IDENTIFICATION OF FACTORS LEADING TO UNFIT MEDICAL PRODUCTS AND OTHER HEALTH COMMODITIES, DISPOSAL MANAGEMENT AND RELATED PERCEIVED CONSEQUENCES TO HEALTH SUPPLY CHAIN IN RWANDA: Case of Rwanda Medical Supply Ltd and Medical & Allied Service Solutions Ltd

Submitted to the University of Rwanda, in partial fulfillment of the requirements for the degree of Master's in Health Supply Chain Management (MSc HSCM)

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Student declaration

I **Faustin KADISI KOTANA** declare that, this Dissertation is my Original Work and has not been presented for a Degree at University of Rwanda or in any other University.

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I, the undersigned, certify that this dissertation has been under my supervision and has been submitted with my approval.

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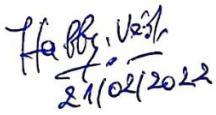

Date 21st February 2022

Dr. Vedaste HABYALIMANA

University of Rwanda

Dedication

This work is dedicated to:

My beloved wife

My beloved son, Exauce Kotana

My beloved daughters, Laurinda Akaliza and Erana Uwase Kotana

Acknowledgement

My first and foremost gratitude goes to God Almighty who renewed my strength and provides onto me throughout my time of working on the research.

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Abstract

Introduction: Unfit medical products, especially poor quality / damaged / expired / and phased out (no longer accepted for use) are among health challenges that need careful attention and adequate management in developing countries health supply chains, including Rwanda. Not only does medical wastage affect the public health in general, but also it affects financial capabilities. Actually, according to the Management Science for Health (MSH), countries on standard spend around 26% of their total medical facilities on drugs, and a significant part of the funds expended on critical drugs is wasted.

Aim: the aim of this study is to identify the factors leading to unfit medical products and related perceived consequences to the supply chain management in Rwanda.

Methods: The mixed method research design was used. Data were collected from key informant interviews, and cross-sectional study and quantitative research design were used to identify the most commonly found unfit medical products at Rwanda Medical Supply Ltd (RMS) and MEDIASOL Ltd and their management, then the shared data were transcribed and translated by the researchers. Main ideas from each key informants were merged under each theme and sub themes by reading and then rereading to identify common words, phrases and perceptions that were coded. Quantitative data were coded and analyzed using SPSS software.

Results: The study found that the most common unfit medico-pharmaceuticals are the laboratory commodities, malaria commodities and program products including quinine, and Haloperidol retard 50mg/ml injection and Insulin combinations, the study indicated that the Lack of local manufacturers of pharmaceutical products according to market needs; Change of medical products protocols; Minimum shelf life not specified while ordering the products; and Lack of accurate data to facilitate quantification were highlighted by the respondents as the main factors leading to unfit medicinal products. And the study found that the total unfit products were 3% of the average annual loss in unfit medicinal products compared to the total stock.

The study recommended that further research should be done on this topic especially by exploring effective mechanisms and strategies to mitigate the wastage of medical products and other health commodities in Rwanda.

Key words: *Unfit medicinal products, supply chain management, disposal methods*

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Abbreviations and acronyms

RMS LTD: Rwanda Medical Supply Limited

MEDIASOL: Medical & Allied Service Solutions

CAPAs: Corrective and Preventive Actions

GDP: Good Distribution Practice

DP: District Pharmacy

GMP: Good Manufacturing Practice

GPP: Good Pharmacy Practice

HSCM: Health Supply Chain Management

HVAC: Heating Ventilation and Air Conditioning

HIV: Human Immunodeficiency Virus

MoH: Ministry of Health

MPPD: Medical Procurement and Production Division

RBC: Rwanda Biomedical Center

FDA: Food and Drug Authority

RSB: Rwanda Standards Board

SMS: Short Message Service

SOPs: Standards Operating Procedures

SPSS: Statistical Package for Social Sciences computer

WHO: World Health Organization

CHAPTER I. INTRODUCTION

1.1. Operational key definitions

A. **Distribution**: It applies to elements related to the movement and delivery of various products such as drugs and other goods [1]

B. **Environmental Management System**: A management system that helps the drug products to comply with quality essential environmental conditions (such as temperature, humidity, etc.) and ensuring that appropriate procedures are in place to preserve the recommended conditions [1]

C. **Expiry date (or expiration date):** The date located on the bottle, container or tickets of the products (raw materials or finished products) labelling the period during which they are predictable to remain within recognized shelf-life provisions if stored under well-defined circumstances and after which they should not be used [2]

D. **Medical product**: Product(s) counting, but not restricted to, complete health products, medical devices, vaccines and in vitro diagnostics (IVDs) [2]

E. **Pharmaceutical product**: Any component or invention planned for human or veterinary usage offered in its ended dose method, or as a opening equipment for use in such a dose form, that is subject matter to manage by medical or pharmaceutical regulation in the shipment/exporting government-run and/or the importation government-run [2]

F. **Preventive actions:** the methods to destroy the effect of a possibility noncompliance or other unwanted potential conditions [1].

G. **Storage Management system:** A system that is used to monitor the storage of health products [1].

H. **Supply Chain:** The range of units covering the storage and delivery development of a product to the end user [3].

I. **Unfit Pharmaceutical:** The expired, inadequately sealed, damaged, within expiration date (unexpired) but incorrectly kept, improperly labeled, substandard or false, adulterated, forbidden, or unapproved items) [4].

1.2. Background of the study

The health medical sector is the among of the few sharpest developing sectors in Rwanda [5]. Although, medical products waste also is the one the problem of medical health supply chain in growing states, evidence on the extent and type of wastage as well as its contributing factors are less know [6]. Yet, 33% of the worldwide population do not have normal admittance to medications. The degree of the issue is far and away more terrible in the lowest possible-benefits states in Africa and Asia and more than half of the population do not have normal gain admission to basic drugs [7].

