UNIVERSITY of RWANDA

EAC Regional Centre of Excellence for Vaccines Immunization and Health Supply Chain Management (EAC RCE-VIHSCM)

ASSESSMENT OF STORAGE CONDITIONS OF PHARMACEUTICAL PRODUCTS IN RWANDA

Case of Rwanda Biomedical Center / Medical Procurement and Production Division and District Pharmacies

Thesis submitted to the University of Rwanda, in partial fulfilment of the

requirements for the degree of Masters in Health Supply Chain Management (MSc HSCM)

By

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Declaration

I Charlotte AKINGENEYE declare that "This Thesis is my original work and has not been presented for a degree in any other University". Any parts, words, or ideas in the thesis, however limited, that are quoted from or based on other sources, have been acknowledged as such without exception.

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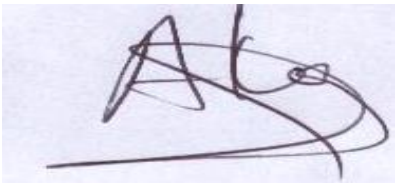
Signature: _____  _____

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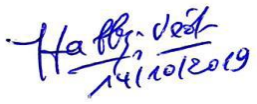

Signature……..

Supervisor: Dr Védaste HABYALIMANA

Date…14……/…10……/…2019……

Dedication

This work is dedicated to:

My beloved husband Dr Leonard GAKINDI

My beloved son Karen Irvin NGANJI

My beloved daughter Kelci Orlane INGANJI

Acknowledgement

First of all I would like to acknowledge my Supervisor Dr Vedaste HABYALIMANA (Phd) and Immaculee MUKANKUBITO MSc for the great work done during my research. Your guidance, contribution, inputs and corrections were of great value. Without all your guidance, support and encouragement this work will not be done correctly. I really appreciate your cooperation and contribution.

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ABSTRACT

Availing quality essential medicines is a wish for every health supply chain player. Appropriate storage conditions are fundamental to maintain the quality and stability of medicines and this is why temperature, humidity, ventilation and other storage conditions must be monitored in a pharmaceutical warehouse. To check how pharmaceutical products in Rwanda are stored, a concerning study was conceived.

The study was a descriptive-Analytical research where the actual status of storage of pharmaceutical products in Rwanda were described and checked for compliance with Good Storage Practices (GSPs) and manufacturers recommended storage conditions. Ten representative district pharmacies out of thirty and RBC/MPPD warehouses were selected to participate in the study. Questionnaire, check list on warehouse premises layout and records of temperature and humidity for the last three years (2016-2018) were used as source of data.

We found that in Rwanda, we have warehouse premises but designed as residential houses for habitation so space is insufficient and they are not well equipped as required by the pharmaceutical warehouse. They are not ventilated, pharmaceutical products are exposed to direct sunlight, devices in cold rooms are not calibrated, temperature monitoring is not done during holydays and weekend at district pharmacies, staffs working in warehouse are using academic background others have been trained long time ago, products in cartons are stacked not respecting Good Storage Practices, at district pharmacies they do not monitor relative humidity, there is a lack of cool storage condition (i.e.8^{o}C to 15^{o}C) in the hall country, dispatching area is not separated with receiving area in all district pharmacies, there is lack of equipment for rifting heavy loads at district pharmacies, there is easy access to pharmaceutical products in the warehouse because there is no security precautions,

As conclusion, we found that pharmaceutical products warehouses are available but there are many weaknesses needing improvements and establishment of some features which are absent. Also, a quick corrective and appropriate actions are needed to save products which are at risk of

degradation because of poor monitoring of required storage conditions or recommended by the manufacturers.

Key words: *Good storage practices, Corrective and preventive actions, District pharmacy, RBC/MPPD*

Abbreviation and Acronyms

CAMERWA : Centrale d'Achat des Médicaments Essentiel au Rwanda
CAPA : Corrective Action and Preventive Actions
GDP : Good Distribution Practice
DP : District Pharmacy
GMP : Good Manufacturing Practice
GPP : Good Pharmacy Practices
HSCM : Health Supply Chain Management
HVAC : Heating Ventilation and Air Conditioning
MoH : Ministry of Health
MPPD : Medical Procurement and Production Division
RBC : Rwanda Biomedical Centre
FDA : Food and Drug Authority
RSB : Rwanda Standards Board
SMS : Short Message Service
SOPs : Standards Operating Procedures
WHO : World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Background

Good Storage Practices (GSP) are essential for the management of quality pharmaceutical products throughout the whole health commodities supply chain (1).

When applied correctly, the assurance that stored pharmaceutical products are safe, good quality increases. In case of inappropriate infrastructure, the stored products can lose their original quality and become ineffective or harmful to the patients' lives (2,3).

As pharmaceutical products are fundamental in disease treatment and diagnostics, but also take the majority of health budget, they must be managed with much attention to prevent wastage of resources and loosing lives because of poor quality or poor management in regards with the recommended good practices.

Moreover, all necessary mechanisms including proper storage conditions should be established at each step in the health commodities supply chain to avoid unsafe pharmaceutical products and protect the public health (4).

Pharmaceutical warehouse is more than a simple storage room where sensitive products are kept in appropriate conditions as required by the manufacturers or regulatory authorities. While pharmaceutical products are kept in the warehouse, strong monitoring of how they are stored is required to make sure that the recommended storage conditions are being respected. Various storage conditions such as: (Temperature, Humidity, Light, Ventilation, and Sanitation) must be strongly monitored on a regular basis (1).

The Rwanda Biomedical Center / Medical Procurement and Production Division (RBC/MPPD) is in charge of procuring, storing and distributing good quality medical products to all public health facilities in Rwanda. To fulfill the mission, RBC/MPPD must procure quality products and receive them from suppliers in good conditions, store them in its warehouses which must be

equipped with appropriate facilities to keep medicines in good conditions according to the good manufacturing practices (GMP) requirements.

Temperature, humidity and other storage conditions must be monitored on regular basis and whenever out-of-specifications are found , there must be immediate corrective actions to avoid long exposure of stored medicines in poor conditions and preserve their quality (5).

1.2. Problem Statement

Pharmaceutical products are very sensitive to poor storage conditions. If those storage conditions (i.e. Temperature, humidity, ventilation, sanitation) are not respected, the quality of pharmaceutical products is compromised, shelf life shortened, active ingredient and excipients degraded and some become toxic to patients. This is why storage conditions for pharmaceutical products must be well considered and seriously applied to protect the public health (6).

As pharmaceuticals take the big part of health sector budget, they must be seriously managed to prevent wastage of financial resources spent on them and dangers related to harmful degraded medicines. To do so, availing necessaries to keep the products in the same status as the manufacturer produced the products is a requirement.

In low-income country , warehouse domain in health supply chain always encounter problems like poor quantification, poor management, insufficient financing, small number of adequate personnel , inappropriate facilities for warehousing which is leading to the waste of health resources (7).

The Rwanda Biomedical Center (RBC) through Medical Procurement and Production Division procures and distributes different types of pharmaceutical products to District pharmacies and the later distribute to hospitals and health centers in their respective catchment areas.

As the government of Rwanda is highly committed to high quality products and high quality services, all levels of the health system including pharmaceutical supply chain must deliver quality assured medicines (8).

In regards to Good Storage Practices, the warehouses in which are kept pharmaceutical products must be well equipped to maintain quality and adequate monitoring being organized.

In the frame of examining the level of compliance of both the central medical store owned by the Government of Rwanda, the RBC/MPPD and its main distribution hubs, the district pharmacies (DPs) with good storage practices, and ensure that the supplied medicines and other health commodities are not exposed to the harmful effects of light, temperature, moisture and other external factors that may alter the original quality and make them ineffective or dangerous to the public health, we conceived this research.

