis Ababa, Ethiopia.

In this study, many health professionals were new to the detailed practices and procedures of reverse logistics at their respective hospitals. Added to that, poor recording of medicines wastage and redistribution tracking log sheets are not recorded well in most hospitals which in turn results to lack of transparency and accountability.

Reverse Logistics Practices

The finding of this research showed that the majority of the public hospitals are not well experienced with the practices of reverse logistics in terms of RL activities. A similar study conducted in Malawi public hospitals indicated that “reverse logistics” is not well experienced by the hospitals as the actual movement of medicines is not reversed well (Chirwa, 2015). The reverse logistics is practiced in the hospitals to the following activities but not limited to redistribution, disposal, recall and recycle. Redistribution is the most practiced activity in the majority of hospitals twenty-two respondents (47%) confirmed. In addition to that, Manchester Royal Infirmary hospital also encountered the same thing that it was unclear whether who, how and why does reverse logistics is done (Ritchie et al., 2020)

All the hospitals are having almost no clear-cut and uniform practice of reverse logistics. Even though hospitals are given the mandate of reversing products either for disposal or redistribution at the hospital level, there is a binding rule which makes the hospitals not exercise it well which in turn makes the hospital full of pharmaceutical junks. Comparatively, redistribution is practiced well between hospitals to hospitals and hospitals to health centers but doing it in the name of transferring the products.

Management of overstocks and expires

These observations are limited to the personal knowledge of the respondent. Hospitals that practice disposal of pharmaceuticals follow the common procedures as stipulated in the Medicine waste management and Disposal directive by EFDA (FMHACA, 2011). Most of them try to dispose of according to EFDA guidelines but there is a huge difficulty in implementation. Whatsoever, they follow the procedures as: they establish a committee, sort and collect expire, identify quarantining areas and report to management body for a decision of disposal. After all, the expired, obsolete and unused pharmaceuticals are disposed of as per the EFDA procedure. However, one hospital uses its own customized way of disposal procedure but waits for EFDA to its final disposal. The issue of disposing or reversing the pharmaceuticals from the hospitals remained a long-year sophisticated problem and needs to be resolved in order to assure the uninterrupted pharmaceutical supply system.

Hospitals are prone to much wastage of medicines due to many reasons and the major one is expiry resulted from overstocks. Similar to this finding, a study conducted in the Oromia region found that delivery of nearly expired medicines to the health facilities by the suppliers, lack of electronic stock management tools and shortage of pharmacy staffs in the health facilities, lack of a system to move nearly expired medicines from one facility to another, presence of overstocked medicines due to improper quantification are the major contributing factors for medicines wastage (Gebremariam, 2017). Regarding the wastage rate, for example, Saint Peter

Specialized Hospital decreased its wastage rate from 1.5% in the year 2011 EFY to 1.2% by the next year 2012 EFY by implementing some reverse logistics activities such as proper redistribution and disposal (SPSH, 2020).

Policy and guidelines of reverse logistics

In Ethiopia, there is no such policy or guideline stipulated for pharmaceuticals reverse logistics. However, most recently, FMOH has prepared the final draft of reverse logistics but has not yet published and disseminated it to health facilities. Thus, it is imperative to say the policy governing reverse logistics at the hospital level is very weak. There are some general guidelines like *Good Dispensing Practice and Pharmaceutical Supply Chain Management (FMOH, 2019)*, *Medicine waste management and Disposal directive (FMHACA, 2011)* and *'National Pharmacy Service, Pharmaceuticals Supply Chain and Media Equipment Management, Monitoring and Evaluation Framework'* (FMOH, 2019). None of the above documents have a direct relationship with reverse logistics but covers the disposal of pharmaceuticals in general. Therefore, it can be concluded that there is policy and guideline governing the disposal of pharmaceuticals but not reverse logistics even though its implementation is questionable.

Challenges of Reverse Logistics

There are certain challenges involved in implementing reverse logistics though there are few researches are done in the area. Added, the truth of practicing reverse logistics in some hospitals is undeniable, though they are limited to redistribution and disposal. This study wanted to assess if there were any challenges that had an effect on the implementation of proper practices and procedures of reverse logistics at the public hospital level. A study done in Brazilian public hospitals concludes that most of them do not achieve Brazilian standardization quality requirements on reverse logistics (Pereira, 2012).