Corresponding to the WHO, unfit medical products are described as undesirable drugs which contain invalidated, unexploited, spilt and infected health products, drugs and vaccines that are no longer needed and required to be placed of properly [3]. Because of side effects, products degradation or unsafety, drugs approaching the expiry date are at risk of disposal [8].

As medical products are important in the treatment and diagnosis of diseases, and also important in the bulk of health expenditures, they must be handled with considerable cautions to avoid the wastage of limited financial resources and negative impacts on patients' lives [9]. On usual, states spend approximately 25% of their overall medical spending on drugs, and according to the Management Science for Health, in typical supply systems, up to 70% of the funding financed in essential medicines can be lost or wasted, while with only basic management improvements it is possible to make significant changes [10].

In nongovernmental clinics and private medicines outlets in Mwanza - Tanzania, the inappropriate disposal of medicinal products was examined in health facilities, where widely recorded disposal procedures were placed into the sink and put in dust bins and some unsuitable medicinal products were left unwrapped or isolated from usable medicinal products and not adequately marked [11]. In developing countries, around 60.4% of medical facilities have been identified with unfit medicines, and more than half of unfit medicines were in the category of antibiotics. Proof suggests that the existence of antibiotics in water contribute to antibiotics resistances [11].

In Nigeria poor planning and forecasting, insufficient information about consumption and current stock levels, funding and capacity constraints and a poor infrastructure are reasons for inappropriate stock levels [12].

1.3. Problem statement

Unfit medical products in supply chain is still a rising health concern in developing nations, where budgets for drugs are regularly tight. The World Health Organization (WHO) held a workshop in 2006 to discuss the challenges of medicine supply in African countries, with the main issues being a lack of information, interaction, and utilization or consumption data, insufficient storage capacity and temperature control systems, and a lack of quality assurance measures [13].

The supply chain must be well managed in developing nations to reduce all forms of wastes, including pilferage/thefts, diversion/deviation, and expiration. Since medical products pay for the majority of the spending of the health sector, they need to be seriously handled to reduce wasting of the financial capital expended on them and the risks of dangerous degraded drugs [16-17]. The literature summarizes medical supply chain problems such as poor data, insufficient storage services, and a lack of leadership developments, whereas interviews reveal that human reserve capability and procedure management are the most serious factors for effective inventory management, transportation, and delivery [12].

In Rwanda, efforts to make sure effective healthcare products and associated wastes operating are remarkable in public health facilities settings and in community [15]. Those efforts are followed by high commitment to high quality products and high quality services at everything stages of the medical structure, including the pharmaceutical sector [16].

On the other hand, even though there were studies on quality and storage conditions of medical products in Rwanda, there was lack of research-based data on the root causes and nature of the wasted medicines, as well as their perceived consequences on the overall logistics and budgeting [14]. This research was developed to detect the leading causes of unfit health products in Rwanda,

disposal management and their perceived consequences to the supply chain of two important medical stores at the national level, namely the RMS Ltd. and MEDIASOL.

1.4. Objectives of the study

1.4.1. Main objective

To identify the factors leading to unfit medical products and related perceived consequences to the supply chain management in Rwanda.

1.4.2. Specific Objectives

i. To identify the most commonly found unfit medical products in RMS Ltd. and MEDIASOL.
ii. Explore factors contributing to unfit medical products in RMS Ltd. and MEDIASOL.
iii. To explore perceived consequences of unfit medical products to the supply chain management in RMS Ltd. and MEDIASOL Ltd.
iv. To explore the disposal methods of unfit medical products in RMS Ltd. and MEDIASOL

1.5. Research questions

i. What unfit medical products are commonly found in RMS Ltd. and MEDIASOL?
ii. What factors contribute to unfit medical products in in RMS Ltd. and MEDIASOL?
iii. What are the perceived consequences of unfit medical products on supply chain management in RMS Ltd. and MEDIASOL?
iv. What is the management of disposal of unfit pharmaceuticals in RMS Ltd. and MEDIASOL for unfit medical products?

1.6. Significance of the study

The findings of this scientific work shall be useful to the national health supply chain and to the Rwanda Food and Drugs Authority (Rwanda FDA) because revealed gaps and weaknesses in the management of medicines and other health commodities towards the minimization of wasted products at the targeted lowest level.

Once gaps and weaknesses are known, appropriate recommendations for corrective and preventive actions (CAPAs) were proposed for countering them. Then, the perceived consequences to the supply chain management shall be assessed to serve as scientific evidences to decision makers on the best way unfit products should be properly treated.

The findings shall also be useful to further research projects in the area of health supply chain, quality assurance & quality control systems.

1.7. Limitation

Limitations were expected but the researcher tried to suggest solutions to overcome them so as to conduct the research as planned, the first limitation was the sample size, while the study was restricted to a small number of respondents who were expected to fulfill their work duties and responsibilities, and sometimes they were unable to provide all information necessary for this study, To counter this, the researcher used purposive sampling and chose respondents to participate in the study based on population availability.

Furthermore, the study concentrated on two elements in the entire supply chain; RMS and MEDIASOL ltd due to budget limitations; The findings cannot be generalized to the entire Rwandan medical products supply chain structure since they may be different from one stage to the next.

1.8. Delimitation

The study employed secondary data as documented by the two organizations on 2021 year from January to December, and the major source of data/information based on inventory reports on unfit medical products (expired, damaged, phased out, poor quality / substandard and falsified).

CHAPTER 2. LITERATURE REVIEW

2.1. Introduction

Well-functioning supply chains are essential for the availability of health care to distribute drugs, vaccines and other health goods. [17] With public and private companies such as private manufacturers, government warehouses and NGOs with multiple levels, such as National Level Medical Stores and District Level Medical Stores, the medical supply chain is a dynamic structure. An organized, cohesive and effective national procurement and distribution strategy is challenged by procurement and distribution, which often act as distinct roles with weak, erratic coordination and knowledge sharing.[12]

Furthermore, due to inefficiency, a lack of cars, and bad vehicle conditions, several programs established their own supply chain systems in the private sector. In fact, the National Academy of Medicine (USA) discovered in 2012 that discarded medical goods in pristine, useable condition cost an estimated $765 billion each year[18]. Consumption and stock level information are critical for planning procurement, ordering, and distribution. As a result, different Sub-Saharan African countries employ a variety of systems, ranging from paper-based procedures to totally electronic alternatives such as mobile technology. In general, current information is required, but the system must balance requirements and available resources[12].