The results of this research helped to know where there is a gap and Corrective Action and Preventive Actions were recommended accordingly.

1.3. Objective of the Study

I.3.1. General Objective

The main objective is assess if pharmaceutical products in Rwanda are stored in respect with the Good Storage Practices to assure their quality at the central medical store and peripheral district level warehouses. We will be assessing if storage premises available at the central medical store (RBC/MPPD) and districts pharmacies (DPs) are properly designed for this function by comparing with the recommended standards.

1.3.2. Specific Objectives

- To inspect the availability of appropriate storage premises for pharmaceutical products.
- To assess compliance with good storage practices
- To identify risks of products degradation due to poor storage conditions
- To propose appropriate corrective and preventive actions (CAPA) for the inefficiencies found.

1.4. Research Questions

i. Are available storage premises for pharmaceutical products designed according to the required standards?
ii. Are the available and applied storage conditions complying with good storage practices?
iii. Are staffs working in warehouse aware of good storage practices?
iv. Are the stored pharmaceutical products under risk of degradation?
v. What are Corrective and Preventive Actions (CAPA) to be considered regarding the risks observed?

1.5. The Study significance

After our research, the results were of great significance to the central medical store (RBC/MPPD) and to District Pharmacies (DPs) and even to the Rwanda Food and Drug Authority (Rwanda FDA) because they revealed where there are gaps and weaknesses in pharmacy warehousing along with Good Storage Practice and monitoring system in the assessed medical warehouses purposively selected to represent the whole supply chain of medicines in Rwanda. Once gaps and weaknesses discovered, appropriate recommendations for corrective and preventive actions (CAPAs) were proposed in order to keep delivering good quality medicines to the Rwandan population.

In that case, the population benefited from this research by lately accessing to good quality medicines after implementing corrective and preventive actions (CAPA).

The findings were also useful to further research projects in the scope of pharmacy Supply Chain and quality assurance/quality control system.

1.6. Delimitation and Limitation of the study

1.6.1. Delimitation

This research assessed storage conditions for pharmaceutical products stored in public medical warehouses. The focus was on the assessment of appropriateness of storage premises and assessment of warehouse staff and managers awareness about storage conditions and Good Storage Practice of pharmaceuticals.

1.6.2. Limitation

The study was limited to the warehouses owned by RBC/MPPD and 10 out of 30District Pharmacies purposively selected to represent the supply chain in Rwanda.

CHAPTER 2: LITTERATURE REVIEW

2.1. Introduction

Maintaining pharmaceutical products in appropriate conditions of storage as it is required by products manufacturers is crucial for ensuring their intended use. The shelf life of the products to be maximized will depend on how it was stored thus protecting its originality till the end so that the quality is assured and customers can be saved and resources not wasted (9).

Pharmaceutical products must be kept in conditions which strictly protect the products from all possibility of being damaged. While kept in the store, the products integrity must remain intact till the end of shelf life. Temperature, humidity, air quality are factors with major influence on the final products status, consequently on release or rejection for produced batches. Hence, all recommended good practices such as GMP, GCP, GDP, GSP, GPP, etc. must be well implemented or applied to have the right medicine that are safe at the right place from the right person (professional) to the real beneficiaries.

During their shelf life, pharmaceuticals must be kept in their dedicated storage facilities respecting conditions as it is written or suggested on the label. Each pharmaceutical products have their required suitable conditions to be kept on in the warehouse depending on their character and all those exigencies must be respected. Keeping the original packaging for pharmaceutical products kept in the store is a must to increase their protection. All storage conditions are required to be respected at each steps of health commodities supply chain (10).

2.2. Personnel

At every storage site (e.g. at the factories, wholesaler, distributor, community pharmacy) there might be all required human resources in adequate number to properly manage the health products for their intended use. Moreover, all necessary regulations and qualification needed might be used to find those required human resources(11).

For human resources working within the pharmaceutical products warehouse, appropriates training in different aspect regarding the storage conditions of pharmaceuticals and other necessary regulations might be prepared and provided to them regularly (11)

2.3. Premises and Facilities

2.3.1. Storage areas

A health commodities warehouse premise is much more than a building that provides a space for storage. It must be designed appropriately to receive, store, protect and organize products efficiently and must allow effective distribution for life-saving products. This requires adequate transport, receiving, storage in appropriate conditions for the commodities, and adequate work space to ease access and compile onward shipments for products going out to regional or other warehouses or service delivery points (12) .

Warehouse dedicated for pharmaceutical products storage must be designed accordingly. All necessary storage conditions must be well instored in it to keep product in good status.

The warehouse should be prepared to host even special pharmaceutical products requesting special conditions of storage and the monitoring of those conditions must be performed on regular basis. Health commodities in a warehouse should be staked not touching the floor and the wall and they must be appropriate species between stacked cartons to easy access and circulation (13).

For pharmaceutical products warehouse, good sanitation is paramount to protect stored products from pests, accumulated waste inside the warehouse, and other source of contamination. Cleaning must be scheduled, written SOPs must be prepared and displayed for use, cleaning reagents use must not harm the stored products and people working within the warehouse.
All cleaning and pest control reagents must be of assured quality and the method of cleaning or removing pest being used must be assured to prevent cross contamination. (13).

2.4. Storage conditions

Medicines and other health commodities have special storage area because they are sensitive to different conditions which can alter their nature. They must be stored respecting the recommendations from the manufacturer written on the product label and those recommendations are obtained after a series of stability testing of the produced products. So, they must be respected as written to safeguard the stability of the stored products. They are more detailed with all necessaries to not confuse anyone concerned and if there is any storage condition specified on the label, this must be strongly monitored (2).

Warehouse premises should be well designed or adapted appropriately to the products to be kept in it. If pharmaceutical products are requiring special storage, these must be clearly written on the products labels. In the warehouse, clear Sops specifying what to do in case storage conditions have outranges measures must be there and understandable by the personnel in charge of warehousing the products. Strong monitoring is required to detect all out of ranges on time and take corrective measures on time (2).

2.4.1. Storage conditions monitoring

Monitoring of data from temperature and other conditions of storage must be strongly performed and data kept or archived at least for the time equal to the shelf life of the stored products or instruments adding one year for future review or consultation. Data concerned also can be kept for a period defined by the regulatory authority (13).

To provide reliable data, storage conditions monitoring devices must be regularly checked and calibrated and the results from those operations must be kept for future review. During installation of monitoring devices, areas with high fluctuation of a concerned condition will be the first to be installed (13).

2.4.2. Storage requirements

Documentation

There should be written instruction specifying all warehouse activities including storage activities with more details and how pharmaceutical products are handled. The flow of pharmaceutical products and data related to them must be all detailed for the organization to have traceability for all managed products (13).

Containers and labelling

To preserve the integrity of stored pharmaceutical products and other health commodities, they might be kept in containers not able to affect their nature and quality. Those containers might play a role of barrier for all negative influences to the pharmaceutical products and might protect against any possibility of cross contamination of the inside products. They might have all necessary details such as conditions of storage, batch number, expiry date, the name of the products and unauthorized languages, codes , abbreviations are not welcomed (13).

Transport

Transportation of pharmaceutical products and other health commodities might be performed in a way not affecting their quality thus their storage conditions. For example cold chain products, their transport must be carefully performed to prevent them from cross contamination between products and dry ices. So, a continuous monitoring of storage conditions must be performed even during transport (13).