In this study, emphasis related to challenges is given to the core reverse logistics activities such as redistribution, recalling, recycling and disposal of pharmaceuticals. Redistribution has the

highest grand mean as compared to other reverse logistics activities. The second and third are disposal and recycle respectively and recall had the lowest grand mean among all. Furthermore, it is hard to get a clear mechanism for the collection of expired pharmaceuticals from the clinics, health centers and other hospitals. (Chirwa, 2015)

Amongst most common challenges that highly affected the effectiveness of reverse logistics is, the refusal to receive back the products by supplier, difficulty in processing the returned products due to long bureaucracy procedure, no well understanding of reverse logistics at health facilities, no well-stipulated policy and guideline that helps to apply, no proper disposal of expired drugs at the right time, lack of (quarantine) storage place, lack of support from management body, difficult procedures during disposal, improper reversing of products from different wards of the hospital, shortage of transportation, the long-distance between one health facilities from the other, limitations with technology, rejection of redistributed pharmaceuticals from the nearby health facilities, no focal person for reverse logistics duty at the facility level. Similar to this finding, a study conducted in the manufacturing industry showed the same challenges encountered like lack of defined rules and regulations on handling returned products, lack of appropriate technology, lack of infrastructure, and managing the cost of handling RL are the most known challenges (Rediet, 2016).

Facilities are forced to keep pharmaceutical junks for several years. For example, one hospital did not dispose of for a period of 6 years. That is, the hospital management members do not give attention though the hospital is suffering from storing place either for unused or to be used pharmaceuticals. However, it is not good to undermine the small scope of reverse logistics implementation happening in some hospitals.

Hospitals are losing much money from not implementing timely reverse logistics activities and this, in turn, brings an economic burden as a country-millions birr is lost due to such problems. During this research study period, the six hospitals lost 5,680,468.31ETB (USD 142,011.7) in

the 2013 EFY. Another study in the Amhara region, Ethiopia showed a similar trend having a total of about ETB 606, 545 worth of medications were found wasted at the 4 hospitals in 1 fiscal year (Ebrahim, 2019).

Concerning their operational standard of reverse logistics, hospitals were surveyed and only two hospitals were illegible. Given 14 criteria on the operational standard of reverse logistics, 2 hospitals scored more than 70% fulfilling some criteria of returning pharmaceuticals for different reasons.

In summary, both quantitative and qualitative studies somehow showed similar results except to some minor differences in the qualitative study. This is resulted from the personal experience, information gap and knowledge difference of respective respondents. However, the general practices of RL such as redistribution and disposition have similar experience in all the studied hospitals. All agree that the practices and implementation status of RL are at its young stage. For example, the collaboration between the higher and the lower personnel of the supply chain system should work hand in hand to ensure a robust RL implementation.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 SUMMARY

The Pharmaceutical reverse logistics practiced at each respective study hospitals is practiced but not efficiently and effectively. Redistribution has the highest grand mean as compared to other reverse logistics activities. The second and third are disposal and recycle respectively and recall had the lowest grand mean among all.

In summary, the details of reverse logistics are different from hospital to hospital according to their setups. However, there might be some bright future when the new guideline is enacted. The practices of pharmaceutical reverse logistics in public hospitals are yet to be redefined and should be implemented according to specific activities involved in guidelines. The procedures have remained in the documents, but are not practiced well, as a result, the management of overstocks and expiry has become a bottleneck to most studied hospitals. The reverse logistics activities such as redistribution, recalling, recycling and disposal are not implemented to their fullest extent. Moreover, the documentation and reporting of data are invisible. This all-in turn made the public hospitals move away from the practical implementation. Furthermore, the interview participants claim that the higher officials and the executing organizations should play lion's share in improving the implementation status and alleviating the challenges confronting pharmaceuticals reverse logistics.

5.3 CONCLUSION

The Pharmaceutical supply chain system needs to be overseen by health professionals especially by supply chain pharmacists as per the national guidelines for sustainable supply chain management and rational use of medications. Equal to this, reverse logistics management should get attention in the pharmaceuticals supply system of the country for the proper management of unused medications at the health facilities and to assure the proper disposal or redistribution of unusable and usable pharmaceuticals respectively.

The implementation status and challenges of pharmaceuticals reverse logistics are believed to be at their young stage. Some hospitals even do not start practicing proper reverse logistics management while failure to do so may result in wastage and expiries. The problem of stock imbalances in most hospitals has remained the bottleneck for not implementing reverse logistics in connection with disposal activities.

However, the good thing practiced in most hospitals is that redistribution or sometimes they call it transferring of medicines within the hospital and to the nearby health facilities is encouraged. Next to it, disposal is practiced in a lesser capacity, however, recall and recycle can be said very poor in implementation.