Over all, the medication must be kept in the warehouses under sufficient protection, temperature, humidity and storage conditions. Careful inventory management is necessary to ensure sufficient stock levels.[12]

2.2. Quantifying the required health products

Quantification is the opening step of the procurement procedure used to decide how much a component is needed for procurement purposes and entails calculating not the amount of a single item needed, but rather the financial means necessary to purchase the item. [19]

Quantification is not a one-time, periodic process that comes to an end until the final quantity and cost of goods have been calculated, it is a vital operation of supply chain management that, after outputs have been generated as a result of the exercise, the optimization process of analyzing and refining quantification details and expectations, and the recalculation of overall product needs and costs should be motivated to reflect current service supply and use of goods, as well as improvements in program policies and plans over time.[20]

2.3. Storage, distribution and Transport

Great storage capacity and supply methods apply to all organizations and individual engaged in any characteristics of the storage and distribution of all drug products.[1] Under adequate protection, temperature and storage room conditions, medications must be stored in appropriate warehouses. Furthermore, proper inventory control is required to assure adequate supply levels. Annual inventory taking, inventory reconciliation, first-expired-first-out rules, and batch traceability are all useful strategies[12]. In order to know the time for drug products to be distributed, interactions amongst reliable personnel in the supply chain should be organized. Transported and obtained, taking into account of the plans for holidays, weekends or other types of disruption.[1]

2.3.1. Storage in Buildings and facilities

Health products storage spaces are necessary to preserve adequate temperature among the restrictions as set on the products labels and to avoid overcrowding the storage facilities. [1]

Enough number of trained employees at each warehouse dealer and wholesaler should be planned or tailored for good storage conditions to meet pharmaceutical quality assurance requirements. They should in particular be clean, dry, and kept in a temperature that is appropriate. Where special label storage requirements (e.g. temperatures, relative humidity) are needed, those conditions should be given, controlled, registered and monitored. Cleanliness and fixing pallets should be maintained in decent conditions.[21]. In addition, a storage capacity evaluation should be

performed to determine space optimization, potential, and mid- to long-term supply chain storage requirements[22].

In terms of space, construction, maintenance and protection, transport and information management systems, the overall storage facilities and equipment for health products and technologies needs to be strengthened.[23]

2.3.1.1. Documentation

Written guidelines and documents detailing all operations in the storage space facilities, together with the management of expiries stock, would be available. They should identify the storage processes, define the path of materials, prescription goods and details through the company in the case of the need for a product recollect. Furthermore, for each distribution, related documents should be retained. They should contain the product summary, cost, quantity, source, batch number of the supplier, allocated batch number, date of expiry and date of receipt[21]

2.3.1.2. Temperature monitoring

Temperature is one of the most critical elements to be controlled, and the requirements for every health product have to be based on acceptance criteria. Temperature must be monitored for the products stability, and preventive maintenance of storage equipment and facilities is necessary to ensure good storage conditions. Some medical can be damaged if exposed on light as they are photosensitive products. These include for instance chlorpheniramine maleate, hydrocortisone, furosemide, furolatex products(such as male condoms),multiple vitamins, x-ray films etc.[1]

2.3.1.3. Storage areas

i. Distribution warehouses must ensure that facilities and storage areas receive a pest control program on a daily basis or ensure that pest control operations are outsourced to a specialist firm that is routinely monitored.

ii. To allow all activities to be carried out properly and efficiently, storage areas should be supplied with appropriate lighting.

iii. Storage areas should be capable of allowing for the orderly storage of different types of pharmaceutical goods, both commercial and non-commercial products, isolated health products and issued, refused, recalled or removed medical products, as well as products assumed poor quality.[24]

2.3.1.4. Cleaning and pest control

The store should be kept orderly and cleaned at least 2 to 3 days a week, and the busy stores should be cleaned everyday with adequate materials. Pest management to prevent potential infection and physical harm to the stored products; rats, mice and other pests must be kept out of the storage room to prevent damages from pests.[25]

2.3.1.5. Refrigerators and freezers

Refrigerators and freezers used for storing of medicinal products are expected to keep the temperature of the products within the limits as specified on the product labels. Usually, the unit specification will be set at 5°C with an allowable range of ±3°C for the handling of goods labelled 2°–8°C. The temperature of the freezer can vary and usually range from −25° to −10°. However, certain frozen medicines need lower temperatures, e.g. dry ice or liquid nitrogen temperatures.[1]

2.4. Medical products distribution

Distribution is an essential activity in the integrated pharmaceutics supply chain management, the pharmaceutical industry is more retail-oriented, and most pharmaceutical companies sell drugs from different sources/suppliers, and distributed to various parts of the country.[26] The distribution channel describes the path from producer to marketers (e.g. wholesalers, dealers and retailers) for the products and services to meet the ultimate customer of the commodities.[26]

2.4.1. Personnel

All employees engaged in the allocation events have to, where applicable, be qualified and trained in terms of good distribution practices (GDP) requirements, and their work should follow written standard operating procedures (SOPs). The workers should be initially educated and regularly allocated for their duties and should be evaluated on the basis of training schedules aligned with their job descriptions.[27]

2.4.2. Vehicles and equipment

Vehicles and equipment for the delivery, storage or processing of medical products should be safe for use and properly prepared to prevent damage to the stability, packaging safety and to minimize all kinds of contamination. The devices used in cars and containers for measuring environmental conditions such as temperature and humidity, should be regularly calibrated. Moreover, defective cars and equipment should not be used and marked or withdrawn from service.[27]