Rwanda Supply flow of medicines from RBC/MPPD to DPs and other health facilities

Once pharmaceutical products arrived at central medical store (RBC/MPPD) from different suppliers and manufacturers, they are checked for compliance to the requested products, controlled by quality assurance team and when they comply, they are received and stored in the warehouse according to the recommended storage condition by the manufacturer.
The products stored at RBC/MPPD are transported to District pharmacies after requisition and district pharmacies distribute them to health facilities i.e. hospitals, health centers and health posts in their catchment areas.

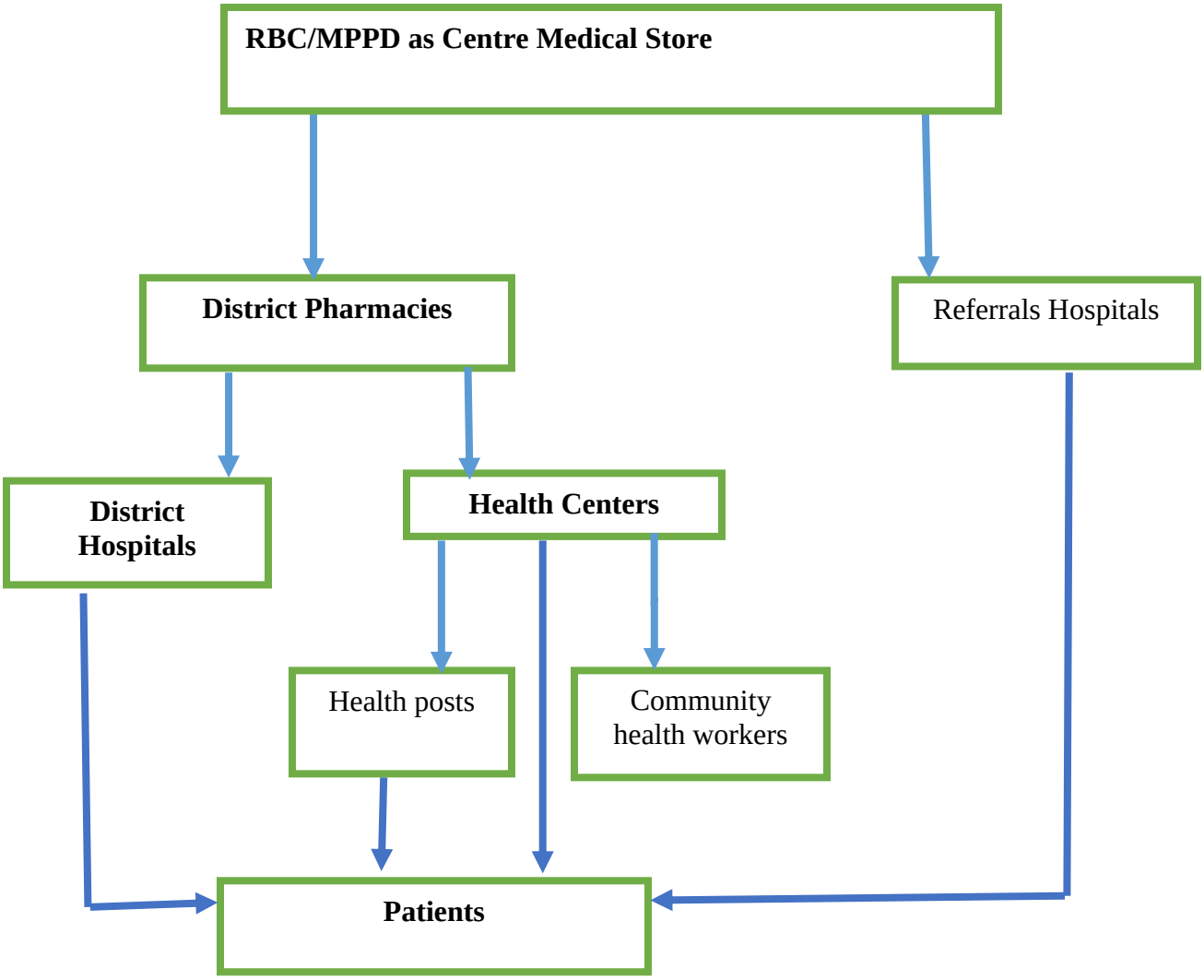

Figure 1: Supply flow of medicines from RBC/MPPD to DPs and other health facilities

2.5. Freezers and refrigerators

Freezers, refrigerators and other cold chain equipment are tasked to keep the temperature of stored pharmaceutical products between the limits as specified by the manufacturer on the label of the products. Refrigerators might keep the temperature of $5^{o}C \pm 3^{o}C$ meaning that the temperature would range from $2^{o}C$ to $8^{o}C$. Freezers temperatures may range between $-25^{o}C$ to $10^{o}C$ (14).

Refrigerators and freezers containing drugs should be placed in locations with maximum security to prevent easy access and that place must have stable temperature to prevent stored drugs from being affected by the fluctuation unstable temperature (15).

2.6. Conceptual framework

It is the structure showing how variables are interlinked in a research. This is done either in graphic or in narrative way to show the main things in your study.

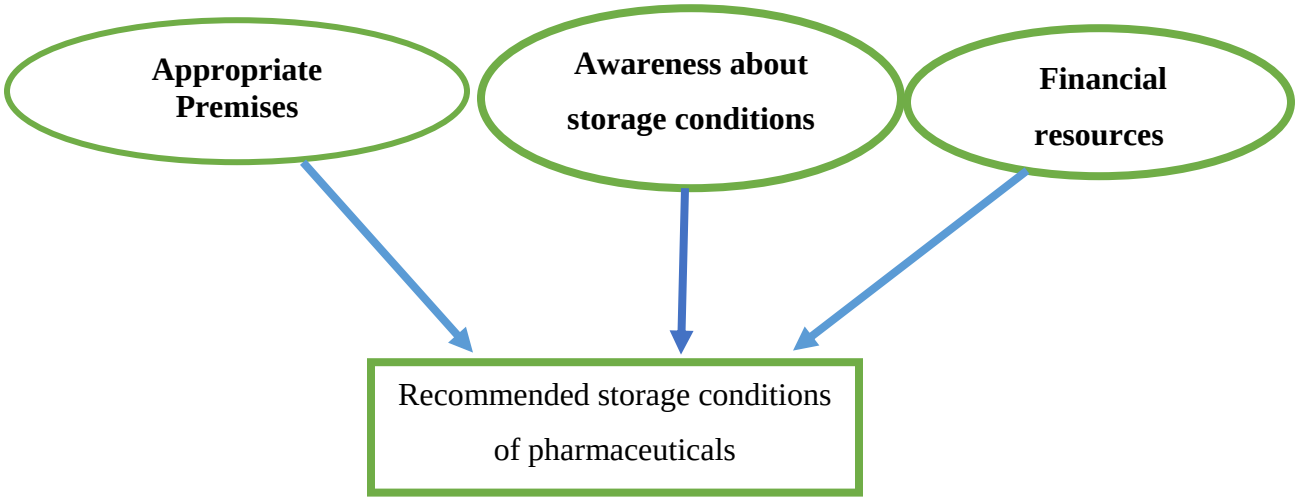

Figure 2: Conceptual framework

In our research, recommended storage conditions of pharmaceuticals products depend on availability of appropriate premises, employee's awareness about pharmaceutical storage

conditions and financial resources to make everything possible. Recommended storage conditions is a dependent variable which depend on those three independent variables.

CHAPTER 3: METHODOLOGY

3.1. Research design

The current study is a **descriptive-Analytical** research where the actual status of storage of pharmaceutical products in Rwanda is going to be described against Good Storage Practices and manufacturers recommended storage conditions in order to find out any deviation and recommend corrective measures.