The study also concludes that the policy and guidelines of reverse logistics have tremendous financial and operational advantages to the public hospitals and the Ethiopian pharmaceutical supply chain system. This importance can be seen as it will highly lower the expiry of pharmaceuticals in hospitals by redistributing overstocked within the reverse logistics system. Redistribution has a great role in saving the loss of overstocks the expiries by relocating to the nearby hospitals that are suffering from the medicine stocked out. Push system or donations of medicines is acceptable only and only if it is based on fact-based good consumption data and prior need of hospitals should be considered. Unless, the push dumping system will remain a bottleneck in the way of pharmaceuticals reverse logistics.

The interviewed respondents emphasized the weak initiation of top managers towards adopting reverse logistics and the absence of clear-cut guidelines for the implementation. It is commendable to give genuine attention to the system application, and receiving reports from all hospitals. Generally, the implementation status of reverse logistics is very poor in all hospitals.

They generally also blame the concerned bodies such as EPSA, EFDA and professional Disposal Firms. EPSA is blamed not to have been an exemplary agency in implementing proper and timely reverse logistics actions, EFDA is very weak in executing the guidelines and directives after being proclaimed and Disposal Firms are few in number and their cost is skyrocketing in the case of incineration. Therefore, the aforementioned problems, in turn, contribute to the disastrous and unfriendly environment.

Finally, proper and scrutinized practices and procedures should be put in place in implementing the RL as it will save a huge amount of money especially in the public hospitals. All the designated bodies who are involved in the pharmaceutical supply chain sector should create a long-term plans and follow-up. This might improve the unfocused area of practicing and implementing the reverse logistics system.

5.4 RECOMMENDATIONS

Following this study finding, recommendations are given to the *Hospitals*.

- Train the pharmacy and other professionals in the managing of PRL
- Creating customized facility-based reverse logistics guidelines
- Proper implementation of wastage of pharmaceutical disposals
- The drug management cycle should be aware by all the hospital administrators and hospital workers
- The unused medicines should be recorded and reported on a regular basis

5.5 Suggestions for Future Work

Since the topic is new in its implementation status, similar studies should be conducted in different public or private health facilities so that to gain general pictures of pharmaceutical reverse logistics in Addis Ababa and beyond. Therefore, this will help us to compare the different findings based on tangible facts. Furthermore, it would be interesting to investigate the extent of private hospitals' implementation status and practices with public hospitals to learn the impacts in order to avoid the barriers from the ways of reverse logistics and assure uninterrupted supply of pharmaceuticals.

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ANNEXES

Addis Ababa University, School of Pharmacy
Department of Pharmaceutics and Social Pharmacy
MSC program in Health Supply Chain Management
“Assessment of Implementation Status and Challenges of pharmaceutical reverse logistics in the case of selected public hospitals in Addis Ababa, Ethiopia”
Consent form

Dear participant,

My name is Zerihun Zekariyas, MSc Student at AAU. This survey is being carried out for the above program fulfillment. The purpose of this study is to assess the Implementation status and challenges of pharmaceutical reverse logistics in the case of selected public hospitals. Thus, I confirm that at the end of the survey the finding will not refer individual facilities but rather will describe the overall picture of the selected public hospitals. This will take you no more than 20 minutes to complete.

NB: The survey information we got from you will only be used for the academic purpose.

For any question, contact at **0910691242** or email: **zerihun_zekarias@yahoo.com**

Thank you in advance!!!

Annex 1. Assessment of Pharmaceutical Reverse Logistics

Part I: Self-administered Questionnaire for data collection on Assessment of Reverse Logistics of Pharmaceuticals

1: Background Data of Respondents

1. Your Gender? A) Male B) Female
2. Age? A) ≤ 20 years B) 21 -30 C) 31-40 D) 41-50 E) ≥ 51
4. Highest level of education?
 - A) *General Practitioner*
 - B) *Pharmacist (MSc)*
 - C) *Pharmacist (B. Pharm)*
 - D) *Diploma in Pharmacy*
 - E) *Health Officer (MSc)*
 - F) *Health Officer (BSc)*
 - G) *Nurse (MSc)*
 - H) *Nurse (BSc)*
 - I) *Nurse (Diploma)*
 - K) *Other, specify.....*
6. Your department currently you are working?
 - A) Pharmacy Stores
 - B) Pharmacy Dispensing Unit
 - C) Laboratory
 - D) Wards
 - E) Management
 - F) Other...
7. For how many years did you worked?
 - A) ≤ 1 -year B) 1 – 3 years C) 4 – 6 years D) 7 – 9 years E) ≥ 10 years

2. Questions on Practice and Implementation Status of Pharmaceuticals Reverse Logistics at health facility

Reverse Logistics is the process of planning, implementing, and controlling the efficient, cost-effective flow of raw materials, in-process inventory, finished goods and related information from the point of consumption to the point of origin for the purpose of recapturing value or proper disposal (Brito and Dekker 2002).

In the hospital set up, Reverse Logistics can be the flow back of products from wards to pharmacy stores for the purpose of disposal, reuse etc.

No.	QUESTIONS	
1	PRACTICES OF REVERSE LOGISTICS AT THE PUBLIC HOSPITALS	
1(a)	Does your hospital practice proper reverse pharmaceutical logistics? (RL processes and activities are implemented)	Yes properly <input type="checkbox"/> To some extent <input type="checkbox"/>
1(b)	If <i>Yes for Q#1(a)</i> , would you mention some of the procedures?	_____
1(c)	If <i>Yes for Q#1(a)</i> , What can be the challenges in line with reverse logistics in your hospital?	_____ _____ _____
	How is the implementation status?	_____ _____
1(d)	What are the Pharmaceutical Reverse Logistics activities applicable in your facility? <i>Circle all that apply.</i>	1. Redistribution (<i>can also be borrowing/lending to other health facilities</i>) 2. Recall 3. Recycle 4. Disposal
	Please, if you have other comments:	
2	OVERSTOCK MANAGEMENT IN THE HOSPITALS	
2(a)	Have you ever experienced overstocks in your hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/> Sometimes <input type="checkbox"/>

2(b)	If your respond is Yes to Q#(2a), how often do you experience?	Just less than one week <input type="checkbox"/> Only one time in a month <input type="checkbox"/> Over one month <input type="checkbox"/>
2(c)	If your answer is Yes in Q#2(a), why then?	
2(d)	What are the ways you use to manage overstocks in your hospital?	_____ _____ _____
2(e)	How often do you respond to overstocks?	
2(f)	Are there any reference guidelines on the overstock management?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Any other comment:		
3	EXPIRY MANAGEMENT IN THE HOSPITAL	
3(a)	Have you ever experienced drug expiry in your hospital?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3(b)	If Yes for Q#3(a), would are some of the causes for expiry do you think?	_____ _____ _____
3(c)	How are the expired pharmaceuticals managed?	_____ _____ _____
3(d)	How often do you respond to expiry?	Only times a month <input type="checkbox"/> During the personal investigation <input type="checkbox"/> Every time when expiry is identified <input type="checkbox"/>

3(e)	Are there any reference guidelines on management of expires?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Any comments:		
4	GUIDELINES and POLICY	
4(a)	Do the hospital have any policy governing the reverse logistics for the medicines	Yes <input type="checkbox"/> No <input type="checkbox"/>
4(b)	If yes, how is it done?	
4(c)	Is there any guideline governing disposal of pharmaceuticals?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4(d)	If yes, how is it done?	
Comments:		

3: Questions on Challenges of Pharmaceuticals Reverse Logistics at health facility

Please encircle your degree of agreement on the five-point scale for;

- *Strongly Disagree(SD) =1*
- *Disagree(D) =2*
- *Neutral(N) =3*
- *Agree(A) =4*
- *Strongly Agree(SA)=5*

	Description	SD	D	N	A	SA
	<i>Challenges on Reverse Logistics Activities</i>	1	2	3	4	5
	<i>related to Redistribution</i>					
3.1	There is no clear standard for redistribution of pharmaceuticals	1	2	3	4	5
3.2	Redistribution of pharmaceuticals has a vague concept	1	2	3	4	5
3.3	Poor implementation of Stock Status Analysis to identify which items are redistributable	1	2	3	4	5
	<i>related to Recall</i>					
3.4	Lack of knowledge about the procedures of recalling	1	2	3	4	5
3.5	No technical support from EFDA, EPSA and disposal firms	1	2	3	4	5
3.6	Never received a recall initiation from manufacturers or regulatory authority	1	2	3	4	5
	<i>related to Recycle</i>					
3.7	No well-documented policy for recycling	1	2	3	4	5

3.8	Unavailability of responsible body for segregation, collection, storing and recording	1	2	3	4	5
3.9	Lack of definite rules and regulations on managing returned products	1	2	3	4	5
	<i>related to Disposal</i>					
3.10	There is no simple procedure and guideline for disposal	1	2	3	4	5
3.11	We use traditional ways of disposing the unwanted pharmaceuticals	1	2	3	4	5
3.12	We do not have an easy access to incinerate the wasted products	1	2	3	4	5
	<i>General challenges on Reverse Logistics PROCESS</i>					
3.13	Lack of appropriate technology	1	2	3	4	5
3.14	The reverse logistics policy is not included on the annual plan	1	2	3	4	5
3.15	Transportation problem (moving products back to supplier or disposal sites)	1	2	3	4	5
3.16	Absence of internal and external follow up and inspection	1	2	3	4	5
3.17	Most of the time the products are unfriendly to the environment	1	2	3	4	5
3.18	Others (Specify)	1	2	3	4	5

Part II: Data Abstraction Format

1. Background information for health facility

1.2.Name of the Health facility: _____

1.3.Facility Code: _____

Review and take secondary data from the facility pharmaceutical records (such as medicines wastage registration, disposal registration, and Model 19 documents.)

2. Data Collection Sheet for Medicines Wastage Record from April 2020 – July 2021

#	Drug Name	Strength	Dosage Form	*Reason for wastage	Amount wasted	Cost in birr
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Total Value of all Budget Medicines wasted in April 2020 – July 2021 = _____						

*Reasons for wastage:

✚ Damaged

✚ Obsolete

✚ Other, Specify

✚ Expired

✚ Theft

Part III: Assessment Checklist for Pharmacy Directorate

Observe and check for the implementation of Reverse Logistics of Pharmaceuticals in the selected public hospitals.

S. n	Operational Standards Assessment Checklist	Yes	No	Remark
1	Did the facility properly select, quantify, and order/procure/acquire only useable products (pharmaceuticals)?			
2	Did the facility conduct stock status analysis & identify stocks that cannot be used every two months?			
3	What are the reasons for the products not to be used within the facility? a. Over stock b. Near expiry c. Service interrupted d. Level of health facility e. Damaged pharmaceuticals f. Expired g. Lack of professionals			
4	Did you notify about unused stock in the facility to responsible bodies for further action?			
5	For products that are unable to be used with in the health facility, did the facility try to exchange with other products, or lend to another health facility?			
6	Did the facility report to supplier to reverse the products?			
7	Did the facility sign mutual written agreement (for reimbursed / disposed product)?			
8	Did you sort products to be returned?			
9	Did you prepare/arrange and properly pack for return?			
10	Did you fill necessary data of reversed products in standard issuing formats/ vouchers?			
11	Did the transportation mechanism ensure manufacturers storage condition recommendations?			
12	Did the facility reverse to respective supplier, refurbishment center, and manufacturer?			
13	Did the facility receive verification documents for products that are returned to supplier (Received with receiving voucher for useable products/ letters)?			
14	Is there a mechanism to sort & collect recyclable plastic container (IV fluid bags, & others)			
15	Report on how much cost saved/revenue generated by doing reverse logistics			

PART IV: Semi structured guiding for Key Informant Interview (English version)

1. Back ground information of the key informant

- 1.1 Name of Facility
- 1.2 Interviewer's name.....
- 1.3 Highest level of education
- 1.4 Total Work experience
- 1.5 Current position in the health facility.....

2. Guiding questions for in-depth interview

- 2.1. Does the facility practice reverse logistics?
 - ✚ **Probe 1:** *with respect to current practices*
 - ✚ **Probe 2:** *with respect to procedures experienced*
- 2.2. Is there any practice of reversing products back to pharmacy store from hospital wards to either for disposal, reuse etc.? If yes, how?
 - ✚ **Probe:** *Is there any system to reverse drugs back to store from respective wards*
- 2.3. How is the implementation status of RL in your hospital?
 - ✚ **Probe:** *how do you see it in relation to the guidelines and directives at least for disposal*
- 2.4. What are the techniques you use to manage the overstocked and expired pharmaceuticals in this hospital?
 - ✚ **Probe:** *Reverse Logistics guideline and wastage disposal policy*
- 2.5. What are the challenges related with implementation status of RL in your hospital?
- 2.6. Would you suggest some better strategies for the proper and regular RL system in the public hospital and other health facilities, how would you improve?
 - ✚ **Probe 1:** *Quantification of pharmaceuticals?*
 - ✚ **Probe 2:** *Policies?*
 - ✚ **Probe 3:** *LMIS?*
 - ✚ **Probe 4:** *Procurement of pharmaceuticals?*
 - ✚ **Probe 5:** *Storage?*
- 2.7. How do you explain the poor implementation status of RL in affecting the environment in unfriendly way?
- 2.8. If you have any comment on opportunities the future holds to your hospital for improving reverse logistics practice and its implementation status?
 - ✚ **Probe 1:** *Comment for higher officials such as EPSA, EFDA, FMOH*
 - ✚ **Probe 2:** *Comment for AACAHB, and hospital managers*

I highly appreciate your immense cooperation and welcoming!!!

Annex 2: The AMHARIC version of verbal consent for the KII

አዲስ አበባ ዩኒቨርሲቲ

የፋርማሲ ትምህርት ቤት

የፋርማሲዮቲክስና ሶሻል ፋርማሲ ዲፓርትመንት

የ MSc ፕሮግራም በጤና አቅርቦት ሰንሰለት አስተዳደር ውስጥ “የመድኃኒት ተገባቢ ሎጂስቲክስ የመተግበሪያ ምዘና

ሁኔታ እና ተግዳሮቶች በሕዝብ ሆስፒታሎች”

አዲስ አበባ ፣ ኢትዮጵያ።

ውድ ተሳታፊ ፣ በአዲስ አበባ ዩኒቨርሲቲ የጤና አቅርቦት ሰንሰለት አስተዳደር ውስጥ የ MSc ተማሪ ነኝ ። ይህ የዳሰሳ ጥናት በዚህ የድህረ-ምረቃ መርገግብር በከፊል የተዘጋጀ ነው ። ርዕሱ ከላይ እንደሚጠቁመው የዚህ ቅኝት ዓላማ በአዲስ አበባ በሚገኙ የመንግስት ሆስፒታሎች ውስጥ የመድኃኒት ተገባቢ ሎጂስቲክስ የትግበራ ሁኔታ እና ተግዳሮቶችን ለመገምገም ነው ። በጥናቱ መጨረሻ ውጤቱ የግለሰብ ተቋማትን አይመለከትም፤ ይልቁንም የሁሉንም ተቋማት አጠቃላይ ስዕል ይገልጻል። እርስዎ የሚሰጡት መረጃ በጣም በሚስጥር የሚያዝ እና ለአካዳሚክ ዓላማ ብቻ የሚያገለግል ነው ። ለማንኛውም ጥያቄ በ 0910691242 ይደውሉ ወይም በኢሜል zerihun_zekarias@yahoo.com ።

ለዚህ አስፈላጊ ጥናት(ቃለመጠይቅ) ውድ ጊዜዎን ስለሰጡ እናመሰግናለን !!!

ለቁልፍ መረጃ ሰጭ ቃለ መጠይቅ የተዋቀረ መመሪያ (የአማርኛ ቅጽ)

1. የቁልፍ መረጃ ሰጭው መረጃ

- 1.1 የተቋሙ ስም
- 1.2 ቃለ-መጠይቅ አድራጊው ስም
- 1.3 ከፍተኛ የትምህርት ደረጃ
- 1.4 ጠቅላላ የሥራ ልምድ
- 1.5 አሁን በጤና ተቋሙ ውስጥ ያለው ቦታ

2. ለጥልቅ ቃለ መጠይቅ የሚረዱ ጥያቄዎች

- 2.1. ተቋሙ የተገባቢ ሎጂስቲክስ አሰራር አለው?
- 2.2. ከሆስፒታል ክፍሎች ወደ ቆሻሻ ማስወገጃ ፣ እንደገና ለመጠቀም ፣ ወዘተ ምርቶችን ወደ ፋርማሲ መደብር የመመለስ ልምድ አለ? አዎ ከሆነ እንዴት?

2.3. በሆስፒታል ውስጥ የተገላበጠሽ ሎጅስቲክስ የትግበራ ሁኔታ እንዴት ነው?

2.4. በዚህ ተቋም ውስጥ ጊዜ ያለፈባቸው እና ከመጠን በላይ ጫናዎችን እንዴት ይተዳደራሉ?

- ምርመራ-የተገላበጠሽ የሎጅስቲክስ መመሪያ እና የብክነት አወጋገድ ፖሊሲ

2.5. በሆስፒታል ውስጥ ካለው የተገላበጠሽ ሎጅስቲክስ አተገባበር ሁኔታ ጋር የተያያዙ ተግዳሮቶች ምንድናቸው?

2.6. በሕዝብ ሆስፒታሎች ውስጥ ለትክክለኛው ተገላበጠሽ የሎጅስቲክስ ስርዓት የተሻሉ ስልቶችን እንዲጠቁሙ እድል ቢሰጥዎ እንዴት ማሻሻል ይችላሉ? ለምሳሌ፤

የመድኃኒቶች ብዛት?

ፖሊሲዎች?

የሎጅስቲክስ አስተዳደር መረጃ ስርዓት?

የመድኃኒቶች ግዥ?

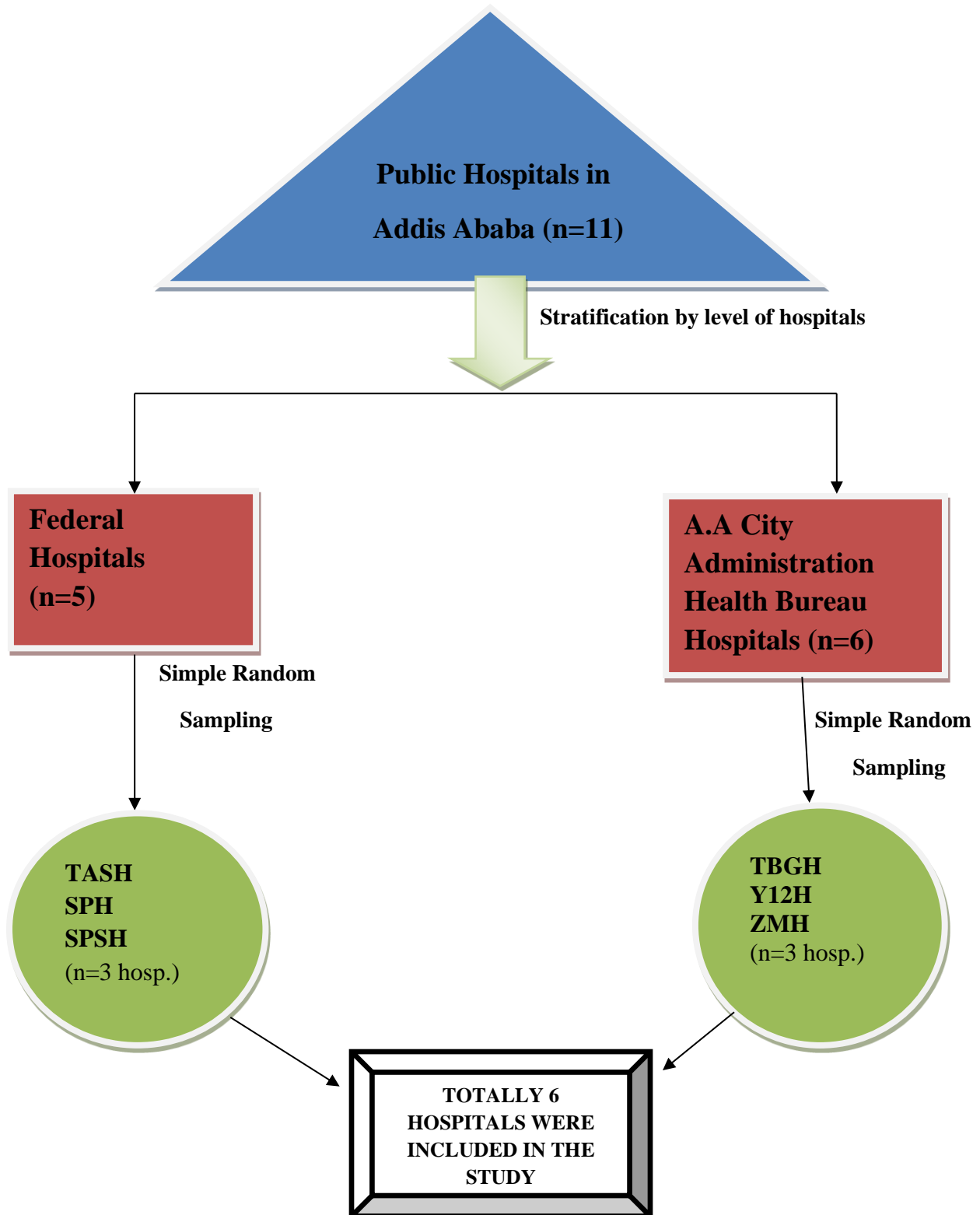
ማከማቻ?

2.7. የተገላበጠሽ ሎጅስቲክስ ደካማ አተገባበር ሁኔታ ለአካባቢው ስሙም ያልሆነ ነገር ሲፈጠር እንዴት ይገልጹታል?

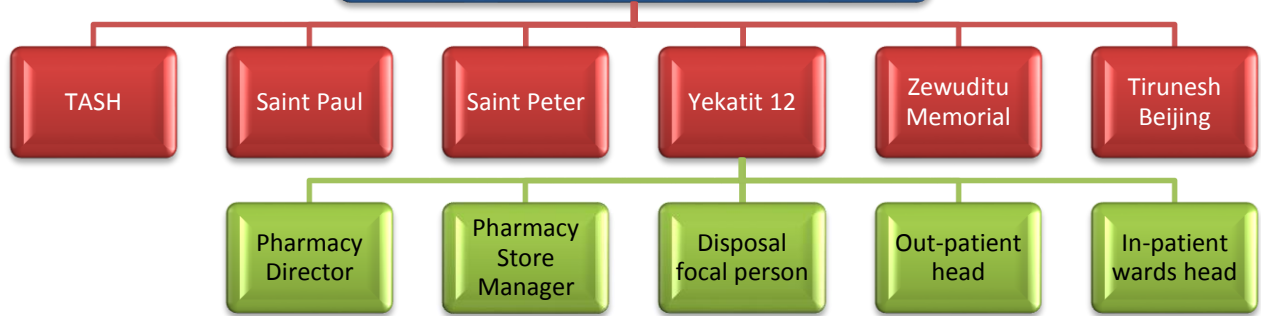
2.8. ለወደፊቱ የሎጅስቲክስ አሠራርን እና የአተገባበሩን ሁኔታ ለማሻሻል ለወደፊቱ በሆስፒታል ስለሚኖሩት ዕድሎች ላይ አስተያየት ካለዎት?

ስለከፍተኛ ትብብርዎን እና አቀባበልዎን በጣም አመሰግናለሁ !!!

Annex 3: Sampling frame for health facilities survey



Sampling Technique at each Hospital Level



Annex 4: List of Public Hospitals where data was collected

	Facility	Type	Facility Level	Facility Location
1	TASH	Specialized HOSPITAL	Federal	Kirkos sub city
2	ZMH	General HOSPITAL	Regional	Kirkos sub city
3	TBGH	General HOSPITAL	Regional	Akaki Kalitiy sub city
4	Y12 H	General HOSPITAL	Regional	Arada sub city
5	SPH	Specialized HOSPITAL	Federal	Gulele sub city
6	SPSH	Specialized Hospital	Federal	Gulele subcity

Annex 5: Reference for Questionnaires


Questionnaire Types	Title	Authors	Year
Self-administered Questionnaires	The Impact of Reverse Logistics in Public Hospitals; A Case of Kamuzu Central Hospital and Ntchisi District Hospital	Chirwa, D.C.S.	2015
Checklist	Reverse Logistics Management Guideline for pharmaceuticals and medical device	FMOH	2021
Interviewer guided questions	Researcher's own formulation after consulting the anticipated problems and pre-interviewing experts on the topic	Researcher	2019
Data Abstraction Format	Assessment of Medicines Wastage and Its Contributing Factors in Selected Public Health Facilities in South West Shoa Zone, Oromia Regional State, Ethiopia	Gebremariam, E. T	2017

Annex 6: Copy of Ethical Clearance Letter

በ ፋርማሲ ት/ቤት
የኢትዮጵያ ሪፑብሊክ ቦርድ

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

School of Pharmacy
Ethical Review Board



ቀን
Date September 23, 2020

ቁጥር
Ref. No. ERB/SOP/203/09/2020



To: **Zerihun Zekariyas**
School of Pharmacy

Re: **Ethical Clearance**

It is to be recalled that you submitted a study proposal entitled "**Implementation status and challenges of Pharmaceutical reverse logistics in public hospitals in Addis Ababa Ethiopia**" for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Arebu Issa
Chairperson, ERB



00251156 0212 1176

tāhh
Telex: 21205

ፋክስ
Fax: 00251(11)1558566

ኮድ
Cable: AAUNIV

Date 23/04/2021

St. PETERS SPECIALIZED HOSPITAL (SPSH)

RESEARCH & EVIDENCE GENERATION DIRECTORATE; THE ETHICAL REVIEW COMMITTEE OFFICE (ERCO) OF SPSH; ETHICAL CLEARANCE LETTER

Title: Implementation Status and Challenges of Pharmaceutical Reverse Logistics in Public Hospitals in Addis Ababa, Ethiopia

Site Principal Investigator/Project Holder: Zerihun Zekarias

Project type: A research proposal submitted for partial fulfillment of Requirement of Masters of science in health supply chain management

Protocol/Version no: V275/23/04/2021

The office of ERCO of SPSH has reviewed the research proposal with the above title on the day of **April 2021** & passed the following decision.

- **Approved**
- **Approved with recommendation**
- **Approved on condition**
- **Disapproved**

This decision is valid for consecutive 12months taking this decision date as day one, & the proposal should be implemented as presented to the office with the incorporated comments. If there is any plan to make changes in any part of the approved protocol, it is obligatory to inform the office to have another review. It is the researcher duty to inform & submit a summary of each and every activity of the study every three months to the office & finally submit the final completed work of the research to the office.

Regards

Cc

Academic, Research & Training Directorate

Signature
A/C ገለጻ ገሰ ገሰ
የ-ፍትህ ፕሮጀክት ለፈተና ለፈተና
Dr. Millon Molla Sissy
Research & Evidence Generation
Directorate director