2.4.2.1. Dispatch and receipt

The individuals or organizations licensed to buy such goods in compliance with the relevant national standards shall sell and/or supply pharmaceutical drugs. Shipments and transport of prescription goods can only take place after a legitimate shipping order or material refilling plan has been issued and should be registered.[27]

2.4.2.2. Pharmaceutical’s transportation

Transportation approaches should be carefully selected, including the equipment to be used, and local factors including temperature and seasonal changes should be considered. The distribution will be in compliance together with the required storing and carrying situations of goods requiring controlled temperature. Vehicle drivers should be well trained and qualified for transporting healthcare products. All applicable storage and transportation requirements should be notified.[27]

2.5. Remaining shelf life of medical products upon delivery

Each medical product should be given an expiry date by the manufacturer. The expiration date should be determined based on the stability test results, and be well shown on the product packaging together with other relevant storage conditions such as the temperature, humidity, protection to light exposure, etc. [2]

Note that there are products generally used in laboratory which have extendable shelf life dates after retesting them at the indicated periods, and the extension has to be sufficiently supported by competent testing laboratory reports. [24]

2.6. Healthcare Expiration Date Management

Essential procurement functions such as supply requisitioning, patient billing, inventory control and information capture are simplified by digital point-of-use monitoring systems (which typically includes expiration dates). When they are placed on shelves, then again at the point of use, items are screened, many of these programs also document expiry dates, enabling supply chain workers to note the details for the products already on the shelves in order to track and control inventory rotation.[18]

It is suggested that a particular commodity code describing its commercial type be paired with such a serial code. This would allow statistical data from serial sets to be collected for the same commodity. The combination of the model code and the serial code must be unique in both situations and must only be used once.[28]

2.7. Disposal of expired or damaged stock

While waiting for the disposal authorization, defective or obsolete stock should be placed in dedicated area(s) separated from good quality products. It is recommended that each commodity be valued at its purchase cost, and that a written list of all stocks consigned to each area be maintained. It is important to notify the responsible authority in writing that the stock is to be written off. The disposal will be awaited until all concerned managers or committees have provided their approval. Both drugs and other potentially harmful materials should be disposed of in a way that does not pose a danger to public health, in compliance with the local legislation.[25]

2.8. Human resources management in medical stores

Appropriate job trainings and refresher courses should be continually provided to all staff directly involved in the supply chain of medicinal products, and where warehouse workers are non-technical, the most successful solution is to be in-service teaching and personnel monitoring.[25]

2.9. Conceptual framework

It is the structure showing how variables are interlinked in this research.

Figure 1 Conceptual framework

In this study, the applied good practices (GxP)s for appropriate stock management of medical products and other health commodities depends on the employees' awareness on good storage practices (GSP) and good distribution practices (GDP), the availability of appropriate premises and the appropriate management of unfit medical products.

Therefore, the current study on "To identify the factors leading to unfit medical products and related perceived consequences to the supply chain management in Rwanda (Case Study: RMS & MEDIASOL) is based on the interrelated factors as illustrated in **Figure 1**.

CHAPTER 3: METHODOLOGY

3.1. Description of the site

The selected study companies i.e. RMS Ltd. and MEDIASOL Ltd. are Wholesalers, Distributors / Importers Pharmaceutical establishments. Both companies are located in Kigali (the capital of Rwanda) and the RMS Ltd. has 30 branches in all provinces and districts of the country. They have been selected as the primary suppliers of medical products to the public health facilities in Rwanda.

RMS Ltd. located in Kacyiru Sector, Gasabo District, Kigali City is a large-scale corporation created and owned by the Government of Rwanda. Its objective is to ensure availability of medicines, medical supplies and consumables in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to the Rwandan population. It is procuring, storing and distributing drugs, medical supplies and consumables to be used in all public health facilities. [29]

MEDIASOL Ltd. (MEDIASOL PHARMACY Ltd. and MEDIASOL PHARMACEUTICAL DEPOT Ltd.) is a franchise created by shares categorized under Health Services mainly owned by the Ministry of Defense. It started on 26 July 2012, involved in procuring, storing and distributing drugs, medical supplies and consumable to be used in all public health facilities, and located in Remera Sector, Gasabo District, Kigali City. [30]

3.2. Study design

Mixed method research design was used. The data were collected from key informant interviews, and cross-sectional study and quantitative research design were used to identify the most commonly found unfit medical products in RMS Ltd. and their management, then the shared data were transcribed and translated by the researchers.

The main ideas from each informant were merged under specific themes and subthemes by reading and then rereading to identify common words, phrases and perceptions that were coded. Quantitative data were coded and analyzed using Excel and SPSS software.

3.3. Target population, sample size and study sites

Our target population are Rwanda Medical Supply Limited (RMS Ltd.) staff made of 250 workers, located in Kacyiru Sector, Gasabo District, Kigali City and the Medical & Allied Service solutions (MEDIASOL) which has two different private companies (MEDIASOL PHARMACY Ltd. and MEDIASOL PHARMACEUTICAL DEPOT Ltd.) by shares categorized under Health Services MEDIASOL located Remera Sector, Gasabo District, Kigali City with approximately 54 workers.

Table 1:Sample size based on key informants

Key informants' positions	**Sample size**
Pharmacist	7
Quality Assurance & Quality Control manager	1
Dispatch officer	1
Validation officer	1
Assistant Inventory officer	1
Inventory officer	2
Distribution officer	1
Director Safety, Health, Environmental & Risk Management (SHERM)	1
Driver	1
Regional Hazard manager	1
Advisor (technical)	1
Sales & Marketing officer	1
TOTAL	**20**

3.4. Sampling

Two main medical stores at the national level i.e., the RMS Ltd. and MEDIASOL were purposively selected to represent a variety of other pharmaceutical companies providing wholesale and distribution / importation services in Rwanda. Purposively, the above mentioned 19 key informants were selected to allow having the maximum information and data that are needed to meet the objectives of this study.