3.1.1. Study site and locations

We selected purposively the central medical store and 10 representative DPs following different geographical location.

As the central medical store has several warehouses, we selected the biggest based at Kacyiru (Gasabo/Kigali city) and the selected 10 DPs are *Rubavu, Karongi* and *Rusizi* (Western Province), *Burera* in (Northern Province), *Kamonyi* and *Gisagara* (Southern Province), *Gasabo* (Kigali City), and *Nyagatare, Kayonza, Kirehe* (Eastern Province) as shown in the map below.

Description of the sites

RBC/MPPD have two main warehouses in which medicines and other health commodities are stored and those are Kacyiru and Free Trade Zone warehouse. In additional to those owned warehouses, the RBC/MPPD can also rent other warehouses to increase space when needed as it was the case during our study. We were informed that there is another warehouse in rent at Utexirwa (Gacuriro, Gasabo district) mostly used for storing non-medical products such as insecticidal treated meds, medical equipment and medical devices.

We selected Kacyiru warehouse as the one hosting more different products requiring different storage conditions including cold rooms. It is well equipped with different devices to monitor storage conditions.

Free Trade Zone warehouse is in the process of up-gradation by installing air conditioning system to allow further storage of products that need controlled temperature and humidity levels. So far it is also used to store medical devices and equipment that do not need strict controlled conditions.

On the other hand, the selected ten DPs have relatively small warehouses hosted in formal administrative buildings or newly constructed but still in medium sized layout.

In general, at the central medical store and the DP levels, there is need of space to store all health products properly. Moreover, we have also noticed that there is need to comply with the Good Storage Practices at different levels as presented in the following parts

Figure 3: Sample sites location

Source: **https://maps-.com/rwanda-map-with-districts**

3.2. Data collection

3.2.1. Primary data

Primary data were collected using a survey questionnaire (**Appendix 1**) which was distributed to the selected DP directors or assistant directors able to provide accurate information on storage conditions monitoring in their respective district pharmacies.

We also used a warehouse premises evaluation check list **(Appendix2**) to collect useful information on the status of compliance or noncompliance with the standards.

To approach our respondents, first of all we called them by phone and sent emails a week before collecting data. The emails were telling them about our study and requesting them for their

participation. We sent to participants clearances and questionnaires then we discussed when to meet and collect data.

Arriving on site, we had conversation with the District Pharmacy's Director and when he were not around, he/she assigned someone among pharmacy's staffs to respond to us then after having conversation, we took photos and photocopies of temperature records and he/she signed for us.

3.2.2. Secondary data

In this research, previous records on temperature and humidity recorded in the last three years (2016-2018) were collected for analysis and comparison with the recommended acceptable limits.

Documentary review on other reports, SOPs, and publications about the same topic or related subject were consulted in order to collect useful information for better interpreting the study findings.

3.2.3. Data Capturing and Analysis

Data from questionnaires, warehouse premises checklist and from previous records on temperature and humidity were captured in excel to be analyzed using Descriptive statistics.

3.2.4. Ethical consideration

To conduct this research, we had permissions from different institutions allowing us to have access to data in need. We had Clearance from University of Rwanda Institution Review Board allowing us to conduct the research.

We had permission from the Ministry of Health allowing us to have access to the data from all institutions under Ministry of Health. We had also a recommendation letter from College of Medicines and Health Sciences East African Regional Center of Excellence for Vaccines, Humanization and Health Supply Chain Management which helped as to apply for each clearance. All those clearances helped us to be able to conduct the research.

To approach our respondents, we assured them that data collected will be used only for this research purpose and that the participation were voluntary. We sent them clearances and questionnaires on emails before collecting data. No consent form were signed because no human subjects were used and no financial means were paid before accepting to participate in this research. Only voluntary participants accepted to work with us.

CHAPTER 4: FINDINGS

4.1. Warehouse premises layouts status

The table below presents the summary of what we collected concerning availability of appropriate storage premises for pharmaceutical products.

Table 1**:** General findings on warehouse layouts status

#	**Features**	**% of Good**	**% of Medium**	**% of Poor**	**% of Absent**
1	Warehouse well ventilated	72.7% (8/11)	27.3% (3/11)	0.0%	0.0%
2	Warehouse well cleaned with intact pavement	72.7% (8/11)	18.2% (2/11)	9.1% (1/11)	0.0%
3	Warehouse well equipped with temperature and Humidity monitoring devices	81.8% (9/11)	18.2% (2/11)	0.0%	0.0%
4	Availability and usable air conditioning system	27.3% (3/11)	9.1% (1/11)	0.0%	63.6% (7/11)
5	Controlled substances kept in locked cupboard	54.5% (6/11)	18.2% (2/11)	9.1% (1/11)	18.2% (2/11)
6	Protection against direct sun light	72.7% (8/11)	9.1% (1/11)	18.2% (2/11)	0.0%
7	Availability and usable cold rooms / fridges	100% (11/11)	0.0%	0.0%	0%
8	Areas for flammable products	18.2% (2/11)	27.3% (3/11)	18.2% (2/11)	36.4% (4/11)
9	Receiving area separated with dispatch area	18.2% (2/11)	0%	0%	81.8% (9/11)
10	Enough and adequate lighting in the warehouse	72.7% (8/11)	27.3% (3/11)	0.0%	0.0%
11	Security system to prevent easy access of unauthorized personnel/visitors	72.7% (8/11)	9.1% (1/11)	0.0%	18.2% (2/11)
12	Cartons are stacked at least 10 cm (4 inches) off the floor on pallets and/or shelves	54.5% (6/11)	45.5% (5/11)	0.0%	0.0%
13	Cartons are stacked at least 30 cm (1 foot) away from walls and other stacks	18.2% (2/11)	45.5% (5/11)	36.4% (4/11)	0.0%
14	Stacked cartons are not more than 2.5 m (8 feet) height	27.3 %(3/11)	36.4% (4/11)	36.4% (4/11)	0.0%

15	Separate storage area for expired and other unfit products	90.9% (10/11)	0.0%	9.1% (1/11)	0.0%
16	Availability of ladder to allow access to higher locations	90.9% (10/11)	9.1% (1/11)	0.0%	0.0%
17	Availability of equipment for lifting heavy loads	45.5% (5/11)	0.0%	9.1% (1/11)	45.5% (5/11)
18	Zones and locations labeled	45.5% (5/11)	36.4% (5/11)	0.0%	9.1% (1/11)
Total		**58% (114/198)**	**19% (38/198)**	**8% (16/198)**	**15% (30/198)**

Source: Primary data, 2019

We had eighteen (18) evaluation criteria for a well-designed and organized working pharmaceutical warehouse. For each criteria, we had to rank every visited pharmaceutical warehouse as Good, Medium, Poor or absent depending on the availability or compliance with the assessed criteria.

In facts, 100% of Good, Medium, Poor or absent evaluation grades correspond to 198 evaluation responses i.e 18 criteria x 11 sites. Then, in general we observe that 57% of warehouse premises layouts i.e 114/198 are ranked Good by considering all evaluation criteria, 19%(ie 38/198) were ranked Medium, 8% i.e (16/198) were ranked Poor and 15% i.e.(30/198) were ranked Absent. This is the overall situation on warehouse premises layouts status.

By putting together all Poor and Absent status we noticed that there is need to improve or establish where we do not have air conditioning system, a well cleaned warehouse with intact pavement, controlled substances kept in locked cupboard, Protection of pharmaceutical products against direct sun light, Available and usable cold rooms, Areas for flammable products, Receiving area separated with dispatch area, Security system to prevent easy access of unauthorized personnel/visitors, Cartons stacked at least 30 cm (1 foot) away from walls and other stacks, Stacked cartons not more than 2.5 m (8 feet) height, Separated storage area for expired and other unfit products, equipment for lifting heavy loads and Zones and locations labeled.

The remaining 19% of medium status need some improvement to become Good in some Dps for almost all evaluation criteria as shown by the table 4.3.

As it can be noticed, some evaluation criteria are simple to implement and unfortunately in some assessed sites, they were found as Absent, Poor, and Medium levels while they can easily be established and implemented.

Those are for example having Warehouse well cleaned with intact pavement, separate Controlled substances and keeping them in locked cupboard, Protection of pharmaceutical products against direct sun light, having Security system to prevent easy access of unauthorized personnel/visitors, stacking cartons at least 10 cm (4 inches) off the floor on pallets and/or shelves, stacking cartons at least 30 cm (1 foot) away from walls and other stacks, stacking cartons not more than 2.5 m (8 feet) height, Separating storage area for expired and other unfit products and zoning and locations labeled.(16)

During the sites visits, we discussed with the responsible who committed to immediately improve the situation.

On the other hand, there are other criteria that need financial mean such as availability and usable air conditioning system and availability of equipment for lifting heavy loads.
Every warehouse is supposed to have them and funds must be mobilized to acquire them to comply with the GSP (11,17).

4.2. Questionnaire and warehouse premises status findings

4.2.1. Findings on questions related to Good Storage Practices

Storage and distribution are important activities in the supply chain of medical products and products may be subjected to the risk of losing their original quality due to poor handling in the warehouse where they are stored waiting for distribution to health facilities for use. In this

regards, we assessed the status of compliance with good storage practices in the Rwandan health supply chain using an evaluation tool based on questions inspired by WHO GSP guidelines (13).

Question 4: Even if all respondents said they strictly check and consider the labeled storage conditions, we noticed that this is applied only on products stored at cool temperature (i.e. 15^0C - 25^0C or 30^0C) and in refrigerators or cold rooms (i.e.2^0C – 8^0C) but none of them was found to have **cool place** storage condition (i.e. 8^0C to 15^0C) for a number of products such as flammable liquids commonly found in health facilities like (acetone, alcohol) and numerous other types of medicines that are recommended to be stored in that condition.

Note: This is a critical point that must be considered as the lack of that condition lead to warehouse managers to storing the products dedicated to the cool place and in ambient room conditions that are almost twice hotter than the recommended condition and therefore expose the products to the loose of their original quality for example alcohol evaporate and build pressure inside the containers and several other products may present similar problem due to exposure to inappropriate storage condition.

Question 5: All assessed warehouse follow the SOPs provided by the Ministry of Health (MOH) entitled *"Standard Operating Procedures (SOPs) for Health Commodities Management in Health Facilities"*.(8) In addition to the MOH SOPs, other SOPs from the USAID Deliver Project like: *"Guide d'Entreposage Correct des Produits de Santé"* and *"Directive pour un bon Entreposage des Contraceptifs et autres Médicaments"*, and the contents of followed SOPs are satisfactory.

Questions 6 & 7: All assessed warehouses monitor storage conditions primarily temperature on regular basis i.e. every day as recommended in the SOPs before work by 7:30 AM and during the hottest part of the afternoon by 2:00 PM, and monitoring is done in all ambient rooms and in the refrigerators or cold rooms.

However, apart from the central medical store, all other assessed warehouse do not monitor storage condition the weekends and holydays and this is taking high risk especially cold chain

products in case refrigerator or cold rooms stop functioning on Saturday, Sunday or holiday and none would be aware to call the maintenance technicians for corrective actions timely.

Moreover, we noticed that it is also time to start planning for automatic monitoring devices that can send alerts by SMS (Short Message Service) and emails whenever alarming conditions are attained. Such conditions can happen even during nights caused by power cut offs, floods, fire, etc., and automatic monitoring devices may help sending alerts timely for corrective actions in due time.

We have also noticed that the number of thermometers is not enough in all assessed warehouse to allow monitoring temperature in the principal parts in the warehouse i.e. at entrance, in the middle, on the ceiling and on the floor apart from the central medical store that has installed automatic data loggers for monitoring both temperature and humidity.

Concerning calibration, we noticed that only the central medical store is the one that invites every two years the National Metrology Services of the Rwanda Standards Board (RSB) assessing recommended temperature ranges in the cold rooms and refrigerators to ensure that cold chain products are properly stored.

Question 8: All assessed warehouses have a clear instruction from MoH SOPs that each facility must have a corrective actions form or book with procedures to be followed when temperatures deviate from the normal range, and the corrective actions form / book should be implemented as part of the overall quality management system. To this specific questions, all responded that in case of deviation from the normal range they must: (i) Call maintenance technician to address the issue as soon as possible, and (ii) Move the products in another warehouse or refrigerators / cold room in case maintenance processes will take long time that may affect the quality of the stored products. (8)

Question 9: All assessed warehouses confirmed that their staffs working in warehouse operations are trained about different storage conditions mainly from their academic back ground and most of them got additional training from the USAID Deliver Project. But, they all wish to

have fresh and continuous updates on GSP as well as on other best practices (GxP)s applied in the pharmaceutical supply chain.

Questions 10 & 11: All assessed warehouses were found good in stock management on FEFO (First Expiry First Out) or FIFO (First In First Out) principles as well as in the management of unfit products (expired, damaged and poor quality) by disposing them using hospital high temperature ($850^{o}C$ – $1{,}100^{o}C$) incinerators for medical wastes destruction available in all districts.

Note that in addition to the incineration method, the central medical store apply also recycling as other type of disposal method by giving expired or declared poor quality I.V fluids packed in plastic materials to local recycling plastic companies instead of incinerating them and polluting the environment.

Question 12: The majority of the visited warehouses ranked themselves as Good and one self-ranked Medium in complying with GSPs, but all are committed to continuous improve towards full implementation of the recommended standards, and we agree on their self-ranking.

Questions 13 & 14: All assessed warehouses kindly accepted to share the storage records in their possession for the studied period 2016-2018 and also allowed us to take pictures for more illustrative details by pictures.

4.2.2. Experience of respondents

In all work environment, qualification and experience are good indicators for institutions performances. The Table 1 shows the situation on the professional experience of the respondents, and therefore gives an idea on the accuracy of the received information.

Table 2: *E*xperiences of respondents

Experience in years	Frequency	Percentage
1-5 years	2	18
6-10 years	2	18
11-15 years	7	64
Total	11	100

Source: Primary data, 2019

One can notice that the range of professional experience of the respondents is between 3-15 years and the majority (64%) of the respondents have between 11-15 years in the pharmaceutical supply chain. This gives us insurance of having collected reliable information.

4.3. Findings on temperature and humidity records on the last three years (2016-2018)

To comply with Good Storage Practices for pharmaceutical products, effective temperature and humidity monitoring is paramount in all stores. Associated record-keeping is a critical component to ensure the maintenance of proper storage conditions for health commodities, vital component to ensuring their quality. As known, the product expiration dates are based on ideal storage conditions and products should be kept under labeled storage conditions, defined by the Manufacturer until their expiration date (15).

Equipment for storage condition monitoring should be available and also be calibrated at defined intervals.

For identifying the risks of products degradation due to poor storage conditions; we analyzed the records about temperature and humidity monitoring for the last three years (2016-2018) to check the possibility of out of range during this period.

4.3.1. Overall status in 2016-2018 on temperature records in ambient storage rooms and cold chain

Ambient storage conditions are defined as storage in dry, well-ventilated premises at temperatures of 15–25°C or up to 30 °C, depending on climatic conditions. Extraneous odors, other indications of contamination, and intense light must be excluded (9).

Note: Dash in the table means that data were not available during data collection at specified site.

Table 3 : Overall status of ambient room temperatures in 2016

Site measurements	**Site 1**	**Site 2**	**Site 3**	**Site 4**	**Site 5**	**Site 6**	**Site 7**	**Site 8**	**Site 9**	**Site 10**	**Site 11**	**National Average**
Mean (^{o}C)	24	-	-	22	23	23	22	20	22	21	-	**22**
SD (^{o}C)	1	-	-	0.75	1	1	1	1	1	1	-	**1**
Mode (^{o}C)	24	-	-	22	23	23	22	18	22	21	-	**22**
Max. (^{o}C)	25	-	-	23	25	25	24	23	23	22	-	**24**
Min. (^{o}C)	22	-	-	21	22	22	19	17	21	20	-	**18**

Source: Records of district pharmacies, 2018

Note: To each studied year, we collected temperature and humidity records where both are available for February (28 days), May (30 days), August (31 days) and November (30 days). These months were purposively selected to represent the annual seasonal

variations: (i) February for short dry season, (ii) May for end of long rainy season, (iii) August for long dry season, and (iv) November for short rainy season, all characterized by different temperature and humidity variations.

The presented data in **Table 3**, show that the national average level was 22^{o}C ± 1^{o}C in ambient room with modes i.e. the most frequently occurring data ranging between 18^{o}C and 24^{o}C, maximum temperatures ranging between 22^{o}C and 25^{o}C and the minimum temperatures between 17^{o}C and 22^{o}C which demonstrate that temperature was good in ambient rooms in 2016 as no records was outside the recommended range of 15^{o}C to 25^{o}C up to 30^{o}C.

Table 4: Overall storage status by refrigeration in 2016

Site measurements	**Site 1**	**Site 2**	**Site 3**	**Site 4**	**Site 5**	**Site 6**	**Site 7**	**Site 8**	**Site 9**	**Site 10**	**Site 11**	**National average**
Mean (^{o}C)	5	7	-	4	5	5	4	-	5	5	-	**5**
SD (^{o}C)	1	1	-	0	1	1	0	-	1	1	-	**0.8**
Mode (^{o}C)	5	7	-	4	4	5	4	-	4	5	-	**5**
Max. (^{o}C)	7	8	-	5	9	7	5	-	5	6	-	**7**
Min (^{o}C)	5	6	-	4	4	3	3	-	4	4	-	**4**

Source: Records of district pharmacies, 2018

The presented data in **Table 4**, show that the national average level was 5^{o}C ± 0.8^{o}C in refrigerators and cold rooms, with modes ranging between 4^{o}C and 7^{o}C, maximum temperatures ranging between 5^{o}C and 9^{o}C and the minimum temperatures between 3^{o}C and 6^{o}C which demonstrate that temperature was good in general by considering the recommended range of 2^{o}C to 8^{o}C, except an out of range temperature occurred once for a short period in Site 5.

In addition we can notice that the records for Site 2 are relatively high closer to the upper acceptable limits (8^{o}C). Such situation needs cautious attention and preventive maintenance of the refrigerators or cold room to reset the equipment in the normal conditions.

Table 5: Overall status of ambient room temperature in 2017

Site measurements	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10	Site 11	National average
Mean (^oC)	22	-	-	22	23	23	21	19	23	21	-	**22**
SD (^oC)	1	-	-	1	0	1	1	1	1	1	-	**1**
Mode (^oC)	21	-	-	22	23	23	21	19	22	21	-	**21**
Max. (^oC)	23	-	-	22	23	25	21	20	24	22	-	**23**
Min. (^oC)	21	-	-	21	24	21	19	18	20	20	-	**21**

Source: Records of district pharmacies and RBC/MPPD, 2017

The presented data in **Table 5**, show that the national average level was $22^oC \pm 1^oC$ in ambient room with modes ranging between 19^oC and 23^oC, maximum temperatures ranging between 20^oC and 25^oC and the minimum temperatures between 18^oC and 24^oC which demonstrate that temperature was good in ambient rooms in 2017 as no records was outside the recommended range of 15^oC to 25^oC up to 30^oC.

Table 6: Overall status of storage by refrigeration in 2017

Site measurements	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10	Site 11	National average
Mean (^oC)	-	7	-	5	6	5	4	-	4	5	-	**5**
SD (^oC)	-	1	-	0	1	1	0	-	1	0	-	**1**
Mode (^oC)	-	7	-	5	8	5	4	-	5	5	-	**6**
Max. (^oC)	-	8	-	5	13	7	5	-	6	6	-	**7**
Min (^oC)	-	6	-	4	6	3	3	-	5	5	-	**5**

Source: Records of district pharmacies and RBC/MPPD, 2017

The presented data in **Table 6**, show that the national average level was $5^oC \pm 1^oC$ in cold room and refrigerator with modes ranging between 4^oC and 8^oC, maximum temperatures ranging between 5^oC and 13^oC and the minimum temperatures between 3^oC and 6^oC which demonstrate that temperature was good in cold rooms and refrigerator by considering the recommended range of 2^oC to 8^oC except an out of range temperature occurred once for a short period in Site 5.

Table 7: Overall status of ambient room temperature in 2018

Site measurements	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10	Site 11	National average
Mean (^{o}C)	22	-	23	23	23	23	21	19	22	20	20	**22**
SD (^{o}C)	0	-	1	1	1	1	1	1	1	1	1	**1**
Mode (^{o}C)	22	-	23	23	23	23	21	19	22	20	20	**22**
Max. (^{o}C)	22	-	24	29	23	25	29	20	23	21	22	**24**
Min. (^{o}C)	22	-	22	22	22	22	20	18	20	19	19	**21**

Source: Records of district pharmacies and RBC/MPPD, 2018

The presented data in **Table 7**, show that the national average level was 22^{o}C ± 1^{o}C in ambient room with modes ranging between 19^{o}C and 23^{o}C, maximum temperatures ranging between 21^{o}C and 29^{o}C and the minimum temperatures between 18^{o}C and 22^{o}C which demonstrate that temperature was good in ambient rooms in 2018 as no records was outside the recommended range of 15^{o}C to 25^{o}C up to 30^{o}C.

Table 8: Overall status of storage by refrigeration in 2018

Site measurements	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10	Site 11	National average
Mean (^{o}C)	5	7	-	5	5	4	4	-	4	5	5	**5**
SD (^{o}C)	0	0	-	0	1	1	1	-	1	0	2	**1**
Mode (^{o}C)	5	7	-	5	5	4	3	-	4	5	5	**5**
Max. (^{o}C)	5	7	-	5	7	6	4	-	6	5	7	**6**
Min (^{o}C)	5	7	-	5	4	2	3	-	4	4	2	**4**

Source: Records of district pharmacies and RBC/MPPD 2018

The presented data in **Table 8**, show that the national average level was 5^{o}C ± 1^{o}C in refrigerators and cold rooms, with modes ranging between 3^{o}C and 7^{o}C, maximum temperatures ranging between 4^{o}C and 7^{o}C and the minimum temperatures between 2^{o}C and 7^{o}C which demonstrate that temperature was good in general by considering the recommended range of 2^{o}C to 8^{o}C in 2018.

4.3.2. Overall status in 2016-2018 on relative humidity (RH %) in ambient storage rooms

The table below summarizes our findings on relative humidity in ambient storage rooms.

Table 9: Overall status on relative humidity (RH %) records in ambient rooms during 2016-2018

Measurements	**2016**	**2017**	**2018**	**Average for 3 years**
Mean (RH %)	50	64	67	**60**
SD (RH %)	6	3	5	**5**
Mode (RH %)	50	62	68	**60**
Max. (RH %)	66	67	72	**68**
Min. (RH %)	39	60	62	**54**

Source: RBC/MPPD records, 2018

Humidity monitoring devices were found in one of the studied sites and humidity monitoring is necessary recommended for the products that are humidity sensitive or labeled to avoid moisture.

Considering that recommended conditions of relative humidity, one can noticed that the humidity has increased every year from 50 %(RH) to 64% (RH %).

In 2016 and 2017, still below the recommended limit, up to 67 %(RH) level which is above the recommended limit. This trend of progressive increase of the RH must be investigated to know the root cause and urgently plan for corrective and preventive actions to avoid exposing the stored products in high humidity condition that can affect the quality of the products that must be stored in dry conditions.

CHAPTER 5: DISCUSSION

Monitoring of relative humidity is very important for stored pharmaceutical products to protect them from being degraded the moisture. Temperature and relative humidity are found to be among the major cause of pharmaceutical products degradation when they exceed the recommended measures and this is why in all pharmaceutical warehouses temperature and relative humidity monitoring devices must be always available and well monitored in order to preserve the stability of pharmaceuticals (6,18).

For one site found to monitor relative humidity, we found that the national average of relative humidity for 3 years (i.e.2016,2017,2018) , was 60 ±5% and this is normal according to the stability condition for WHO member states by region where Rwanda is in climatic zone II Mediterranean in sub-tropical countries with (30^{o}C 65%) of stability condition (10).

As shown by this study, storage condition monitoring devices are not calibrated at all sites and this can be the cause of inaccurate data leading to pharmaceutical products degradation and wastage of resources. Storage conditions monitoring devices must be calibrated by a certified authority to make sure that all possibility of storage conditions affecting the stored products negatively are minimized at maximum (2,19).

In our study, we found that the products to be stored at ambient room are not at risk of degradation because the temperature was ranging between 15^{o}C to 25^{o}C up to 30^{o}C which is normal range of temperature for products to be stored to this storage condition (4).

During our research, we found that warehouse staffs are using academic back ground to perform their daily duties. Meaning that there is lack of continuous and refresher training for pharmaceutical warehouse operations. These findings are similar to those found by Bernard MUNYANGANZO during his previous research at central medical store where he was assessing compliance with Good storage practices, he found that 56% of all warehouse staffs were not trained in warehouse activities they do (20).

CONCLUSION AND RECOMMENDATIONS

Conclusion

To ensure the quality of stored pharmaceutical products, storage conditions must be strictly monitored and quick interventions done whenever needed. This study investigated the storage conditions of pharmaceutical products in Rwanda by using a series of questions and warehouse premises checklist inspired by WHO guidelines on GSP.

The study revealed that in Rwanda, appropriate Pharmaceutical warehouses for storing are available but there is a number of major weaknesses that were noticed such as insufficient storage spaces due to warehouses designed as residential houses, lack of humidity monitoring devices at almost all the country, negligence to take records and monitor storage conditions in weekends and holydays.

We noticed that also there is a total lack of cool place (i.e. 8^{o}C to 15^{o}C) storage condition for a number of dedicated products, lack of sufficient space and appropriate design of district pharmacies that need corrective and preventive actions (CAPA) in order to improve implementation of good storage practices (GSP) and therefore protect the public health by preserving the quality, safety and efficacy of the stored pharmaceutical products.

Recommendations

After conducting this study, we highlighted some recommendations in the following table as corrective and preventive actions on major weaknesses observed to improve and safeguard the quality of pharmaceutical products stored in public warehouses.

Table 10: Recommended corrective and preventive actions (CAPA) for major weaknesses (CAPA) found

Weaknesses	**CAPA**
District pharmacies warehouses are designed like resident houses and this is hindering good storage of pharmaceutical products	Ministry of health to plan for and mobilize funds to increase the warehouse space necessary for storing all DP health commodities in good conditions and this should be planned in the next annual plannification.
Lack of updates and continuous trainings on GSP for warehouse staffs	District pharmacies to have annual plan of trainings for all warehouse staffs by hiring experts on the subject for better learning and upgrade of the knowledge beginning by next fiscal year.
Lack of Humidity monitoring devices at almost all studied sites except one.	District pharmacies plan and mobilize funds for the acquisition of the devices preferably equipped with alarm system and automated and this might be done even during revision of annual budget because the problem is serious.
Pharmaceutical products exposed to direct sunlight.	For District pharmacies, quick intervention is needed to protect light sensitive products by buying and installing curtains of windows where needed or use unclear windows. This can be implemented as soon as possible because it is not too costly.
The records of temperature monitoring devices are not taken during weekends and holydays.	District pharmacies to prepare SOPs obliging warehouse staffs in charge of monitoring and taking records of storage conditions to never miss the activity even in weekends and

	holydays from now. Note: Planning for automated monitoring devices equipped with alerts system by SMS and Emails should be a better solution.
Total lack of cool (i.e. 8^{o}C to 15^{o}C) place storage condition in all assessed sites.	District pharmacies to plan for and mobilize funds for establishing that storage condition applied to a large number of products in the next annual prannification.

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APPENDICES

QUESTIONNAIRE IN ENGLISH

My name is AKINGENEYE Charlotte a student at the Regional Centre of Excellence for Vaccines, Immunization and Health Supply Management (RCE-VIHSCM) / University of Rwanda (Kigali), and I am conducting a research to fulfill the requirements for a Master's degree in the same program.

My research topic is about the "**ASSESSMENT OF STORAGE CONDITIONS OF PHARMACEUTICAL PRODUCTS IN RWANDA. Case of Rwanda Biomedical Centre / Medical Procurement and Production Division (RBC/MPPD) and District Pharmacies (DPs)".**

I will humbly need your contribution in this research to make it successful by providing the needed information on the following questions that will not take you more than 20 minutes of direct interview, and the answers you provide will be treated in confidentiality for this research purpose only.

Note:

- Kindly fill blank spaces and tick appropriate answers corresponding to your view(s) and knowledge on the question(s);

1. Your gender: Male ☐ Female ☐
2. Number of years of experience in pharmaceutical supply chain management: ……..
3. Department / Unit of work (tick the right answer):

a) Central level (RBC/MPPD)

Quantification	
Procurement	
Warehousing and logistics	
Sales and marketing	
Quality Assurance and Quality Control	
Finance and Administration	
Production	

b) Peripheral level

District Pharmacy	
Other health facility (Hospital, Health center, etc.)	

4. While storing pharmaceutical products, do you strictly check and consider the labeled storage conditions of temperature, humidity, protection to light, and other recommended conditions by the manufacturer? **Yes** / **No**

a) For cold chain products (2 °C – 8 °C)
b) For products to be stored in cool storage (8 °C – 15 °C)
c) For products to be stored between 15 °C and 25 °C or 30 °C
d) For products to be stored in freezing (-5 °C and -20 °C)
e) Other conditions

5. Do you have a SOPs explaining all these processes? If yes show it to us.

6. Are environmental conditions, primarily temperature, monitored on an ongoing basis at appropriate locations throughout the parts of the premises in which medicinal products are stored? **Yes / No**.

If yes, can you show us where temperature monitoring devices are placed in the warehouse?

7. Is the environmental temperature (maximum and minimum) monitored on a daily basis, at a specified time, by a designated staff member, using a calibrated thermometer (manual or automatic device) and the results analyzed instantly for rapid intervention in case of results falling outside ranges? **Yes** / **No**

If yes, can you show us some of the reports where such situation was handled?

8. Is there any temperature monitoring procedure outlining actions to be taken when the results are outside the required ranges for both cold chain and non-cold chain medicinal products? **Yes** / **No**

9. Are staffs working in the warehouse trained about different storage conditions of pharmaceutical products? **Yes** / **No**

If yes, show the certificates of training or other related documents?

10. Are the stored medicinal product regularly reviewed, removed from stock if damaged, defective or contaminated, and the responsible person/department or authority (e.g. QAQC, NMRA, etc.) informed when a medicinal product is thought to be defective or poor quality? **Yes** / **No**

If yes, please show us one example where poor quality products were reported to a responsible person such as QAQC manager/officer?

11. Is there an appropriate stock rotation system in place, based on a system of first expiry, first out (FEFO) for all medicinal products, including those stored in the refrigerator or controlled substances, and all expired or unfit products removed from stock for appropriate disposal? **Yes**/**No**
Can you show the dedicated room/zone for expired and other unfit products?

12. Which level of compliance can you give to your institution in implementing the good storage practices (tick the right answer):

Fully implemented	
Good	
Medium	
Low	

13. Can you please share the temperature and humidity records for the last three years i.e. 2016-17-2018 for further analysis in the frame of this study?

14. Can I take pictures outside &inside the warehouse to help me completing the collected information in this study?

Thank you very much for your contribution!

Interviewee:	
Names:	……
Institution:	……
Telephone:	……
Email:	……

Interviewer:	
Names:	Charlotte AKINGENEYE
Institution:	……
Telephone:	……
Email:	……

1. WAREHOUSE PREMISES EVALUATION CHECK LIST

Feature	**SITE: ……**
	Status: *Good / Medium / Poor / Absent*
a) Warehouse well ventilated	
b) Warehouse well cleaned with intact pavement	
c) Warehouse well equipped with temperature and Humidity monitoring devices	
d) Availability and usable air conditioning system	
e) Controlled substances kept in locked cupboard(s)	
f) Protection against direct sun light	
g) Availability and usable cold rooms	
h) Areas for flammable products	
i) Receiving area separated with dispatch area	
j) Enough and adequate lighting in the warehouse	
k) Security system to prevent easy access of unauthorized personnel / visitors	
l) Cartons are stacked at least 10 cm (4 inches) off the floor on pallets and/or shelves	
m) Cartons are stacked at least 30 cm (1 foot) away from walls and other stacks	
n) Stacked cartons are not more than 2.5 m (8 feet) height	
o) Separate storage area for expired and other unfit products	
p) Availability of ladder to allow access to higher locations	
q) Availability of equipment for lifting heavy loads	
r) Zones and locations labelled	

Note: Smart phone camera and visual inspection will be used to take pictures and other relevant information that will be used in describing the status of inspected warehouses.

DATA COLLECTION SHEET FOR TEMPERATURE AND HUMIDITY IN DRUG STORE

SITE NAME	Collected Data		JAN	FEB	MAR	AP	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	Mean of 12 months
Tick the right site: 1) MPPD 2) Gasabo DP 3) Kamonyi DP 4) Gisagara DP 5) Rusizi DP 6) Karongi DP 7) Rubavu DP 8) Nyabihu DP 9) Burera DP 10) Nyagatare DP 11) Kirehe DP	2016														
	TEMPERATURE	Mean of Minima													
		Mean of Maxima													
		Mean of daily averages													
		Down Pick													
		Max Pick													
	R. HUMIDITY	Mean of Minima													
		Mean of Minima													
		Mean of daily averages													
		Down Pick													
		Max Pick													
	2017														
	TEMPERATURE	Mean of Minima													
		Mean of Maxima													
		Mean of daily													

		averages													
		Down Pick													
		Max Pick													
	R. HUMIDITY	Mean of Minima													
		Mean of Maxima													
		Mean of daily averages													
		Down Pick													
		Max Pick													
	2018														
	TEMPERATURE	Mean of Minima													
		Mean of Maxima													
		Mean of daily averages													
		Down Pick													
		Max Pick													
	R. HUMIDITY	Mean of Minima													
		Mean of Maxima													
		Mean of daily averages													
		Down Pick													
		Max Pick													

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 19th/07/2019

AKINGENEYE Charlotte
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 348/CMHS IRB/2019

Your Project Title ***"Assessment Of Storage Conditions Of Pharmaceutical Products In Rwanda. Case of Rwanda Biomedical Center/Medical Procurements and Production Division And District"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umuresi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 19th July 2019, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

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

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 19th July 2019

Expiration date: The 19th July 2020

Professor GAHUTU Jean Bosco
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Ce:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

Republic of Rwanda

MINISTRY OF HEALTH

National Health Research Committee
Ref: NHRC/2019/PROT/040

To: **Charlotte Akingeneye**
Principal Investigator

Scientific Review Approval Notice

With reference to your request for approval of the Research Protocol entitled; "**Assessment of storage Conditions of Pharmaceutical products in Rwanda.**"; We are pleased to inform you that, following a thorough review and critical analysis of your proposal (**NHRC/2019/PROT/040**), your Research Protocol Has been approved by National Health Research Committee. However,

1) Changes amendments on approach and methodology must be submitted to the NHRC for review and approval to validate the changes.
2) Submission to NHRC of final results is mandatory
3) Failure to fulfill the above requirements will result in termination of study

Once again National Health Research Committee appreciates your interest in research and requests you to submit this proposal to the National Ethics Committee (NEC) and then share a copy of the approval letter from them.

Your final approval reference number is **NHRC/2019/PROT/040.**

Sincerely,

Dr. Parfait UWALIRAYE
Chairperson of NHRC

Date: 31/05/19

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES

EAC REGIONAL CENTRE OF EXCELLENCE FOR VACCINES, IMMUNIZATION & HEALTH SUPPLY CHAIN MANAGEMENT

RECOMMENDATION LETTER FOR APPLICATION FOR ETHICAL APPROVAL AND FOR DATA COLLECTION

Project title:	ASSESSMENT OF STORAGE CONDITIONS OF PHARMACEUTICAL PRODUCTS IN RWANDA. Case of Rwanda Biomedical Center/ Medical procurement and Production Division and Districts pharmacies.
Student ID.	21801464O
Supervisor/s:	1. Dr VEDASTE HABYALIMANA 2. JURDAS SEZIRAHIGA, (MSc) 3. Immaculee MUKANKUBITO, MSc
Degree enrolled in	Masters in Health Supply Chain management
Project location:	RBC/MPPD and Ten Districts pharmacies
Project Period:	From June – September, 2019

RECOMMENDATION

This is to certify that Mr./Ms. Charlotte AKINGENESE

Is an MSc Health Supply Chain Management student from the University o Rwanda, College of Medicine & Health Sciences, School of Public Health, EAC RCE-VIHSCM since October, 2017. The candidate has developed a thesis project as titled above. It has been presented to the Supervisors' Workshop, held from 27-29 May, 2019, in Kigali, as part of Quality Assurance and scientific panel approval process.

The candidate is recommended to the relevant ethical body in his or her country for IRB approval and permission to collect data where applicable. The data collection is supposed to last not later than mid-August 2019. The research will not involve any intervention or randomisation of human subjects and it has been cleared by the University of Rwanda.

In case of any questions, please do not hastate to contact **Dr. Regis Hitimana, RCE Research Coordinator**, E: regis.hitimana@gmail.com, T: +250 788 528 533

Any support rendered to the candidate will be highly appreciated.

Stephen KARENGERA
RCE Director

Email: director.rcevihscm@ur.ac.rw P.O Box 4285 Kigali, Rwanda www.hscm.ur.ac.rw