3.5. Procedures of data collection

The head of each selected company was informed about the study and asked to facilitate the selection of key informants after understanding and allowing the conduct of the study in their institutions.

The research team presented the purpose of the study, and informed the participants about confidentiality and voluntary participation. All participants were advised to participate freely and to sign a consent form as planned in the study.

The procedure for collecting qualitative data was using semi-structured interview guide; Pharmacists, Quality Assurance & Quality Control manager, Dispatch officer, Warehouse manager, Validation officer, Driver, Inventory officer and Disposal workers as key informants to discuss their perceptions, opinions, attitudes and experiences with flexible probing techniques by using semi-structured interview guide.

All interviews were performed by a moderator and a note-taker for taking summarized notes during interviews. The language used in all interviews was mainly Kinyarwanda and the interviews took almost 20 minutes per category of interviewees. All interviews were digitally recorded with participant's permission and the recordings were transcribed verbatim before translation into English for the purpose of analyses. All collected data were grouped and examined for quality and accuracy before analyzing them.

For quantitative data, the records on past disposal of unfit medical products were analyzed to identify the most commonly disposed of.

3.6. Data collection tools

Semi structured conversation/interview guide has been established for qualitative interview by the team (research) based on the study objectives and relevant literature.

The audiotape-recorder also as a commonplace instrument often used to record spoken data to avoid missing important information. For unfit medical products, a checklist tool has been developed to collect necessary data from consulted available records at the studied institutions.

3.7. Validity and Reliability

The semi-structured questionnaire was pretested with two key informants from the two studied institutions to confirm its validity. Then, the correctness of the research tool was appropriately verified after collecting pretest data.

3.8. Data analysis

The data for this research initiated from the transcripts made of digital recording methods and notes collected from key informants. All transcripts were read and read again to identify common key words, phrases, observations and coded. The differences and similarities were highlighted in the text and organized into codes, sub-categories, categories, and themes.

For quantitative data, all collected ones were counter checked for transparency and legitimacy. The data coded were evaluated using the Statistical Package for Social Sciences computer (SPSS) analysis software.

3.9. Ethical consideration

Ethical considerations were considered to ensure that the research was conducted according to the requirements. The confidentiality was respected, and all data were collected with consent agreement of the informants. Analysis of the data was presented in a way that excludes the possibility of the identification of individuals. The approval of ethical clearance was issued by the university though Institutional Review Board and National Health Research Committee and the copies are in annexes**.**

CHAPTER 4. RESULTS AND DISCUSSION

4.1. Introduction

This chapter details the presentation, discussions and analysis of the findings in accordance with the objectives (Specific) of the research that: (a) To find the most commonly detect unfit medical products in RMS Ltd. and MEDIASOL Ltd.; (b) To explore the factors contributing to unfit medical products in RMS Ltd. and MEDIASOL Ltd.; (c) To explore perceived consequences of unfit medical products to the supply chain management at RMS Ltd. and MEDIASOL Ltd.; and (d) To explore the disposal methods of unfit medical products in RMS Ltd. and MEDIASOL Ltd.

According to the World Health Organization, the following health products must never be used and must always be reflected as unfit health products waste: (a) all expired drugs and medical consumables; (b) all opened syrups or eye drops (expired or unexpired); (c) all cold chain damaged unexpired pharmaceuticals that would have been kept in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins, and vaccine If the container is still sealed, clearly labelled, or within the original undamaged blister packs, these should only be used if they are not expired; and (e) all open tubes of creams and ointments [31].

Key informant interviews were used to obtain data in order to attain those objectives, and thematic analysis have been applied to analyses the data.

4.2. Demographic characteristics of respondents

4.2.1. Gender of the Respondents

Despite that the study was not gender sensitive, this part of the questionnaire sought to give information on the gender of the respondents.

Table 2:Gender of respondents

Gender	**Frequency**	**Percentage**
Female	7	35%
Male	13	65%
Total	20	100

Based on the data above, it was established that most of the selected respondents to participate in the study were male (65%) while the minority of the study participants (35%) were female.

4.2.2. Educational Qualification

This section sought to determine the educational levels of respondents

Table 3:Educational Qualification

Educational Qualification	**No of respondents**	**Percentage**
Advanced Diploma	1	5%
Bachelor	12	60%
Masters	7	35%
Total	20	100

These results indicate that the large number of the respondents have attained the bachelor's degree level of education and above. Bachelor was found to have highest education number at 60% followed by master education with 35% while advanced diploma represented by 5%.

4.2.3. Years of Service

This parameter sought to find how long respondents have worked in the institution.

Table 4:Years of Service

Years of Service	**Frequency**	**Percentage**
1 – 10 years	9	45%
10 – 20	10	50%
Above 25	1	5%
Total	20	100

According to the statistics above, the majority of respondents had more than 10 years of service at a medical store facility, with 10 respondents representing 50%, those with 1-10 years of service representing 45%, and those with more than 25 years of service represented 5%. None of the respondents had served for less than a year.

4.3. Most commonly found unfit medical products and other health commodities and related factors

4.3.1. Most commonly found unfit medicinal products

The Figure 2 below shows that during the period of this study, the year preceding this study i.e. 2020, Quinine was the most expiring and damaged in the store of selected medical store facilities, followed by t Haloperidol retard 50mg/ml injection and Insulin combinations placed at the third position, the fourth are Paracetamol and Dermobacter.

Figure 2:Most commonly found unfit medicinal products from January to December 2020

The same study done in Uganda to distinguish the expiry of prescription drugs in supply facilities was frequent among medicinal products for vertical health services, including vitamin A capsules, antiretroviral medicines, antituberculosis agents, chloroquine, sulfadoxine/pyrimethamine, and nystatin tablets, though it was also common among anticancer agents, tetracycline eye ointment, and mebendazole [32]. Thus, from that study we can notice that the issue of unfit medicinal products needs a particular attention and be properly managed to avoid all related risks.

According to a study conducted in the Saudi community to determine the prevalence of unused or expired medicine, the prevalence of unused or expired medicine was 89.3%, with inhalers, sprays, asthmatic drugs, cosmetics, and nonsteroidal anti-inflammatory drugs being the most common unused and expired medicines [33].

4.3.2. Commonly unfit medicinal products according to participants views

In order to know the staff's opinions on the common unfit medical products, the respondents were asked their perceptions and provided the following information:

Various respondents stated that the most common unfit medical products are the laboratory commodities, malaria commodities and program products:
"*Lab Reagents, HIV commodities and malaria commodities b*ecause they have short shelf life by nature" (Key informant, 2022).

Other staff emphasized that: *"Program products expired most because of buffer stocks for security measure to prevent stockout and frequently these buffer quantities are likely to expire without being used".*

Moreover, next respondents highlighted that the HIV commodities tend to be expired at the store *Anti-retroviral (ARV), example of Stavudine expired most due to the change of treatment protocol and lack of information before requisition (Key informant, 2022).*

4.3.3. Factors contributing to unfit medicinal products

While interviewing the key informants on the major factors contributing to unfit medical products, they gave the following views:

Due to not having in country industries to produce what needed, this result in expires or stock out problems. (Interview with a key informant, January 2022)

In addition to the first respondent, the following highlighted the lack of manufacturing pharmaceutical industries to make drugs according to market needs and addressed the factor of buying the lowest products due to limited resources:

"We don't have in country manufacturing sites, we don't have quality control labs, we are low-income country, and budget limitations can lead to procure low quality products".

In addition to that, a third respondent stated that: "*The root cause is that all products are from abroad, and we are a limited resource country with limited means to ensure the quality of all imported medical products". (Interview with a key informant, January 2022)*

Respondent 4 stated that there are some drugs which are not covered by health insurance companies, and that can be expired due to low consumption or be stocked out due to a limited number of users.

"Some products are not found on the list of insurance payment like Mituelle de Sante or RSSB" (Interview with a key informant, January 2022)

Furthermore, other respondents stated that inappropriate recording of drugs information in the warehouse system may lead medical products to become unfit.

"Poor or bad recording of medical products information like wrong expiration date or variant names in the warehouse system negatively affect the use of stored products" (Interview with a key informant, January 2022)

Various respondents in the following theme highlighted that it is due to the low consumption of medical products because of the change in customer needs and medical prescriptions:

"Because of low consumption due to the change of number of patients for example, we purchase some drugs that will not be consumed because doctors do not often prescribe them to patients when they have other alternative prescriptions. (Interview with a key informant, January 2022)

Some key informants expressed the issue related to the change of medical protocols:
"Sometimes protocols change suddenly and some medicines become unusable and are disposed of before or when they expire" as expressed by Validation and an Inventory officer.

The following *Table 5* summarized the most factors leading to unfit of medical products as perceived by the staff.

Table 5:Summary of perceived factors contributing to unfit medical products

Factors leading to unfit medical products	**Number of respondents**
Procurement forecasting without clinicians' advice	3
Lack of local manufacturing companies to avail timely the needed medical products	3
Low consumption rate of some products	2
Issues related to the procurement of substandard and falsified (SF) medical products	2
Poor organization of supply chain actors and data system management from central to peripheral levels	2
Issues related to doctors prescribing other medication variants	2
Issues related to medical products not covered by health insurance	2
Procurements without specific minimum required shelf life of products at arrival	2
Lack of accurate data to facilitate quantification	1
Sudden change of medical treatment protocols	1
Weak internal control and monitoring mechanisms, and not controlling on daily basis	1

4.4 Perceived consequences of unfit medicinal products to the supply chain management

At both medical store companies, the study found that the total value of unfit products was not more than 3% in average compared to the total annual stock value.

The following consequences emerged into three parts as the respondent explained the possible consequences of unfit medical products that affect the supply chain management:

After recognizing unfit products, we remove them from stock and sometimes have stock outs as consequence. People will suffer from those stock outs; the company loses money on the unfit products and people lose trust to the supply chain system when they experience the lack of needed products.

The following participants highlighted the consequence to the institutional reputation as follows: "By *not satisfying customer needs, all levels are affected, and the company loses reputation in the eyes of its customers" (Interview with a key informant, January 2022)*

Other participants highlighted the economic impact related to the disposal of unfit medical products which should be invested in other products or services.

Yes, the unfit products affect the supply chain management in terms of cost of disposal, inventory management and their write off. (Interview with a key informant, January 2022)

Moreover, this study highlighted the consequences unfit medical products from stuff perceptive as summarized in the table below.

Table 6:Perceived consequences of unfit medical products

Perceived consequences of unfit medical products to the supply chain management	**Number of Respondents**
Monetary loss	3
Provoke stock out	4
Increased cost of disposal	4
Lack of faith in our supplier chain	5
Dissatisfied customer needs	2
Institution's poor reputation	2

4.5 Applied disposal methods

It was noticed that both studied companies do not have incineration facilities. They hired the external incineration company in handling their unfit medical products using a novel high temperature technology at more than 850°C.

Proper disposal handling and management of unfit pharmaceutical products prevents avoidable toxicities and promotes the safe and friendly environment, and improper disposal can contaminate the environment and pose significant risks to water, air, agricultural products, food chain, harm animals and livestock [11].

Then, in addition to the incineration method, there are two other applied disposal methods depending on the type of products namely the "plastic materials recycling" and "reuse of unfit products for other purposes" such as lab reagents that can be donated to higher education institutions for didactic practical.

4.5.1. **Frequency of the disposal of unfit medicinal products**

Answers with respect to the occurrence of the removal of unfit health products by the two medical store companies indicate that 75% of key informants confirmed their institutions do the disposal on monthly basis; 20% conduct the disposal annually, and 5% anytime where needed.

Table 7: Disposal methods and frequency of unfit medical products

Method used regularly to dispose unfit medical products by RMS Ltd. and MEDIASOL Ltd		**Frequency of disposal**			Total
		On monthly basis	Once a year	When necessary (no specified time period)	
Novel high temperature incineration	Respondents' frequency	15	4	1	20
	Percentage of respondents	75%	20%	5%	100%

CHAPTER 5: CONCLUSION AND RECOMMENDATION

5.1. Conclusion

Medical products are critical for preserving lives in morbid diseases, yet they can get unfit from their intended use for different identified reasons in this study as presented in the summary of factors leading to unfit medical products. Those factors are for example the: Low consumption rate of some products; Sudden change of medical treatment protocols; Procurements without specific minimum required shelf life of products at arrival; etc. Then, were identified twenty-three (23) common unfit products also presented in the results, as well as the perceived consequences of unfit medical products to the supply chain; and three main applied disposal methods are incineration, plastic materials recycling and reuse of unfit products for other purposes.

5.2. Recommendations

From the results, the most unfit medical products and their most factors which led to be expired and damaged were identified. Hence, the following recommendations are provided:

5.2.1. To RMS Ltd and MEDIASOL Ltd

a) Rigorous forecasting, quantification and procurement of needed medical products and other health commodities based on the real needs by customers (health facilities)
b) Establish and enforce the use of effective digital systems to facilitate the proper management of data and related good practices
c) Establish and enforce the implementation of inventory management practices

5.2.2. To Rwanda Food and Drugs Authority (FDA)

To conduct feasibility study on resolving all problems related to the management of unfit medical products and other health commodities.

5.2.3. To Rwanda Environment Management Authority (REMA)

To monitor the implementation of the guidelines related to the disposal (incineration and recycling) of unfit medical products and other health commodities at all supply chain levels, and to provide other disposal methods where needed.

5.2.4. Suggestion for future researches

Future studies are needed to explore this important topic more broadly and come up with sustainable strategies to properly manage the medical products throughout the entire supply chain, as well as the effective and adequate disposal methods minimizing as much as possible the wastage.

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APPENDICES

APPENDIX I. Consent form

This is Faustin Kadisi KOTANA and a graduate student in Health Supply Chain Management who is currently seeking your kind support to conduct research about:
"**IDENTIFICATION OF FACTORS LEADING TO UNFIT MEDICAL PRODUCTS AND OTHER HEALTH COMMODITIES, DISPOSAL MANAGEMENT AND RELATED PERCEIVED CONSEQUENCES TO HEALTH SUPPLY CHAIN IN RWANDA: Case of Rwanda Medical Supply Ltd and Medical & Allied Service Solutions Ltd**

We request that you ask as many questions as you wish in order to make sure that you understand the procedures for the study, the risks and benefits. If you have a question about this document that has not been sufficiently answered or explained, do not hesitate to ask one of the research team members for more information

Kindly find below designed questions that will be answered in the shortest period of your precious time of around 40 minutes. Your shared answers shall be kept safe and confidential and solely used for the purpose of research which will help policy makers, health professionals, to fulfill the gap and to improve medical products management.

There will be no payments or other awards from the study but the results will be helpful in improving wellness of practices of pharmaceuticals management

I……Understand the information explained about the study and I am voluntarily participating. After understanding clearly all regarding the study, I agree myself to participate.

Signature ……. Date: …. /……/……..

Researcher name: …… Date: …. /……/……..

<u>APPENDIX II</u>. Consent form in Kinyarwanda

Muraho turabashimiye ko mwaduhaye umwanyu wanyu ngo tugirane ikiganiro. Amazina yanjye Ni **Faustin Kotana Kadisi**, umunyeshuri urangije ibijyanye no gucunga amasoko y'ubuzima kuri ubu arashaka inkunga yawe nziza yo gukora ubushakashatsi kubyerekeye:
"GUCUKUMBURA IGITERA IJUGUNWA RY'IMITI, UBURYO IJUGUNWA NDETSE NINGARUKA BIGIRA KUBUCURUZI BWAYO"

Nikubw'iyo mpamvu turimo kugirana ikiganiro n'abakozi ndetse nabagira uruhare mukubika imiti, kuyicuruza, kuyitwara ndetse no kuyitanga murwego rwo gucukumbura igitera imiti kujugunywa , uburyo ijugunwamo ndetse ingaruka bifite kubucuruzi bwayo.

Iki kiganiro kiramara nibura iminota 40, turababaza ibibazo bitandukanye byerekeye akazi kanyu kaburi munsi kandi ntabwo ari uburyo bw'igenzura kuko amakuru azavamo azagira icyo ahindura muri uyu myuga.

Ibisubizo mudusangiza bigomba kubikwa neza kandi bikagirwa ibanga kandi bigakoreshwa gusa hagamijwe ubushakashatsi buzafasha abafata ibyemezo, inzobere mu buzima, kuziba icyuho no kunoza imicungire y'imiti.

Turandika ibyo mwatubwiye ariko turanafata amajwi y'iki kiganiro kugirango hatagira amakuru y'ingenzi aducika. kubwibanga nta mazina yanyu tubabaza kandi nta nuwashobora kumenya uwavuze ikintu runaka

Ntabihembo byo guha uwagize uruhare mubushakashatsi ariko ibisubizo bizavamo bizafasha mugutezimbere imibereho y'imicungire y'imiti.

Njyewe …… nsobanukiwe n'amakuru nsobanuriwe kubyerekeye ubu bushakashatsi kandi ndimo kubushake. Nyuma yo gusobanukirwa neza ibyerekeranye ninyigisho, nemeye kubigiramo uruhare.

Umukono …… Itariki ….. /…../……

Icyitonderwa: Waba ufite ikindi kibazo cyangwa ibibazo, nyamuneka twiyambaze

APPENDIX III. RESEARCH QUESTIONNAIRE

PART I. IDENTIFICATION OF RESPONDENT

No	Names	Position	Department	Education Background	Number of years of experience in pharmaceutical supply chain management

PART II. THE KEY INFORMANT INTERVIEW

Objective 1. To identify the most commonly found unfit medical products in RMS and MEDIASOL

1. From your experience, what is the most common unfit medical products in your organization?
2. What are the medical products that are most disposed due to unfit?
3. Probe: Why do you think those products are unfit?

Objective 2: Explore factors contributing to unfit medical products in RMS and MEDIASOL

1. From your professional experience, why do we have unfit medical products? [Probe: What are the internal and external factors contributing to unfit medical products? Which measures do you follow in transportation of the medical products?
4. Do you check the suppliers 'vehicles in terms of temperature, light and humidity?

Probe: For Medical products transportation and distribution, Is there any available guidelines you refer to?

5. From your professional experience, do you think that this facility has appropriate premises?

6. Are the staff working in the warehouse trained about good storage practices of medical products?

Probe: if yes: when was the last time they get training by which institution?

7. how do you regularly revise and remove damaged product from stock, defective or contaminated? and, who is responsible person/department or authority to perform that?
8. How do you report the medical products to be disposed of? Is there any related report in the period of 2017 up today? Do you mention any reason of disposing of those unfit medical products?

According to your perspectives view, what is the root cause of unfit medical products products in your institution?

Objective 3: To explore perceived consequences of unfit medical products to the supply chain management in RMS and MEDIASOL

9. How do you think the unfit medical products products affect the supply chain management? How these unfit medical products threaten your supply chain?
10. Is there anything would you like to add on what we have discussed above?

Objective 4: To explore the disposal management of unfit medical products at RMS and MEDIASOL

1. Explain how you handle such expired/ damaged medicines prior to terminal disposal
2. What do you think will be the dangers and problems associated with delay and improper disposal of unfit pharmaceuticals?
3. In your opinion, what do you think are the barriers to proper disposal of unfit pharmaceuticals?

PART III. STRUCTURED QUESTIONNAIRE TO EXPLORE THE DISPOSAL OF UNFIT MEDICAL PRODUCTS MANAGEMENT

No	Questions	Code	Choice
1	Does it happen that your medicines in the stock get expired/ damaged before use?	a) Yes (1) b) No (2)	
2	How often do you dispose of unwanted stock of medical products?	a) On monthly basis (1) b) On quarterly basis (2) c) Once a year (3) d) When necessary (no specified time period) (4)	
3	What methods do you use regularly to dispose unfit medicines at your health facility	a) Return to donor or manufacturer (1) b) Landfill (2) c) Waste immobilization: encapsulation (3) d)Waste immobilization: inertization (4) e) Sewer (5) f) Burning in open containers (6) g) Medium temperature incineration (7) h) Novel high temperature incineration (8) i) Chemical decomposition (9)	
4	When was your last disposal of unfit products? Mention (See verification form or any official document to verify).	…..... month / ….....year.	
5	What is the average annual loss in unfit medical products compared to the total stock?	a) Below 3% b) Between 3 and 5% c) Between 5 and 10% d) Other (specify)	

ANNEX 3. Checklist on procedures of unfit medicines disposal

No	DESCRIPTION OF INDICATOR	Yes	No
1	Is there a maintained register book for recording unfit medicines? Check: Date of start..... Date of last disposal..... Type of medicines disposed.....		
2	Is there a copy of application form for past disposal of unfit medicines? (observe)		
3	Are unfit medicines separated from the usable medicines? (observe)		
4	Are unfit medicines labelled properly? (“Not for sale” in red ink)		
5	is there a separate area to keep the unfit medicines?		
6	Presence of adequate security measures to avoid pilferage (e.g. Grilled gate and windows) for the area to store unfit medicines		
7	Presence of previous disposal records (certification of destruction document). Check: Date of issue..... Number of disposals per year.....		
8	Types of unfit pharmaceuticals found in the facility (in pharmacological groups)		

ANNEX IV. Response to the request to conduct research at Rwanda Medical Supply (RMS)

RWANDA MEDICAL SUPPLY
Faster | Reliable | Affordable

Kigali 20/01/2022

Ref: 173/RMS/CEO/QAQC/2022

Chief Executive Officer's Offic

Mr. Faustin Kadisi KOTANA
UR / RCE-VIHSCM
KIGALI

Dear Sir,

Re: Response to your request for Permission to conduct research at Rwanda Medical Supply Ltd. (RMS)

Reference is made to the letter number: 4633/21 requesting permission to conduct research at Rwanda Medical Supply Ltd. (RMS) on identification of factors leading to unfit medical products and other health commodities, disposal management and related perceived consequences to health supply chain in Rwanda.

After deep analysis of your questionnaire, we find that you can conduct your research in our institution as the results will contribute to the improvement of our institution. But your questionnaire has some points requesting sensitive information which may need special permission to get and hence delay your results.

NB: You will be required to present this letter on arrival and sign the Nondisclosure Agreement (NDA) before you commence the research.

This letter serves to give you green light for data collection in RMS Ltd, but you will commit to share with us RMS specific research findings after and the draft before publication. Again, please let this information be strictly for academic purposes.

Sincerely,

RWANDA MEDICAL SUPPLY Faster | Reliable | Affordable

Pie HARERIMANA
Chief Executive Officer

Cc:

- ✓ Chief Finance and Administration Officer, RMS Ltd.
- ✓ Chief Operations Officer, RMS Ltd
- ✓ Deputy Chief Executive Officer, RMS Ltd.

Email:info@rmsltd.rw **Website : www.rmstld.rw**

ANNEX V. Ethical clearance

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 20th /10/2021
Ref: CMHS/IRB/303/2021

Faustin Kadisi KOTANA
Master's in Health Supply Chain Management
CMHS, University of Rwanda

Dear Faustin Kadisi KOTANA

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled ***"Identification of factors leading to unfit pharmaceutical products and other health commodities, disposal management and related perceived consequences to health supply chain in Rwanda"***

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance. The ethical clearance is valid for one year starting from the date it is issued and shall be renewed on request. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in this important study.

Dr Stefan JANSEN
Ag Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal, College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw