

# ASSESSMENT OF PHARMACY PRACTICE IN COMMUNITY

# PHARMACIES IN RWANDA

By

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A thesis submitted in partial fulfillment of the requirements for the award of the degree of master in pharmaceutical sciences quality assurance and quality control in the department of Pharmacy, School of Medicine and Health Science in University of Rwanda.

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# DECLARATION

I, Jean d'Amour HABUMUGISHA hereby declare that this thesis entitle" *Assessment of pharmacy practice in community pharmacies of Rwanda*" is original; it is entirely my own work, except where reference to other source has been indicated. I further certify that the document has not previously been presented for a Degree or any awards or examination to this university or any other University/ Faculty.

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I confirm that the work reported in this thesis was carried out by the candidate under my supervision.

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# **DEDICATION**

To Almighty God To my wife To my family To the family of HITAYEZU Felix

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# LIST OF ACRONYMS

**ASEAN:**Association of Southeast Asian Nations ANOVA: Analysis of Variance ADR: Adverse Drug Reaction ASHP: American Society of Health-System Pharmacists **CPD:** Continuous Professional Development EC:Emergency Contraceptive EC: European Commission **EVBP: Evidence Based Practice** E.U: European Union FDA: Food and Drug Administration FEFO: First Expire First Out FIFO: First in First Out FIP: The International Pharmaceutical Federation HIV/AIDS: Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome HbA1c: Haemoglobin (A1C) **GPP: Good Pharmacy Practice GP:** General Practitioner ICH:International Conference on Harmonization **ICT: Information Communication Technology** MEDLAS: Medical Literature Analysis and retrieval System MoH: Ministry of Health NPC: National Pharmacy Council **ORS:** Oral Rehydration Salt OTC: Over-The- Counter **RBS:** Rwanda Bureau of Standard **RDB:** Rwanda Development Board **RH:** Relative Humidity **PP: Pharmacy Practice** SAPC: South African Pharmacy Council SCM: Simulated Client Method SOPs: Standard Operating Procedures STIs Sexual Transmitted Diseases TFDA: Tanzania Food and Drug Authority **TB:Tuberculosis** UK: United Kingdom UR: University of Rwanda USA: United State of America **USP:United States Pharmacopeia** WHO: World Health Organization

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# ABSTRACT

Background: A vast majority of community pharmacists are concentrated in the cities of Rwanda. There is a wide gap between urban and rural dwellers when it comes to accessing pharmacy practice. Currently pharmacy professionalism is becoming more patient centered. Therefore, community pharmacies should improve the quality of their practice as aiming at meeting good pharmacy practice guidelines. **Objective:** The objective of this research study was to assess pharmacy practice in community pharmacies in Rwanda. Methods: A cross-sectional descriptive and analytical study of community pharmacies located in Rwanda was conducted from February to June 2017. A total of 150 out of 245 community pharmacies were randomly selected. The data were collected by using a tool developed and tested by Birna Trup et al in 2010; it composed of 34 pharmacy practices (PP) indicators that cover five components of pharmacy practice: system, storage, services, dispensing and rational drug use. The results were analyzed by using excel and SPSS version 20, and ANOVA was used to analysis if there were true differences between strata (provinces and Kigali city), where the values of p<0.05 was considered as Regarding the system, 80.7% (n=121) of pharmacies surveyed have significant **Results:** computer but more than half of community pharmacy operation activities are not computerized such as stock management 54.5% (n=66), prescription recording 66.1% (n=80) and for patient medication profile99.2%(n=120). 72.78 %(n=109) of pharmacies didn't has a formalized stock management system. In storage, 72.7% (n=109) of pharmacies didn't acceptable, hygienic, and functioning hand washing facilities. 77.3% (n=116) pharmacies didn't monitors the temperature of storage room. A poor 71.2 % (n=42) pharmacies didn't record the temperature of the refrigerator among those with a functioning system for cold storage. 98.7% (n=148), 98.0% (n=147), 30.0% (n=45) of pharmacies didn't labeled opened bottles with opening date, didn't have procedure for disposal of expired medicines and didn't compliant to FEFO respectively. In service only 2.0% (n=3) 0.0% (n=0), of pharmacies work 24hours in normal working and weekend day respectively. 8.7% (n=13) of pharmacies didn't have responsible pharmacist on the day of visit, 48.7% (n=73) of pharmacies use unqualified staffs to be in direct contact with patient/clients during community pharmacy operations. 88.0% (n=132) of pharmacies have didn't guaranty the patient/client privacy during dispensing process, and premises that community pharmacies intervention as a point of care testing and participating in health promotion activities is still low in all most all community pharmacies surveyed. In dispensing, An overall poor access to paper based health information resources by dispenser/pharmacy staffs was observed in most community pharmacies, dispensing envelope and spatula or spoon were the most usable material and equipment by all most all pharmacies, however their quality and hygiene remain uncertain. The average dispensing time was above 61 seconds in most pharmacies surveyed. 91.3 % (n=137) of pharmacies didn't have appropriate dispensing procedures. Poor professional collaboration with different health prescribers was observed in most community pharmacies. Rational use of medicine, Patient leaflets was available as the main source of patient information in 95.3% (n=143) of pharmacies. 78.9% (n=1184); 67.9 % (n=1019) and 62.6 (n=939) of patients/clients riving the community pharmacy didn't know the frequency, the cause and other necessary information of their medicines respectively. All medicine bought/received by patient from community pharmacies surveyed weren't 100% conform to good labeling practice (not adequately labeled with Quantity85.7% (n=1286), Expiry date92.4% (n=1386), Dose73.5% (1102);, Patient name 93.6% (n=1404) and Facility name99.0% (n=1485).Dispensing antibiotics without prescription was a common bad practice in 95.3 %( n=143) community pharmacies surveyed in Rwanda. Conclusion: The majority of the community pharmacies operated privately in Rwanda was not meeting good pharmacy practice guidelines. This implies the lower quality of pharmacy practice in community pharmacy in Rwanda. Therefore, trainings of pharmacy staffs, application of code of Ethics, developing and implementing community pharmacy practice standards under its corresponding scope of practice and regular supervisory visits are recommended for the improvement community pharmacy practice in Rwanda.

Key wards: community pharmacies, professionalism, pharmacy practice guidelines, Rwanda

# **CHAPTER ONE: INTRODUCTION**

This chapter concerns the background of the study, the problem statement, objectives of the study, motivation of the study, and significance of the study.

## 1.1 Background of the study

For many decades, pharmacy practice has dominantly discussed as it is the central part of pharmacy professional (Prathima V et al., 2014, FIP/WHO 2011).) Pharmacy practice is "the discipline within Pharmacy that involves developing the professional roles of the pharmacist and is aiming at providing and promoting the best use of medicines and other health care services and products, by people and society" (WHO, 1993). It is also expresses our covenant with the patient not only the promotion of patient welfare but also to facilitate pharmaceutical care implementation within different health settings such as community pharmacies (WHO, 1996).

Pharmacy practice within community settings varies enormously from one continent to another and from one country to another, including developing, transitional and developed countries(FIP/WHO2011). A survey conducted in 2010 in Ethiopia, Uganda and Zimbabwe revealed that within these community settings, pharmacy staff were often insufficiently trained, inappropriate sales practice was common, drug regulation was often not enforced, and how medicines were stocked were not in line with good storage practices(WHO, 1996). Moreover, the potential benefit of community pharmacy practice is often not realized within the same country. For example a research study conducted in Qatar community pharmacists outlined that the labeling, dispensing, and counseling practices were below expectation, thus urging the need for continuous professional development (Ibrahim et al., 2016)<sup>°</sup>

Despite that variation in practice, uniqueness of community pharmacy practice within the same country should be recognized under established national standard (FIP/WHO2011).

Community pharmacy means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited pharmacy service. It is also defined as a unique primary healthcare position, consider as a valuable resource for health advice and medicines in communities; and a facility to be fully aware of the patient's past and current drug history and, consequently, can provide essential advice to the prescriber (Birnatrap et al., 2010) However, this special pharmacies facility need a special continuous monitoring for responding to public expectations; otherwise it may contribute to some errors and led to death. For instance, a research conduct in United State of American revealed that that medication use and medication error have become increasingly complex and become a major cause of preventable patient harm as more than 250,000 dead per year are due to medical error in the U.S and classify Medical error as the third leading cause of death in the U.S (Martin and Makary, 2015).

Since the economy liberalization in different countries was stared, economic income from many countries was increased in many domains; such as pharmacy, where its income is growing worldwide despite noticeable challenges toward comply with Good Pharmacy Practice guidelines. For instance, in Rwanda in the late 1994s that liberalization gave rise to a significant increase in the number of community pharmacies (RDB 2015). However, this connection between the professional services of pharmacy and retail trade within community pharmacy has dramatically increased in its positive side. But on the other hand, it turning to its negative side where some retail or community pharmacies are becoming economically driven rather than patient care oriented. Therefore, this pharmacy practice output will led to losing confidence in further developing pharmacy professionalism.

Interestingly, World Health Organization in collaboration with International Pharmaceutical Federation have developed different standards and guidelines for pharmacy services such as "Good pharmacy practice in community and hospital pharmacy settings" that are intended to provide a description of ways in which pharmacists can improve access to health care, health promotion and the use of medicines on behalf of the patients they serve (WHO, 2011).

According to Rwanda in its vision 2020, many policies have been set. The National Pharmaceutical Policy that is aiming at improving Rwanda population's health through sustainable provision and rational use of equitably accessible and affordable essential quality health commodities and technologies (MoH 2016).National Quality Policy that guarantee efficiency and effectiveness in the goods and services delivery, better public health, safety, environmental and consumer protection aim at leading to sustainable economic growth as result of well-coordinated government and private institutions (RSB 2010).

Despite Rwandese commitment toward assuring the good healthcare and welfare values of its people, researches are need to know at which extent community pharmacies are meeting Good Pharmacy Practice Guidelines.

#### **1.2Problem statement of the research**

In Rwanda, community pharmacy practice is still on its infant stage, and most community pharmacy staffs seem to develop their professionalism in pharmacy practice based on their academic knowledge only, which is not sufficient to respond to patient needs; hence creating gap in meeting patient expectations toward achieving Good Pharmacy Practice. Besides that, the public are more and more willing to challenge poor services and care delivered, and raises concerns when their expectations are not met. Consequently, community pharmacies will lose their confidence from the public if nothing done early Otherwise continuous malpractices such as irrational use of drugs and other health care services and products, by patients and members of the public may lead to the violation of patient welfare at all times. Unwillingly, community pharmacy staffs may be subjected to preventable punishment as they don't abide to their concerned Law. In fact, some community pharmaceutical products and malpractice as reported by Ministry of health and National pharmacy council in 2016. (NPC 2016)

In addition, community pharmacy practice is not well defined as mother of fact there is no information or a research study conducted about pharmacy practice or the scope of pharmacy practice in general or a research study which highlight what community pharmacy staffs should do and how they should perform with regards to Good Pharmacy Practice. Indeed the lack of community pharmacy standards that highlight required pharmacy premise, materials and equipment, might reduce the quality of pharmacy practice in community settings. Therefore, national community pharmacy practice standard or scope doesn't exist currently; even if National Pharmaceutical Police has been elaborated. One of the aforementioned problems was due to not taking into account the implementation and monitoring of the 2011 update of the joint FIP/WHO guidelines on Good Pharmacy Practice (FIP/WHO 2011).

Furthermore, Pharmacy Practice need to rely on evidence based practice (FIP/WHO 2011), however evidence based community pharmacy practice in Rwanda is remaining unforeseen; as such information is valuable to facilitate development of policies and interventions to optimize community pharmacy practice in the context of Rwanda.

Unless community pharmacy practice will be improved, pharmacy staffs will continue to have trouble in meeting pharmacy profession standard as well as not fulfilling their responsibility toward different pharmaceutical trends like pharmaceutical care ,pharmaceutical evidence-based practice. Consequently, this practice will causes devastating, debilitating, and life-threatening complications to the patient and the country. Therefore, there is a need to conduct a survey that is aiming at assessing community pharmacy practice and it will come up with many solutions toward improving pharmacy professional and help different stakeholders to take appropriate decision toward the well-being of people in Rwanda.

This research study addressed the following **research question**: To what extent community pharmacies of Rwanda meet Good Pharmacy Practice guidelines?

# **1.3 Research Objectives**

# 1.3.1 General Objective

The general objective was to assess the quality of Pharmacy Practice in community pharmacies of Rwanda.

## **1.3.2Specific objectives**

To evaluate in community pharmacies:

- 1. The system that is being used
- 2. The storage practice
- 3. The service delivery
- 4. The dispensing practice
- 5. The rational use of medicines

## 1.4The rational of the research study

The motivation of this study is relying on the current context of community pharmacy practice in Rwanda; where the numbers of people requiring optimal pharmaceutical services has steadily increased as far as evidence-based pharmacy practice is growing exponentially, and this trend will likely continue. Incessantly, community pharmacists are facing new challenges that expand their responsibilities and opportunities toward making clinical decisions (usually with a physician's consent), that affect their patient's medical care such as changing doses, therapeutic switches between medications, and starting and stopping medication(https://sciencebasedpharmacy.wordpress.com/). The rational of this

research study is to ensure the optimum community pharmacy practice to the patient and society.

Therefore, this research study is just the first step in the journey to implement, monitor and respond to Good Pharmacy Practice Guidelines as well as eliminates malpractice among pharmacies of community settings in Rwanda. It will motivate different stakeholder for taking appropriate decisions toward patient centered pharmacy practice and assuring the welfare of the population.

# **1.5Significance of the proposed work**

This research study is intended neither to give the analysis of pharmacy practice or scope of pharmacy practice in general but rather to end up by fully qualifies and quantifies the real scale of community pharmacy practice in Rwanda and the tools used in data collection will generate a blueprint for improving professionalism in pharmacy practices. It will be used for elaborating National Community Pharmacy practice standard. Moreover, the study will come up by bring expected fruit to different stakeholders, to all practicing pharmacy professional and patients and members of the public.

# **CHAPTER TWO: REVIEW OF LITERATURE**

This chapter concerns the literature review related to pharmacy practices. It highlights definition of some terms and the mains components of community pharmacy practices from the effectiveness of system used in pharmacy to rational use of medicines.

# 2.1 Definition of terms

# 2.1.1 Pharmacy Practice (PP)

Pharmacy practice's objective is providing medication and other health care products and services and helping people and society to make the best use of them (WHO 1996, FIP 1998).

# 2.1.2 Good pharmacy practice

Pharmacy practice's objective is providing medication and other health care products and services and helping people and society to make the best use of them (WHO, 1996). Standards for Quality of Pharmacy Services were drawn up by FIP in 1993 (FIP, 1997), and in 1996 this document was adopted by WHO and introduced as guidelines to Good Pharmacy Practice (GPP) in Community and Hospital Settings (WHO, 1996). GPP in Developing Countries focuses on four major areas: Personnel, Training Standards, Legislation and national drug policy. For each area there is a range of steps representing different levels of pharmacy practice, which ranges from the lowest acceptable to the ideal condition. Of the four areas, "standards" is focusing on the pharmacy practices at the individual dispensing facility. It comprises of recommendations for; premises, dispensing, containers, labeling, instructions to the patient, records, health information, patient counseling and pharmaceutical care, self medication and products (WHO 1996)

# 2.1.3Community pharmacies

Community pharmacy means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited pharmacy service. It is also defined as a unique primary healthcare position consider as a valuable resource for health advice and medicines in communities and a facility to be fully aware of the patient's past and current drug history and, consequently, can provide essential advice to the prescriber (Birnatrap et al., 2010).

## 2.1.4 Evidence-based practice

Evidence-based practice is a holistic approach to treatment, which integrates a clinician's knowledge and expertise, effective treatment interventions, and patient preferences, needs, and values. This approach improves treatment outcomes by taking into account each component of successful treatment. Without evidence-based practice, patients needing care would not receive the most effective treatment (www.mcppnet.org/publications/ISSUE04-1.PDF).

Therefore, for rational use of medicine, pharmacist need to practicing professionally based on the best evidence available and making the evidence of our practice available for policy makers and Practicing pharmacy in an evidence based manner will enhance professional satisfaction and increase the pharmacist's capability to do what is best for the patient (Melnyk, 2010).Some research studies have revealed that Evidence Based Practice leads to quality of care and improve patient outcomes and reduce health costs (Melnyk, 2010).

#### 2.1.5Professionalism

Is defined as a member of a profession who displays the following 10 traits: knowledge and skills of a profession, commitment to self-improvement of skills and knowledge, service orientation, pride in the profession, covenantal relationship with the client, creativity and innovation, conscience and trustworthiness, accountability for his/her work, ethically sound decision making, and leadership. Therefore, the essence of professionalism is the ability to display the characteristics of a professional" (American Pharmaceutical Association Academy of Students of Pharmacy American 2000) and (WHO 1998).

# **2.2The concept of pharmacy practice within community settings move forward to professionalism**

Over the past years, the pharmacy practice has changed from that of compounder and dispenser to one of "drug therapy manager". Currently, Pharmacy practice includes patient-centred care with all the cognitive functions of counseling, providing drug information and monitoring drug therapy, as well as technical aspects of pharmaceutical services, including medicines supply management. Therefore, pharmacists are now making a vital contribution to patient care through their role of managing drug therapy problems. (Karin Wiedenmayer et al 2006).

Pharmacy practice is interconnected with Pharmacy professional, but due to its considerable expansion with respect to professional delivery services in the past few

years, the pharmacy profession is now acknowledged as an essential profession in the multidisciplinary provision of health care (Azhar et al., 2009). One of the main aims of the pharmacy profession is promoting safe and rational use of drugs (Smith, 2004).

Pharmacy practice is involved in wide variety of settings such as community pharmacies, where in many developing countries; they serve as a vital primary source of medical advice (Lara et al, 2006). They are often the most accessible and available healthcare outlets in many communities (Sneeringer et al., 2012).

In addition waiting periods in community pharmacies are typically short and services rendered including information and direct sales of medications are often less costly than those of other health-care providers (Sneeringer et al., 2012). Qualified community pharmacists and other pharmacy employees have been known to effectively deliver care related to stigmatized health conditions, including sexually transmitted infections (STIs), family planning, and emergency contraception (EC) (Sneeringer et al., 2012). They have been highly successful because of their ability to ensure rapid access to medications, supplies, medical information, and guidance while maintaining client confidentiality (Sneeringer et al., 2012).

Competent of pharmacy practice

## 2.3System and computer use in pharmacies

# 2.3.1 Importance of using computer in community pharmacies

Computers are used by community pharmacy staffs for various functions. Managerial functions include generation of multiple sales analyses for a day, month, and week and to date for number of prescriptions handled and amounts in cash. Estimation of profits and financial ration analysis, calculation of number of prescription handled per unit time, printing of billing and preparation of annual withholding payrolls details. In addition some accounting functions are like preparation of prescription label, providing a receipt for patient, generation a hard copy record of transactions and automatically ordering the low quantity products via electronic transitions (Yadhav, 2008).

Computers can be effectively used for purchasing and inventory control in community pharmacy and other drug outlets. Whenever an item is added to the stock or removed from the stock, immediately position of the stock can be updated by computers. For annual auditing, records of numerous items are required; this can be easily handled by using appropriate computer software. Billing process can also be computerized. Demands of various products can be easily evaluated by using computers by tracking the movements of stock.

Complete search of the drug information is necessary for the pharmacist to satisfy the queries about pharmacological actions, pharmaceutical care activities and toxicology. This search job is simplified by use of computers. The computerized information recovery is time saving and satisfying with the extra advantage of more detailed and timely than manual search. For gathering of information, international data banks are available such as World standard drug database, Drug bank, MEDLARS (Medical Literature Analysis and Retrieval System) and DIALOG(Shaha et al., 2008).Drug Bank database is a unique bioinformatics and cheminformatics resource that combines detailed drug (chemical, pharmacological and pharmaceutical) data with comprehensive drug target (sequence, structure, and pathway) information. The database contains 6826 drug entries including 1431 FDA-approved small molecule drugs, 133 FDA-approved biotech (protein/peptide) drugs, 83 nutraceuticals. Additionally, 4435 non-redundant protein (i.e. drug target/enzyme/transporter/carrier) sequences are linked to these drug entries (Shaha et al., 2008).

Currently, new pharmacy services and innovative ways of working are being developed, such as electronic prescribing and dispensing which require real-time access to electronic logistic management information, pharmaceutical records and ease medical records for responding to patient needs (S. Goundrey-Smith2013).

## 2.3.2 Pharmaceutical inventory management system

Inventory management refers to the process of managing inventory in order to meet patient needs at the possible cost effeteness investment. It is an important component of the drug supply system. Unlike many factors in pharmacy, inventory is controllable, and the pharmacy department normally decides how much inventory investment to make, when to reorder, and in what quantities (Blackburn, 2010). Accurate and current stock records are essential to good inventory management. Instant, good pharmaceutical management of some medicines like ant malarial and other essential medicines has great contribution in reducing the cost of purchasing medicines, both at the national, health facility levels and patient. Therefore, if the system is well used, it will be a prominent source of information for calculating the needs of patient. Otherwise inaccurate records produce inaccurate needs estimations (and problems of stock outs and expiry) (Dobler et al, 1996).

# 2.4 Storage conditions of medicines in pharmacy

Saying storage condition of medicines involves the stability test of medicine and guidelines which refer to temperate climates. Indeed, storage condition tolerance is another component to consider as it refers to acceptable variations in temperature and relative humidity of storage facilities for stability studies (Taylor, 2001). However, the stability of medicines distributed and used in hot and humid climates can pose serious problems which may not be relevant in extreme climatic conditions (Hogerzeil, 1992).

The storage conditions of medicine and the extent of stability studies selected should sufficiently address storage, shipment and subsequent use of a particular medicine with regard to climatic conditions in which the same medicine is intended to be marketed; and the equipment used should be capable of controlling the storage conditions within the ranges (Center for Biologics Evaluation and Research, 2012).

# 2.4.1Global storage conditions and climatic zones

The standard climatic zones for use in pharmaceutical product stability studies for storage conditions of different climatic zones are shown in Table 1(Cha et al., 2011),whereas table 2showns list of the components in the long term testing conditions.

Zone	Type of Climate
Zone I	Temperate zone
Zone II	Mediterranean/subtropical zone
Zone III	Hot dry zone
Zone IVa	Hot humid/tropical zone
Zone IVb	Hot/higher humidity

 Table 1: Climatic zones

Source: Makala, 2013

Climatic Zone	Temperature	Humidity	Minimum Duration
Zone I	$21^{\circ}\text{C} \pm 2^{\circ}\text{C}$	45% RH ± 5% RH	12 Months
Zone II	$25^{\circ}C \pm 2^{\circ}C$	60% RH ± 5% RH	12 Months
Zone III	$30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	35% RH ± 5% RH	12 Months
Zone IVa	$30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	65% RH ± 5% RH	12 Months
Zone IVb	$30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	75% RH ± 5% RH	12 Months
Refrigerated	5°C ± 3°C	-	12 Months
Frozen	$-15^{\circ}C \pm 5^{\circ}C$	-	12 Months

**Table 2: Long term testing conditions** 

Source: Makala, 2013

Globally, storage conditions is still an issue to manufacturers when they send labeled packaging materials with instructions for climate zone II to the markets in climates of tropical zones of IVa and IVb(E-DRUG, 2012). This practice is due to that they do not find the necessity of spending money on instituting relevant packaging and conducting stability studies(Makala, 2013)

Some countries accept drugs developed at much lower standards to circulate in their markets. One example is India where most of its products are labeled, store below 25oC as the national accepted that standard irrespective of the fact that medicines are frequently sold in drug outlets openly without air conditioners and / or refrigerators (E-DRUG, 2012).

The International Conference on Harmonization and the World Health Organization have argued for many years on the question of storage conditions in ASEAN countries, and came up with climate zone IVb accelerated testing at 40oC/75% relative humidity. (Makala, 2013).That conference end up by recommended that storage condition for medicines that meets the requirements for climate zone IVb should not be above 30oC. In addition long-term (real time) and accelerated storage conditions for pharmaceutical

products can be observed as in a climatic zone IVb (TFDA, 2008). However, there is no storage instruction for relative humidity(E-DRUG, 2012).

Therefore, this recommended storage instruction is sometimes not clear to patients because they can even store tablets in the refrigerators during hot conditions as mother of fact they don't have a real limit on how the temperatures and humidity are supposed to be complied with. Otherwise storage in refrigerators is accompanied with exposure to high humidity leading to fungal growth on the medicine (Makala, 2013).

# 2.4.2General medicine storage procedure and instructions in pharmacy

Pharmaceutical products must be stored under conditions which minimize deterioration, contamination and damage. They should also be stored under conditions compatible with their recommended temperature and humidity storage requirements. The appropriate temperatures for materials labeled "store in refrigerator" should be between 2oC and 8oC and those labeled "store in freezer" between -5oC and -20oC(Zeinab et al., 2004). In the absence of more stringent storage requirements, pharmaceutical products and raw materials should be stored on the average below 25oC to 30oC(Zeinab et al., 2004).

#### **2.5**Services offered in community pharmacies

Since 1970, community pharmacists have been encouraged to play active role in public health by displaying health education literature(Anderson S .2007). In 1978, a working party on general practice, pharmacy argued that health education and diagnostic testing were their important roles (Anderson S .2007). As documented by a survey run jointly by the Family Planning Association and the Pharmaceutical Society, many pharmacists were already involved in giving advice on contraception and related problems, and were enthusiastic to extend this role further (Pilot scheme for extending pharmacists' advisory role Pharmaceutical, 1982). Also pharmacist play a crucial role in sexual health services and services for drug users (Anderson et al., 2003). It was also found that pharmacists were able to actively involved in safety of medicines, dental health, prevention of coronary diseases ; and patient compliance and information was conveyed to patients using posters, leaflets and audiovisual displays (Blenkinsopp et al., 1999). Some pharmacists were trained to monitor blood pressure. A systematic review report from Pharmacy Health Link demonstrated the effectiveness of pharmacy-based interventions in reducing high-risk behaviors and risk factors for coronary heart disease (Blenkinsopp, 2003).

All Community pharmacy should have a comfortable area that guarantees patient privacy. Every patient must be treated with respect especially when explaining the use of some types of medicine (WHO, 1996). The number of qualified pharmacy staff can ascertain the competence of dispensing site/pharmacy personnel and indicate the degree to which good pharmacy practice can be implemented. However pharmacist is responsible of all activities carried out in pharmacy (FIP, 1998). Lastly, weekly opening hours of the dispensing site is an indicator that shows Pharmacists' workload and increase working hour in pharmacy would imply the increase in access to pharmaceutical services by patient/client (Jon C. Schommer, Ph.D. 2001).

#### 2.5.1 Diagnostic screening

In Estonia, Netherlands, South Africa, Brazil, Nigeria and Belgium, within the scope of extended services, many community pharmacies provide diagnostic screening for blood pressure, blood cholesterol, and capillary glucose (Flobbeet al., 1999; Wasmann-Van Wisseet al., 2002; Simoenset al., 2005; Pamela, 2006; Volmeret al., 2006; Adje and Oparah, 2013). In German, apart from the promotion of rational prescribing and appropriate use of medicine, community pharmacists provide health promotion, drug information, pharmaceutical care and preventive care services for asthma, diabetes, and hypertension (Eickhoffet al., 2001; Eickhoff and Schulz, 2006).

A survey in Australia found significantly more positive attitudes in pharmacists who had experience of pharmacy health screening or promotion than those who did not have. In addition, attitudes from pharmacist with experience of public health services were also found to be significantly more positive compared to a similar survey carried out around seven years previously (The et al., 2001).

Community pharmacists could also be involved in osteoporosis risk assessment and risk screening service; the later service was provided for women in Thailand (MacLaughlinet al., 2005; Chaiyakunapruket al., 2006; Johnson et al., 2008). Several studies described the uptake assessments on osteoporosis risk and bone density measurement with advice and referral. Overall the results show that community pharmacy-based bone health assessments can identify people who need to be referred for further medical assessment (Elliott et al., 2002, 2002; Lataet al., 2002; Lai et al., 2003; Cerulli and Zeolla, 2004). There is some evidence that advice given to women identified to be at lower risk may result in increased dietary intake of calcium and increased exercise. Use feedback about the services was highly positive (Gray et al., 2002; Cerulli and Zeolla, 2004). A cost-

effectiveness evaluation found that offering such a service could be financially viable depending on the local situation (Cerulli and Zeolla, 2004).

In Nigeria," the community pharmacists osteoporosis educational program" was a community pharmacist intervention pilot project in which high risk individuals were followed up for up to six months. At the end of the study, more than half of the patients began taking calcium supplementation, an equal number sought consultation from primary care physicians, and nearly one third obtained bone density test. Apart from screening for osteoporosis, portable devices like the Lunar Achilles Utrasonometer have been used to do actual determination of bone density in the pharmacy and this demonstrated that pharmacists involvement in osteoporosis is both feasible and practical (Newman and Hanus., 2001). A study which had assessed the impact of a community pharmacy osteoporosis risk assessment service in collaboration with GP practices showed that patient knowledge about bone health ,appropriate daily calcium intake increased and appropriate high risk patients were referred to the GP (Gray et al., 2002). In USA, nearly all individuals receiving community pharmacy osteoporosis screening and education reported that the information provided increased awareness (98%), they were satisfied with the interaction (92%), and found the advice valuable or highly valuable (Law and Shapiro, 2005; McLaughlin, 2005).

## 2.5.2 Sexual health advices

Community pharmacists have a prominent role in sexual healthcare services. They are providing emergency contraception (Harrison-Woolrychet al., 2001); pregnancy tests, condoms, and treatment for vaginal Candida infection (Hassellet al., 2001); information on hepatitis B and HIV (Watson et al., 2003) and sexual health promotion (Vic, 2004). Two pilot studies from UK and Netherlands demonstrated the feasibility of providing Chlamydia screening through community pharmacies. The authors of the UK study concluded that the provision of Chlamydia testing in community pharmacy seemed to increase access to those tests among those who were in need of them, and could potentially reduce demand in other sexual health services. Community pharmacies are a suitable location for Chlamydia testing and treatment, because clients valued speed and convenience in the service and a friendly non-judgmental approach have been offered at that place (Van Bergen et al. 2004; Baraitseret al., 2007). In Swedish, the majority of participants in studies on health screening(71%) and promotion (74%), and Chlamydia

testing (75%), revealed that pharmacists were appropriate providers of these services (Lawrieet al., 2004; Baraitseret al., 2007; Bjorkmanet al., 2008).

## 2.5.3 Immunization

Immunization services were being given by community pharmacists in USA and Aderemi-Williams and Agile (2007) argued that community pharmacies could be possible centers for routine immunization. A study from USA also showed that pharmacists have been already permitted by law to administer vaccination to adults in all 50 states (Krisberg, 2012). The vaccines administered by pharmacists to adult patients included influenza, pneumococcal, tetanus, diphtheria, pertussis, hepatitis A, B, C, Human papilloma virus, measles, mumps, rubella and shingles vaccines (Neuhaseret al., 2004). Evidence in published medical literature with respect to immunization services suggests that pharmacies are uniquely positioned to influence previously difficult-to-reach populations (Hogue et al., 2006; Uscher-Pines et al., 2010; Westrick, 2010; Crawford et al., 2011). Francis and Hinchliffe (2010) conclusion based on a review of pharmacy-led immunization programs found that pharmacies could be effective in immunizing highrisk, older adults who are more likely to need prescription medications and, therefore, use pharmacy services. Pharmacist interventions have been shown to improve medication adherence, provide increased access to health care expertise and advice and perform a variety of primary care services (Jiang et al., 2010). It has also been supported by Weitzel and Goode (2000) that immunization services can be provided safely through community pharmacies. Pharmacy patient medication records are effective in identifying "at risk" clients who can then be invited for immunization and pharmacy-based services can extend the reach of immunization programmes (DavidseandPerenboom, 1995).

"Users" satisfaction with the immunization service is high and support for non-physician immunization, as it was found to be greater for adult than for child immunization (Grabenstein and Ernst et al., 2001). A UK pharmacy-based immunization service (for influenza in particular) seems to have been reasonably well-accepted by patients, physicians and pharmacists (Hind et al., 2004). A survey of users of pharmacy-based immunization services conducted in the US (Grabenstein, 2001) also stated a preference for pharmacy immunization based on access, convenience, trust, and cost. Most users reported being satisfied with the service received and said they would recommend it to others. A study report in West Virginia, USA also concluded that convenience of location and opening times were the most influential factors in mothers" preferences for their

children to be vaccinated at the pharmacy (Ndiayeet al., 2003). In the Netherlands, community pharmacists worked with local family doctors to promote vaccination and the coverage of vaccination was found to increase by 50% to 75.5% in the intervention group, compared with an increase of 18% in a comparable group composed of only participating family doctors (Davidse and Perenboom, 1995).

## 2.5.4 Weight management services

Regarding weight management services, one study in Denmark reported the results of the effort to lose weight for obese clients. Average weight loss (self-reported by clients measured on scales in the pharmacy) was 5.3 kg for females and 6.2 kg for males. At one-year follow-up, 20% of clients who completed the course had maintained a weight loss of 5 kg or more (Tubro, 1999). In a Swiss study, 3800 people who had participated in community pharmacy-based screening for diabetes were asked to take part in a program of lifestyle counseling. Of the 1370 who took part, the mean weight loss of 2.25% at 3 months. People in the high-risk counseling group (245) showed weight loss of 2.25% at 3 months and 2.74% at 1 year (Botominoet al., 2008). In Sweden and Belgium, fitness check services, providing advice on weight loss, diet and health, as well as lectures on fitness, health and group exercises have been delivered (Westerlund and Björk, 2006; Mehuyset al., 2009).

#### 2.5.5 Chronic disease management

The evidence for positive outcomes of community pharmacists" involvement at improving general health and maintaining the health of those with existing disease is strongest, particularly in cardiovascular disease prevention, blood pressure management, diabetes and possibly asthma and heart failure (Van Wijk, 2005; Blenkinsopp and Bond, 2008; Agomo, 2012). Community pharmacies have an important role to play in diabetes management (Johnson and Beach, 1997; Blake et al., 1999; Jacobson, 2000). In addition to dispensing prescription medications, their involvement shows beneficial effects in patient education and disease management (McElnayet al., 1993; The et al., 2001). Diabetes management in both clinics and community pharmacy settings are highly effective, and a high proportion of consumers currently support pharmacist provision of health testing services (Jaber et al., 1996; Davidson et al., 2000). Such programs may include a range of services: support of self-blood glucose monitoring and promoting patient adherence with medication and other components of self-management, identifying

and resolving drug-related problems, providing targeted education, monitoring blood pressure, weight and lipids (Armouret al., 2004; Clifford et al., 2005). In Finland and Portugal, since the late 1990s, pharmacies have actively participated in national public health programs, in the areas of asthma and diabetes, and in the treatment and prevention of heart disease (Bell et al., 2007; Costa et al., 2006).

There is also evidence from Australian studies of effectiveness of pharmacy-based diabetes management services that lead to a significantly greater reduction in HbA1c compared with controls. An Australian RCT also showed that pharmacy-based targeting of people with risk factors for diabetes together with "point of care" blood glucose testing prior to referral was more effective and cost-effective than targeting and referral alone (Krasset al., 2007b). A survey in Sweden found that around three quarters of pharmacy customers thought that pharmacy could influence people's willingness to improve their health (Larsson et al., 2008).

With respect to blood pressure management, a study in Finland found out that there is room for improvement in hypertension management and that many problems were caused by patients' behavior with medicines (Enlundet al., 2001). In Switzerland, "resistant hypertension" was the main problem which was caused by poor adherence (Burnieret al., 2001). Under the name "disease management," the Portuguese has implemented a pharmaceutical care program for hypertensive patients and the program resulted in significantly better blood pressure control (Garcao and Cabrita, 2002). A pilot study in the UK showed that the implementation of a pharmacist-led hypertension clinic improved blood pressure control and appropriate prescribing of anti-platelet agents and statins for primary prevention of coronary heart disease and secondary prevention of arthrosclerosis (Reid et al., 2005). Similarly, in rural Portugal, a RCT in one community pharmacy tested an intervention comprising an individualized plan for action in relation to diet, physical activity, obesity and alcohol intake and blood pressure control were found to be improved significantly in the intervention group (Garcao and Cabrita, 2002). A similar study by Cote et al (2003) also found that the blood pressure control was improved in the intervention arm of a community pharmacy-based health promotion program.

Many studies into the effect of pharmaceutical care for asthma patients in community pharmacies have been conducted in a number of countries, including Denmark, Finland, Germany, Malta, Northern Ireland, the Netherlands and Spain. Most studies were successful and showed significant impact on economic, clinical and humanistic outcomes (Mangiapaneet al., 2005). A study in New Zealand determined the impact of a community

pharmacy-based pharmaceutical care service to asthma patients. The service involved the creation of a patient record, identification of medication-related problems and development of strategies to resolve these problems and monitor outcomes. The study showed that this service led to improvements in asthma management and quality of life for the majority of patients (Shaw, 2000). In USA, the majority of participants receiving self-management interventions from community pharmacists for asthma (89%) and diabetes (97.5%) were satisfied with the care they received from the pharmacist (Nahriet al, 2002; Feraet al., 2008). However, only 71% and 61% of those receiving the asthma self-management interventions were satisfied by the education and counseling provided by physicians and nurses respectively (Nahriet al, 2002).

# 2.6Dispensing practices in community pharmacies

#### 2.6.1 Dispensing process

Dispensing process involves preparation and dispensing of medicines according to a prescription or not to a patent/client. It also involves proper preparation and labeling of medicines for patient according to the instructions of prescriber (Agrawal et al., 2012). Dispensing is crucial process for assuring rational use of drugs as a small mistake can lead to wrong drug, wrong dose , wrong advice, therefore it is important that drug should be dispensed correctly (Balzer et al.,2012). Dispensing practice also involve, have basic, independent (not promotional material) and up-to-date welfare and healthcare information and appropriate dispensing equipment and packaging materials to be able to respond to patient/client needs (FIP, 1998; WHO, 1996).

# 2.6.2Role of pharmacist in dispensing practices

The professional services and activities of the pharmacist have considerably evolved in the last decades. Today, the main health-related activity of a pharmacist is to ensure quality of dispensing (Caamano, 2005). The role of pharmacists in dispensing medicines is very important and all the resources involved in patients' care, up to the point of dispensing, may be wasted if dispensing is erroneous. World Health Organization, (1988) recognizes and advocates the role of pharmacist as 'seven star pharmacist' who is a care giver, decision maker, communicator, leader, manager, lifelong learner and a teacher.

The role of pharmacist is usually laid down in the drug laws of a particular country, thus making it possible for the community to get lawful benefit of the pharmacist's presence in health care system. The pharmacist is required to procure good quality medicines from the right source, store them as per their specifications, dispense them in a lawful and

professional manner when required, communicate vertically with the physicians and ensure that the patient uses his medications as per advise and monitor their therapy (Caamano, 2005).

#### 2.7Rationale use of medicines in community pharmacies

Community pharmacies act as major healthcare site throughout the world. Diversity in their distribution and operational setups make them an easily accessible and economical source for healthcare delivery (Adepu and Nagavi, 2006). Personnel working at pharmacies are consulted for health advice on problems of all kinds, and remedies are sold or dispensed. Some of the remedies are safe and effective when used correctly, but others are dangerous (WHO, 2000).

Community pharmacies are seen as a quick source of advice, referral, medicines and information by the patients (Qadwai et al., 2006) .The way drugs are procured, stored and dispensed, and the information given by the dispensers dictates the quality of their use, thus leading to rational or irrational use of medication(WHO, 2000). Perhaps rational use of medicine could be a challenge in these settings.

According to World Health Organization (WHO), rational use of drugs necessitate that 'patients receive medicines appropriate to their clinical needs, in doses, that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community'(WHO, 2006). The perspective of a patient is to get less number of drugs in few doses with minimum cost to cure in the shortest possible time. From business perspective, community pharmacies should always generate profits; this inherent conflict of interests among the stakeholders which makes the promotion of rational drug use extremely complex. It is also difficult in countries where laws and ethics are not properly implemented. The major factors which contribute to irrational drug use can be tagged as originating from patients, prescribers, dispensers, the place of work, the medicine supply system including influence of industry, pharmacies, information on drugs, regulation and combination of all these factors(Ambwani and Mathur, 2008).

Community pharmacies can be considered as the important players affecting drug use; owing to their scale of operations and placement in the healthcare delivery system. Keeping in view the importance of community pharmacies and their outreach to the patients, many developing countries have used their potential to promote safe and effective treatments by enhancing their dispensing practices (Azhar et al., 2012).

## 2.7.1 Medicines information in theoretical context

Medicines information is seen as an important part of health and everyday life information, e.g., information people need in their everyday life in the contexts not relating to their work. This is based on the fact that medicines information has been commonly included as a sub-category in studies on health and everyday life information (Williamson 1998, Fox 2006). Consumers may not only want to have information on how to manage their medicines, but also information to make therapeutic choices (Newby et al. 2001). Therefore, it is suggested that medicines information should be provided within the wider framework of general health information (Newby et al. 2001, Raynor et al. 2007, Commission of the European Communities 2008).

Medicines information (British) and drug information (American) are synonyms that are used to describe a variety of statements that relate to medicines. However, there is no single generally accepted or established definition. Instead, medicines information has been defined from several perspectives: the perspective of consumer, pharmaceutical industry, society, regulatory authorities or media depending on the purpose and approach of the study or on the context in which the term is used (Wahlroos 2003, Närhi, 2006). The definition, content, and interest of communicating about medicines are related to the actors involved.

In a widest sense, the term 'medicines information' refers to all kinds of medicine related information available to the public and health care professionals. Different sources and methods of delivery may also be included in the definition (Wahlroos, 2003). The International Pharmaceutical Federation (FIP), Pharmacy Information Section has defined medicines information used in drug information centers and services as a process of providing information on the safe and effective use of therapeutic and diagnostic pharmaceuticals. Another definition defines medicines information as a system of knowledge and techniques that allows the transfer of knowledge about drugs, in order to optimize therapeutics for the benefit of patients and of society (Hall et al., 2006). Both of these definitions are restricted to the process of delivering information. They do not explain either who is the user of medicines information sources and services or the content of medicines information. In the EU legislation instead (Directive 2001/83/EC), the content of medicines information in patient information leaflets is defined as: information on the identification of the medicinal product; the therapeutic indications; information which is necessary before the medicinal product is taken; the necessary and

usual instructions for proper use; and information where the medicinal product is authorized.



# **Figure 1: The concept of medicines information**

Medicines information is considered from the perspective of the consumer. It refers to allkinds of medicines-related messages that can be communicated via different modes of delivery (face-to-face, written, electronically) and from different sources available to the public (Lilja et al., 1996). Medicines information includes information required by law, but also other information readily available to consumers (Grymonpre and Steele, 1998). In addition to evidence-based information on medicines, information may refer to intangible issues such as opinions of medical experts and experiences of peer consumers (Eriksson-Backa, 2003).

## 2.7.1.1 Medication counseling and electronic medication counseling

The concept of medicines information is closely related to the concepts of patient counseling, medication counseling, patient education, pharmacist-patient-communication, patient information and advice-giving. All of those have been used to refer to the communication between pharmacists and patients (Vainio 2004). Although communication between pharmacists and customers in community pharmacies has been actively studied, there is neither established term to use nor consensus of what constitutes of good counseling or medicines information practice (Puumalainen 2005). A recent review of 39 studies on patient counseling found that most researchers have used the term counseling instead of advice-giving or education, and conceptualized pharmacist-patient communication as a pharmacist information providing activity (Shah and Chaewning 2006). The United States Pharmacopeia (USP) Medication Counseling Behavior Guidelines are the only validated tool to measure the content of the counseling

(Puumalainen et al., 2005). In those guidelines, the term medication counseling has been used. It has been defined as an approach that focuses on enhancing the problem solving for the patient to improve or maintain quality of health and quality of life (Puumalainen and Kansanaho, 2005).

The term medication counseling is also used in this study when communication between pharmacists and consumers is referred to. The term electronic medication counseling is used to describe counseling by using electronic based devices such as mobile telephones and/or computers as facilitated by the internet and e-mail. Communication is seen as a dyadic two-way process involving a sender and a receiver in which the communicated information is understood by both the sender and receiver. Information behavior is used to refer to human behavior in relation to the sources and channels of information (Wilson, 2006). This includes both active and passive information seeking and covers issues such as: how people need, seek, give, and use information.

# 2.7.1.2Modes and sources of medicines information

Information can be accessed and delivered via different modes (face-to-face, written, and electronic) and sources. Those sources can be classified as: personal or interpersonal sources; lay or professional sources; personal, institutional and media sources; and traditional (for example health care professionals) or e-technology-based sources (Cleary et al., 2008). E-technology is commonly understood to include the Internet and related technologies (Eysenbach, 2000). In relation to medicines information, e-technology is linked to the concept of telepharmacy (Angaran 1999). Although no formal definition exists, telepharmacy can be broadly understood to include all pharmacy services that can be provided remotely (Angaran, 1999). This definition includes telepharmaceutical information sources such as pharmacy websites, e-mail medication counseling services (e.g., ask-the-pharmacist services), and telephone services (Jariangprasert et al. 2007). Telepharmacy is synonymous to e-pharmacy. In this study, telepharmacy is used to refer to pharmacy services provided via the Internet and telephone.

#### 2.7.2The pharmacist's role in achieving rational use of medicines

Community pharmacists play a crucial role in optimizing medication use and improving patient outcomes, whilst preventing medication misuse and reducing costs (Nkansah et al., 2010). Patient counseling is an important service provided by community pharmacies.

Patient education and counseling usually occur at the time prescriptions are dispensed but may also be provided as a separate service (ASHP, 1997). A systematic review of findings indicate that pharmacists led counseling improves clinical outcomes, quality of life, drug and disease knowledge, patients' satisfaction with service, and economic outcomes (Okumura et al., 2014). It is worth noting that the counseling was more comprehensive and extended beyond time of dispensing a medication in the majority of the included trials in the review. At the time of dispensing, evidence exist to suggest that community pharmacists' interventions such as counseling encourage appropriate medicine use and prevents drug related problems (Nicolas et al., 2013).

guidelines Many professional organizations have published that provide recommendations to pharmacists on how to educate and counsel patients on both prescription and non-prescription medicines (Nicolas et al., 2013). Although the scope of content of the counseling recommended in each guideline varies, all agree on providing the following information: name and description of the medicine, indications, route of administration, dose and dosage form, directions for use, duration of therapy, special directions, precautions, side effects, and contraindications (Puspitasari et al., 2009). All guidelines also emphasize that pharmacists need to ask a series of questions to identify a patient's understanding of their medications, and to meet the specific needs of each patient and/or caregiver (Puspitasari et al., 2009).

## 2.7.3 The rationale of generic substitution

Generic substitution is a cost-containment strategy meant to contain pharmaceutical expenditure without compromising health objectives(Kesselheim et al., 2013). In practical terms, generic substitution means that prescribed medicine is substituted by a cheaper medicine with the same qualitative and quantitative composition in active substances, same dosage form, and same route of administration as the reference drug, with bioavailability demonstrated by appropriate studies (Trost et al., 2012).

## 2.7.3.1 Generic substitution in community pharmacies

During dispensing process pharmacists in community pharmacies undertake the substitution of prescribed medicine with a cheaper bioequivalent product. This means that generic substitution policy is performed in community pharmacies and it is there that practice is likely to be influenced by it. It has been shown effective with regard to lowering the price of medicine, but the practice is still debate as it is found to worry and confuse patients and thereby poses a risk to patient safety (Erika Olsson 2015). While the

impact of cost containment policies on quality of care is often unclear (Rathe et al., 2014), the importance of evaluating pharmaceutical policies has become increasingly apparent(Nutbeam, 1998). The effect of generic substitution on the price level of off-patent medicines is well known from international economic evaluations (Himmel et al., 2005).

# 2.7.4 Labeling

Medicines should be unmistakably and legibly labeled using the generic name and expiry date. Any information should be in the local language, accompanied by correct and proper instruction for the prescriber and the patient. Translations of labels can be time consuming, but it will contribute to the prescribers' understanding of the proper usage of the provided medicine (Melina, 2011).

A case study in Russia demonstrates the importance of correctly labeled medicines: Doctors without borders relabeled drugs that were meant for Georgia and Azerbaijan in Russia. This process was without doubt very time-consuming, but it helped the prescribers to explain the drug to their patients, which was helpful in terms of the patient's compliance with these western donated drugs (Schouten, 1995).

# 2.7.5Determinants of antibiotic prescribing

It is commonly believed that physicians' practices are determined by what they know about illness and about correct prescribing. If this is the case, poor prescribing could be improved by updating knowledge alone.

However, the real situation can be considerably more complex. Despite established guidelines on oral rehydration therapy for acute diarrhea in children, Indonesian prescribers on one hand feared that patients might have other infections and prescribing ORS only, was not enough; therefore it was better to prescribe an antibiotic immediately rather than waiting for an illness to become more serious. On other hand, other prescribers might already have exhausted possible treatment options and patients expected to receive other types of treatments from private physicians. Most physicians believed that the advantages of antibiotic therapy outweighed the disadvantages, which were primarily seen to be the increased economic burden for patients (Ismail et al., 1991). As this example demonstrates, many factors besides lack of knowledge are involved in improper use of antibiotics.

#### 2.7.5.1Lack of knowledge

Knowledge of diagnostics and therapeutics can play a role in inappropriate prescribing of antibiotics (Kunin et al., 1987). Javato-Laxer (1989) explains that because of their failure to determine etiologies of infections, physicians often prefer to use broad-spectrum antibiotics, believing that this will cover all possible etiologies and unusual pathogens.

It is often assumed that differences in prescribing practices of healthcare providers are related to a varying level of training and knowledge (Stein et al., 1984). However, there is little evidence to support this assumption. For example, in Bangladesh, prescribing rates for metronidazole were the same for both 'doctors' and 'medical assistants' (Guyon et al., 1994).

There are also discrepancies between biomedical knowledge and actual prescribing practices. In Indonesia, physicians in public hospitals and health centers explained their belief that viruses caused more diarrheal disease than bacteria, and thus they considered antibiotics ineffective. Private practitioners held such beliefs in similar rates. Despite these stated beliefs, more than half of each group prescribed antibiotics for the treatment of diarrhea (Gani et al., 1991). In a Peruvian study most physicians (36 out of 40) knew when antimicrobials were needed to treat diarrhea. However, a practice assessment demonstrated that 35 of these 36 physicians prescribed an antimicrobial to one or more surrogate patients. Questionnaire data showed that absence of blood in the stools had been mentioned, but that this knowledge did not prevent them from prescribing antimicrobial drugs (Paredes et al., 1996).

## 2.7.5.2Fear of bad outcomes

Prescribers in non-industrialized countries frequently weigh the 'risks' of various treatment options. There is often the fear that disease outcomes may be poor without antibiotic treatment. Whereas prescribers in industrialized countries may fear legal action for not practicing evidence-based medicine, their colleagues in non-industrialized countries may fear the risk of losing clientele if they do not deliver a fast cure, or when unpleasant side-effects accompany the prescribed medication.

Peruvian physicians mentioned a need to prevent possible 'complications' from diarrhea and they often feared having to deal with a potential case of cholera. Not prescribing an antibiotic was seen as very risky. They emphasized that mothers of children with diarrhea come only once and that proper follow-up is not ensured. To address that risk, antibiotics were often prescribed during first visits (Paredes et al., 1996). On the other hand
antibiotics are often considered risk-free (Van Staa, 1993), and side-effects or toxicity are thought to be minimal if the appropriate antibiotic is chosen (Ismail et al., 1991).

# 2.7.5.3 Perceived patient demand

Perceived patient demand influences doctor's prescribing decisions. In Latin America, physicians prescribed antibiotics for conditions of viral etiology when pressed to do so by patients (Wolff, 1993). Physicians in the Philippines stated that if they do not prescribe antibiotic to the client, patients may shop around for another doctor, or buy medicines that may be more hazardous than 'the few capsules of ampicillin' they recommended (Van Staa, 1993). An Indonesian study reported that parents' desire for potent drugs influenced private doctors' and health center physicians' to prescribe antibiotics to their children (Gani et al., 1991).

The influence of patient demand on physicians' prescribing behavior is, however, controversial. Most physicians who participated in the Peruvian study believed that mothers expected a prescription. However, observations showed that variations in mothers' behavior (passive or demanding) during visits, did not affect whether drugs were prescribed, which ones, and how many. Prescribing outcomes were generally the same for both groups of mothers. Further, the study investigated whether physicians prescribed antibiotics even if mothers asked them not to do it. Simulated patients visited five physicians who were previously qualified as 'well informed.' This study showed that physicians rarely changed their prescribing habits based on mothers' opinions of treatment options (Paredes et al., 1996).

Physicians can communicate the quality of their services to patients through the act of prescribing. In Peru, mothers visiting physicians with the best knowledge of correct treatment often left the consultation unhappy, since they received only ORS for their child with diarrhea. Paradoxically, they called these physician charlatans (Paredes et al., 1996).

### **2.7.5.4Economic factors**

Financial incentives are an important factor in antibiotic prescribing, and higher profit margins of expensive drugs may result in inappropriate prescribing practices (Gani et al., 1991). In rural China, health-system financing influenced the antibiotic prescription, both in frequency and in type (Dong et al). Physicians tended to prescribe more expensive antibiotics for insured patients, resulting in higher profits for themselves (Dong et al., 1999), while patients requested more expensive drugs because they did not pay the full cost of prescriptions (Dong et al., 1999).

Fear of losing business is another important issue for prescribers. Some believe their reputations would suffer if they do not prescribe desired antibiotics. The majority of prescribers in non-industrialized countries are not well paid, and prescribing a drug may offer extra income. By recommending or prescribing a specific drug or antibiotic, prescribers may obtain a dual financial incentive: from the patient by selling a drug, and a bonus from the industry by recommending or selling a specific drug. Having expectations met, may also deter patients from going to other healthcare providers. This economic rationale is especially strong in private settings where patients pay for services: *It is a Filipino custom. If you see a doctor, you must leave with at least 2-3 prescriptions at hand. Otherwise the patient might be disappointed and go to another doctor. If this is a paying patient, a doctor cannot risk that (In: van Staa 1993).* 

In Vietnam, where doctors are also drug sellers, doctors are even reluctant to disclose the name of the drug that is prescribed. This ensures that patients will return, rather than simply refilling the prescription at a pharmacy (Duong et al., 1997).

### 2.7.5.5Peer norms

Peer norms and the practice standards of senior clinicians also influence antibiotic prescribing. For example, in Indonesia in the early 1960's, drugs were very scarce. At that time, an influential senior pediatrician used streptomycin and Phenobarbital to treat diarrhea. Some nurses apparently still use this formula today (Ismail et al., 1991).

Prescribers can develop a unique local medical culture. In Peru the medical profession has developed a concept of 'diarrhea parenteral' that is quite different from western knowledge about disease causation. 'Diarrhea parenteral' may occur when an infection is present that affects a system other than the gastrointestinal tract (e.g. ARI) and that may cause diarrhea to develop. Antibiotics are felt to be necessary to treat the primary infection, which in turn would result in a cure of the diarrhea episode. As the concept is also taught in Peruvian medical schools, it may explain why many Peruvian physicians give antibiotics from the very beginning of each episode of diarrhea (Paredes et al., 1996).

### 2.7.5.6Timely laboratory results

Lack of access to quality laboratory services is often regarded as a deterrent to the rational use of antimicrobial agents. In Bangladesh, more than 90% of antibiotics were used on an empirical basis. Reasons stated for antibiotic use, included limited availability of facilities for microbiological testing, unreliable results, and frequent differences in test

outcomes from different laboratories. However, lack of laboratory facilities or the inability of patients to pay for microbiological tests were said to be the main reason for prescribing antibacterials and antiamebics in a diarrhea prescribing study in Pakistan. However, the extremely short consultation time between doctor and patient was also a major reason for omitting laboratory tests (Nizami, 1996).

Interestingly, availability of laboratory facilities and personnel does not always stimulate physicians to use them before prescribing antibiotics. All hospitals in a Malaysian study had facilities for microbiological culture, but only 20% of antibiotic prescriptions were made on the basis of microbiological reports (Lim and Cheong, 1993). Javato-Laxer (1989) also found in the Philippines, that despite availability of diagnostic facilities, half of the patients with antimicrobial treatments were given them prior to the identification of an etiologic agent.

#### 2.7.5.7Unstable antibiotic supply

The ability of prescribers to provide appropriate antimicrobial therapy may also be limited by the availability of indicated antibiotics. In Bangladesh and India, it was reported that medicines given in primary care facilities were usually prescribed according to availability patterns, and not according to patient needs. Most prescribers used a list of drugs that were in stock and they adjusted prescribing practices accordingly (Uppal and Sarkar, 1993). A Tanzanian study reached similar conclusions when comparing prescribing practices in different types of health facilities. Overuse of antibiotics in hospitals was thought to be caused by the range of antibiotics available there, which was much wider than in health centers (Massele, 1994).

#### 2.7.5.8Pressure of pharmaceutical promotion

The pharmaceutical industry has a strong financial incentive for marketing drugs to doctors and pharmacists in non-industrialized countries. Company sales representatives and commercially-oriented drug publications are known to be a major source of information for prescribers (Bosu, and Ofori-Adjei, 1997). In Indonesia, prescribers receive payment for issuing certain drugs during promotional events. In the Philippines, pharmaceutical companies reinforce the notion of risk-free medicines and promote a 'why worry' attitude among doctors. However, despite many reports on commercial pressures in drug prescribing, most of this literature is anecdotal. While much is written about the influence of industry in the use of antibiotics, little is known about how this influence works, and how it is able to encourage health care providers to use specific products (Aryanti and Hilbrand, 2002).

### 2.7.6 Determinants of antibiotic dispensing and sales

Antibiotic delivery systems in non-industrialized countries range from free, clinic-based provision in the public sector, to dispensing private physicians, commercially oriented sales systems (pharmacists and shop-keepers), and traditional healers (curanderos and herbalists). In each of these systems, formal, informal, illegal, and clandestine aspects of antibiotic distribution may be present (Van der Geest, 1984). Each setting also presents different incentives for and barriers to appropriate antibiotic prescribing and use. Different types of clients may be drawn to different delivery systems, and patients may prefer to use different systems at different times. The variety in systems and preferences makes studying dispenser related determinants of antibiotic use a difficult task (Aryanti and Hilbrand, 2002).

Day-to-day activities in pharmacies are commonly handled by pharmacy attendants or clerks. Depending on the system, these clerks or attendants can have a variety of educational backgrounds. Igun (1991) found that most Nigerians do not really differentiate between untrained street vendors and pharmacists, and that all are regarded as knowledgeable. In Somalia, nurses and pharmacists were present in private pharmacies, but a variety of lay people (family members, and children) attended customers (Serkkola, 1990). In some countries, anybody working in a pharmacy may be considered to be a 'pharmacist.' In people's opinion, pharmacists are those who deal with pharmaceuticals and able to give them advice when they have a health problem (Duong et al 1997).

Contrary to the term 'pharmacist'—which appears to have similar meanings in most settings—the terms 'chemist' or 'drug seller' have different meanings in different countries. In some countries, this group of professionals may have had simple drug-related training. For example, drug retailers in Nepal can attend a government sponsored training (Wachter, 1999). But in Indonesia, they need a government license to run their shop (Muktiningsih et al, 1987). Shop keepers are another category. This category of dispensers operates from general stores that also sell some medicines. Their level of education is often low, and they usually do not have pharmaceutical training (Van Staa, 1993).

Drug dispensers have a great deal of influence on community drug use. Their position is often to mediate between health professionals and the popular sector (Van der Geest, 1984). The dispenser is not only thought to be knowledgeable on biomedical concepts of health and disease, he is also expected to be acquainted with popular and folk traditions,

and he utilizes both in his communication with clients. People prefer to purchase drugs directly from pharmacies instead of from physicians because: There are more pharmacists than doctors in most regions, the medicines are cheaper to purchase; People have closer social and cultural ties to pharmacy attendants, they can conceal shameful or embarrassing complaints, they have greater confidence in western drugs than western doctors; and a visit to a pharmacy is generally less time consuming than visiting a public health facility (Van der Geest, 1984).

Community members appreciate the help of dispensers, and hold them in high esteem. Haak (1988) reported from a rural town in Brazil that community members considered a particular pharmacist 'better than a doctor.' Logan (1983) reported that her poor and often illiterate Mexican informants referred to some pharmacists as 'casicomo doctor' (almost like a doctor).

In some countries, dispensers prefer to refer patients with serious problems to formal healthcare systems. Price (1989) noted that Ecuadorian pharmacists consider their role as managing the more common health problems. When it comes to serious health problems, such as heart disease, bronchitis, TB and high blood pressure, they refer patients to physicians.

Most of the literature about dispensers focuses on the quantitative aspects of dispensing which antibiotics are dispensed, at what price, for what problem, whether a prescription was presented, etc. Little is known about the characteristics of the dispensers themselves. More research is needed to understand their cultural ideas regarding antibiotics; training; knowledge about drugs; and their social position in the community. Little is also known on the role that dispensers actually see for themselves; what kind of diseases they feel they can handle themselves; which diseases they refer to physicians.

Given the diversity of settings, general conclusions on antibiotic dispensing in nonindustrialized countries are impossible, but available studies give an impression of serious problems in this sector. For example, a Bolivian study reported that antibiotics were dispensed for 92% of adults and 40% of children with watery diarrhea (Bartoloni, 1998). Drug store personnel in Thailand dispensed antibiotics in various dosing schedules, regardless of the diagnosis, and most dispensed antibiotics for 2 days or fewer (Thamlikitkul,1988). A majority of Sri Lankan pharmacies dispensed 2 capsules of tetracycline when asked (Wolffers, 1987) and another Bolivian study reported that a maximum of 4 antibiotic tablets was typically dispensed (Bartoloni et al., 1998).

#### 2.7.6.1 Economic incentives

Pharmacists are usually prepared to negotiate the type and quantity of drugs to be procured, and clients' purchasing power is often the ultimate decisive factor. Quantities of antibiotics dispensed by pharmacies in Bolivia varied according to clients' ability to pay (Bartoloni et al., 1998). Similarly, in India, pharmacies changed prescriptions so that they would suit the financial means of customers (Dua et al., 1994). In Nigeria, every pharmacist believed that other pharmacies would prescribe drugs for watery diarrhea, not just ORS. Hence, they all sold antibiotics for watery diarrhea, and made profits at the expense of those who would prescribe "ORS only" (Igun, 1994).

#### 2.7.6.2 Client demand

To increase their competitive edge over physicians, dispensers may combine advice with popular treatment strategies, such as avoidance of certain foods, drinks and behaviors. They frequently defer to clients' ideas on appropriate care and necessary medicines. For example, chemists in Nairobi, Kenya, were willing to sell smaller doses of antibiotics at the request of patients (Ismail, et al 1994). Similarly, in India, antibiotics were provided at the presentation of prescriptions from non-allopathic physicians, or even without any prescription at all (Dua et al., 1994). Pharmacy staff in Nigeria stated that they believe that parents want medicines that 'stop' their children's diarrhea. If they refuse to meet these expectations, they feared that parents would go to another pharmacy (Igun, 1994).

It is difficult to differentiate whether clients or pharmacy attendants recommend the purchase of medicines. In São Paulo, Brazil, products were bought at the customer's own initiative in 34% of the encounters, at the attendant's initiative in 22%, and in the remaining 44% of the encounters, products were prescribed by a physician(Cunha, 1983). In another study of 226 encounters in two rural areas in Brazil, 42% of the products were self- prescribed (Haak, 1988).). None of these studies focused on antimicrobials, pinpointing to the need for more dispenser focused research into the antibiotic selection process in retail settings.

#### 2.7.6.3 Lack of knowledge

Lack of knowledge of how and when to dispense antibiotics may also be an important determinant. When questioned about their antibiotic dispensing for watery diarrhea, dispensers in Nigeria argued that most clients were living in unsanitary personal and environmental situations, and that antibiotics were therefore indicated (Igun, 1994).

The level of knowledge of dispensers about the ingredients of antibiotic preparations has not been well researched. One client simulation study showed that pharmacy attendants were not aware of which tetracycline preparations they had in stock (Wolffers, 1987). The same study quoted a pharmacy attendant when he explained that knowledge on drugs was not of major importance: "The patient knows what he wants and we know the price" (Wolffers, 1987).

### 2.7.6.4 Influence of the pharmaceutical industry

Pharmacists' dispensing patterns are also influenced by pressure of their suppliers. Ferguson (1981) reported that pharmacists who purchased drugs from pharmaceutical firms recommended more expensive medications and more medications per person than those who purchased medications from wholesale distributors. These differences were attributed to sales incentives offered by pharmaceutical firms. Incomes depended heavily on sales volumes and could go up as high as 600% or 700% through sales' commissions. Haak (1988) described marketing methods in Brazil that resulted in pharmacies trying to sell more of certain drugs because of incentives provided by suppliers. Van Staa (1993) describes a system of sales representatives visiting pharmacies and medical representatives visiting physicians, both try to boost consumption of given drugs. In Sri Lanka, the vast majority of pharmacy attendants admitted that sales representatives of pharmaceutical firms were their major source of information on drugs (Wolffers, 1987).

#### 2.7.6.5 Lack of regulation and enforcement

When selling drugs to customers, dispensers often ignore national legislation. Drugs are routinely dispensed without prescriptions. Dispensers in India stated that they simply ignored legislation on dispensing antibiotics, as they knew that law enforcement was impossible because of the large number of small drug stores (Dua et al., 1994). In Kenya, chemists sold drugs in envelopes without any dosing instructions. Some chemists sold antibiotics under the name "Septrin," as requested by customer, although another antibiotic was actually provided (Indalo, 1997).

Many other possible determinants of antibiotic dispensing practices have not been adequately studied. One particularly important factor is the influence of private physicians as models for dispensers' practices. Dispensers frequently say to customers that a given drug is widely used by medical practitioners. Sri Lankan pharmacy attendants carefully studied physicians' prescriptions to ensure that their advice was in line with that of physicians (Wolffers, 1987).

# **CHAPTER THREE: RESEARCH METHODOLOGY**

This chapter presents details of the research design, target population, sample size and sampling procedures, description of research instruments, data collection procedures and data analysis techniques.

# **3.1 Research design**

Kumar (2011) argues that it is a technical strategy adopted by the researcher to provide the solution for the research questions reliably, objectively, precisely and economically. It is therefore a predefined plan that is used by order to come up with the outcome or the results of the research study.

The research was a cross sectional descriptive and analytic study. It used both qualitative and quantitative method. Data were collected by using a combination of the following techniques: Directed non participant observation, Documentary sources, Interviews by using an indicator-based tool developed and tested by Birna Trap et al in 2010 and a Simulated Client Method (SCM).

At first glance, It was an observational descriptive study (descriptive cross section study) because the information collected for some variables was purely in a descriptive nature and hence their analysis didn't involve the comparison of any strata (provinces) formed on the basis of exposure or outcome status.

Lastly, It was an observational analytical study (analytical cross section study) because data were collected both on exposures and outcomes of interest, and data were analyzed so as to demonstrate differences between exposed and non-exposed strata, with respect to the outcome and between those with the outcome and those without the outcome, with respect to the exposure .Therefore, it involved the comparison of strata (provinces) formed on the basis of exposure or outcome status.

#### **3.2**Study population and sampling

#### 3.2.1 Study population

According to O`Leary (2004) population is the aggregate membership of a distinct class of people, objects, or event. Williaman (2005) also argues that "population is a combined word used to define the total quantity of cases of the type which are subject of your study". The study population was community Pharmacies licensed to operate in Rwanda. The population size was 245 community Pharmacies from private sector, and they were surveyed from February 1<sup>st</sup>, 2017 up to June 30<sup>th</sup>, 2017. The list of the authorized

community pharmacies to operate in Rwanda was downloaded from the Ministry of Health website. The following criteria were taken into consideration:

*Inclusion criteria:* A community pharmacy authorized to operate by competent authorities, and which is running its activity on the day of visit.

*Exclusion criteria:* A community pharmacy that didn't consent to be part of the study.

### 3.2.2 Sample size calculation

William (2004) noted that sampling is a devise or a way that is used in selecting of the members that you are able to question, or who are a fair presentation of all the members in a union. Sampling must be done whenever you can gather only a fraction of a population of a group or a phenomenon which you want to study. A sample size of 150 community pharmacies was selected by using a multistage random sampling from 18 districts of Rwanda stratified under four provinces and the capital city of Rwanda. It was calculated using the following formula.

$$n = \frac{[DEFF * Np(1-p)]}{[\frac{d^2}{Z^2_{-\alpha}} * (N-1) + p * (1-p)]}$$

Where *n* =Sample size, DEFF=1, Design effect, N= 245, Population size, P=50%, the estimated proportion, d=5%, desire absolute precision or absolute level of precision, margin of error,  $Z_{1-\alpha/2}$ =1.96, Confidence level: 95%.

### 3.2.3 Sampling procedure

According to World Health Organization manual of 2007 that entitled "Operational package for monitoring and assessing country pharmaceutical situation", it recommended that 5 different geographic areas have to be selected as aiming at getting a representative sample size of health facilities:

First recommendation: There should be the selection of one area which is the largest city income-generating and other four areas should be selected randomly. However if sufficient data are available, this selection should be followed:

Second recommendation: The largest city with high income-generating should be selected as first area, then three intermediate income-generating areas and one which should be among the lowest income-generating areas should be selected.

#### Sampling of districts stratified into provinces and capital city

The researcher used the second procedure and got5 strata, which were four provinces and Kigali city, and within them, 18 districts of Rwanda were selected.

#### Sampling of community pharmacies within each district

Due to the fact that a community pharmacy was the sampling unity, a total sample size of 150 out of 245 community pharmacies from eighteen districts of Rwanda was selected by using a multistage random sampling. The following sampling technique was used: A technique of proportionate sample size stratification was used to determine the sample size of community pharmacies from each stratum. That technique was proven to produce estimates of overall population parameters with great precision. (Shuttle, 2009).As the sample size of each stratum is proportionate to the population size of the stratum, and the sample size of each district is proportionate to the population size of the district, therefore a total sample size of community pharmacies per each district within each stratum was determined by the following equation and the table 3and figure 2show the number from each sector.

$$n_h = \left(\frac{N_h}{N}\right) * n$$

Where  $\mathbf{n}_{\mathbf{h}}$  is the sample size for stratum *h*,  $\mathbf{N}_{\mathbf{h}}$  is the population size for stratum *h*,  $\mathbf{N}$  is total population size, and  $\mathbf{n}$  is total sample size. (*stattrek.com/sample-size/stratified-sample.aspx*)

After all above calculation, a simple random sampling was used to select appropriate number of community pharmacies to be used within each district.

However, areas with a very closely and concentrated community pharmacies like Kigali city, the same sampling technique as aforementioned was used within each district, sectors and then in cells for getting a total sample size of community pharmacies to be used.

Strata	District Name	Population	Sample Size
Kigali City	Gasabo	73	45
	Nyarugenge	54	33
	Sub-total	127	78
South Province	Huye	19	12
	Muhanga	17	10
	Nyaruguru	2	1
	Ruhango	12	7
	Sub-total	50	30
North Province	Musanze	12	7
	Gicumbi	1	1
	Gakenke	2	1
	Sub-Total	15	9
West Province	Rubavu	15	9
	Rusizi	5	3
	Karongi	3	2
	Ngororero	3	2
	Sub-Total	26	16
East Province	Bugesera	8	5
	Kayonza	6	4
	Nyagatare	6	4
	Kirehe	4	2
	Gatsibo	3	2
	Total	27	17
TOTAL		245	150

Table 3: Community pharmacies sampling framework

Population size (N) = 245, Sample size (n) = 150, Number of strata (h) = 5, Population size for stratum (Nh); Sample size for stratum (nh)



Figure 2: Map showing the distribution of visited community pharmacies

# 3.3 Data collection

# 3.3.1 Plan for data collection

# 3.3.1.1 Organization of data collection

First of all, for obtain specific approval and cooperation for data collection, a formal communication was sent by means of email and telephone to the selected community pharmacies. Then, an authorization letter for data collection issued by University of Rwanda was carried out by every data collector assistants as intended to facilitate good communication and collaboration between all participants. Then before collecting data, an approval was given by community pharmacy owner and/ or manager or Head pharmacist. The schedule of the visit to the selected community pharmacy was random selected during opening hours not to include public holidays and vacation periods.

#### 3.3.1.2 Selection and training of data collector assistants

By considering the implications of geographic and time limit required to collect data in each site ,and by taking into account other same research studies which has been conducted so far ,this survey require on average of one day of data collection and one to two days of travel time for completing the work at one community pharmacy.

Therefore, this study suggested ten data collector assistants to undertake data collection namely, the principal researcher and assisted by nine data collectors with pharmaceutical backgrounds. Data collector assistant were recruited from five year pharmacy students and one licensed pharmacist from University of Rwanda and Mount Kenya University. Collect data in fifteen sites, require at least 30 working days or perhaps 38 to 45 calendar days for the whole group to travel out, complete work, and travel back. Therefore data of this study was collected from 15<sup>st</sup> April up May to 2017.

Recruiting and training of data collectors were carried out by the principal researcher within two weeks. World Health Organization manual of 2007 that entitled "Operational Package for Monitoring and Assessing Country Pharmaceutical Situation and World Health Organization manual for investigating medicines use in health facilities "was used in training data collector assistants where all detailed was explained toward five components of pharmacy practices, and also by doing some exercises about some data collection techniques .For example in simulated client method, a data collector assistant act as patients and enter the pharmacy for seeking a specific consultation to the principal researcher e.g. asking for an antibiotic without a prescription. The some exercise was done between data collector assistants only. Then after, a final test was provided to them for assessing their knowledge and skills toward simulated client method scenarios (mystery shoppers/surrogate patients). Fifteen data collector candidate were recruited, but after doing the test, it ended by passing only nine according to their performance and the requirements of the study. Also their consent to agree to participate in the study and their care has been taken into consideration.

Those who succeeded the text was given addition instruction such as to contact the principal researcher at any time if there were any questions or doubt related to the survey to check whether the questionnaire was filled in completely before finishing each question.

### **3.3.1.3** Validation of data collection tool

The tool was consisted of a close and open end structured questionnaire that contains five components of pharmacy practice with 34 indicators and their corresponding measurement. This tool have been developed and tested for its applicability in the community pharmacy settings by Birna Trap et al in 2010; and it was free downloaded at <u>www.birnatrap.dk</u>. Each indicator included on the tool was described in term of its area to be assessed, its type, objectives, definition, verification, how to score/calculate and its information source. These indicators were grouped into five components of Pharmacy Practice as follow:

- 1. System: it contains 5 indicators that assess the availability and use of a prescribing recording system, degree of computerization, and implementation of stock management and re-order system.
- 2. Storage: it contains 7 indicators that assess presence of pests, cleanliness of the dispensing and storage area, pharmacy hygiene, storage conditions, system and practices.
- 3. Services: It includes 6 indicators that assess prescription load, opening hours, staff availability and qualifications, availability of services, and tests and health promotion activities.
- 4. Dispensing: it covers 8 indicators that assess information available to dispenser, product range, dispensing time, packaging material, and dispensing equipment, dispensing procedure and contact with prescribers.
- 5. Rational drug use: it includes 8 indicators that assess information available to patients, patient care, labeling, rational prescribing, dispensing of 'Pharmacist initiated medicines', dispensing of antibiotics without prescription and generic substitution

These indicators were tailored on a data collection sheet and were taken as questions. The data collection tools was developed in English and filled in by the data collector assistant once his/she was on the field. Patient exit interviews were in some cases conducted in the local language. Translation was done by the data collector assistant her/his self if patient needed. This tool ensured independent data collection of all data required on site of visit, and it is favorable for planning and optimal utilization of the time available to the data collector assistant at each community pharmacy.

However, a pilot study was conducted for testing the reliability and validity of data collection tools in community pharmacies operated in Kicukiro and Rulindo district.

### 3.3.2 Data collection methods

Generally, every research study achieves its objectives by using different effective data collection methods. Therefore, this research study was using interview guide, observation, documentation and simulated client method

# 3.3.2.1 Interview

Kakinda (2007) said that an interview is defined as a face to face conversation between interviewer and respondent conducted for the purpose of obtaining information. The interview used in this research study was more structured. This is a data-collection technique that involves structured oral questioning of respondents, either individually or as a group. It is also known as standardized interview or a researcher-administered survey that provide primary data. This method was compatible with the used structured questionnaire which was designed in checklist format. Also, the provided answers were recorded either by writing them down during the interview itself or immediately after the interview on that structured tool.

# 3.3.2.2 Observation

Is a method where the researcher just observes by paying attention to and analyses carefully researchable objects or situations but does not intervene. It stipulated that it exist two types of observation: Participant observation and non-participant observation. But, in this research study, the research relayed on a non-participant observation which was structured, and importantly able to generate reliable primary data. The researcher as observer used eyes and other senses for watching the situation openly or concealed, but does not participate. Then after, data was recorded by using Paper-based recording, here after called a collection tool.

### 3.3.2.3Documentation

According to Grinnell Jr. Richard and William Margaret (1990), secondary data is the data that exists already inboxes, in some organization basement, books, journal and websites. There is a reason for taking mainly records as the primary focus because documents exist in huge numbers in our society; indeed, research requires investigation of the existing scholarly literatures. Therefore, this method of has been used in this research study because of its advantages despite its drawbacks. It support the observation method by reviewing records and by provided good source of background information relatively

easily, inexpensive. It was also the best means of studying past events in community pharmacies. This method was unobtrusive and provided a "behind the scenes" look at a program that may not be directly observed and brought up issues such as rational prescribing, not noted by other data collection methods.

### 3.3.2.4 Simulated client method

The simulated client method provided important information on the complexities of consultations, service provider behavior, and practices. It used "mystery client or surrogate patient". That patient is a trained person (usually a community member) considered as a client who visits a health facility for seeking information from the service provider, however that provider should be blind about the research which is being conducted; then after the mystery client report (by completing a survey or through an interview) on their experience. Using a simulated client method requires following the same research principals and process such as: planning, developing instruments, training mystery clients, data collection, data analysis, use and dissemination of findings. Those principals and process have been followed in this research study for its importance in generating primary reliable and accurate data.

### 3.4 Data Processing, Analysis and Presentation

#### **3.4.1 Data processing**

This research was a cross section descriptive and analytic study. It was contained 34 categorical qualitative and quantitative variables. Each variable had two pre coded values: yes: 1; no: 0. Then Data were sorted and compiled by using Microsoft Excel and SPSS version 20. For entering data, the research developed a data entry format in SPSS version 20. The researcher used the computer verification system that was built in for data entry verification. As the data were pre coded, the information relating to each subject in the study is keyed into the computer in the form of the relevant code. The response was scaled as dichotomous dependent variables as intended to collect and analyze data efficiently.

#### 3.4.2 Data analysis

Appropriate software such as Microsoft Excel and SPSS version 20 was used in this research study as intended to effectively analyzed the data either as Quantitative and qualitative:

#### 3.4.2.1 Quantitative data

These data were analyzed by mean of frequencies; and the findings were presented through figures, tables and graphs. Additional descriptive cross-tabulations that aim at ascertaining the problem under study were used between one or more different categorical variables. Indeed, analytical cross tabulations were tabulated in order to determine the relationships between variables and between strata. However, ANOVA was used to determine if there were the differences between strata; and the Values of p<0.05 was considered as statistically significant.

#### 3.4.2.2 Qualitative data

Because the observation and interview were two main methods used for collecting qualitative data; a deductive approach that illustrated opinions, values and behaviors of pharmacy staffs toward pharmacy practice was used. In addition a narrative analysis was used where every interview/observation has narrative aspect- and the researcher had to sort-out and reflected up on them, enhance them, and present them in a revised shape to the reader. The core activity in analyzing this qualitative data was to chronologically reformulate key stories presented by pharmacy staffs in community pharmacy settings, people involved, important process used and illustration from patient based on different contexts and their experiences.

#### **3.5. Ethical considerations**

This researcher study was conducted under an approval from University of Rwanda. However, pharmacies participation was relaying on voluntary basis. The simulated client survey was carried out without consent of the community pharmacy staff. In fact, this was crucial for ascertaining the current reliable pharmacy practice situation provided by community pharmacy staffs at the pharmacy. Otherwise informing those staffs; would subsequently change the quality of their practices and create bias in data collection.

All information collected was confidentially protected and the names of respondents and their corresponding community pharmacies were not presented in the findings .Unless, there was a case of criminal offence, only the researcher would look for participant consent for further investigation.

# **CHAPTER FOUR: RESULTS AND INTERPRETATION**

The aim of this survey was to assess the practices of community pharmacies in Rwanda. Data were collected using different techniques including structured interview, observation and simulated client method. After that, data collection, processing and analysis were done by using SPSS Version 20. The results obtained, were presented by means of graphs and tables. The frequency, cross-tabulation, and ANOVA were used to facilitate the analysis.

# 4.1 Distribution of community pharmacies visited in this research study

To reach the objectives of this study, the researcher surveyed 150 community pharmacies countrywide where the number was proportional by stratum (province, city). The following Pie chart shows in details the percentages of community pharmacies selected from each stratum.



Figure 3: Number of community pharmacies visited per stratum (province &Kigali city).

The above pie chart showed that more than half of community pharmacies visited was concentrated in Kigali city. This situation was explicit by urban characters of Kigali city as the biggest city in Rwanda. The same study was conducted in India by Adepu and Nagavi in (2006), and found that most community pharmacies were concentrated in India big cities because of easily accessible of healthcare services and economical source for healthcare delivery available in those cities.

# 4.2 Responding the objectives of the study

The main objective of this study was to describe and analyze the practices of pharmacy in community pharmacies in Rwanda through the system, storage, services, dispensing, and rational use of medicines indicators.

# 4.2.1 Assessing the system that is being used in community pharmacies

That system was assessed basing on better indications of a good community pharmacy operating system which involve the availability of prescribing recording system, the use of prescribing system, computerization, stock management system, and reorder level.

# 4.2.1.1 Availability of prescribing recording system

The system in pharmacy must have the way to record the data in general. Here, the aim was to ascertain if the dispensing site has a system for recording prescription data and storing filled prescriptions throughoutverifying if there is an operating system for recording prescription data such as: Date, patient name, medicines prescribed, and name of prescriber and/or storing filled prescriptions.

	Yes	No
Prescription recording system availability	Frequency (%)	Frequency (%)
Availability of book/ computerized system for recording prescription data	141(94.0)	9(6.0)
If yes, the system provide the date	137(97.2)	4(2.8)
If yes, the system provides the name of the patient	47 (33.7)	94 (66.7)
If yes, the system provides the name of medicine	136(96.5)	5(3.5)
If yes, the system provides the name of prescriber	44(31.2)	97(68.8)
Old prescriptions are kept	61 (40.7)	89 (59.3)

 Table 4: Availability of prescription recording system

Table 4 shows the results on the availability of prescription recording system and necessary information that the system must record. The study revealed that all most all community pharmacies have the prescription recording system; however among them, the majority have the system that don't provide the name of the patient and name of prescriber. These could be due to lack of appropriate pharmacy software. Indeed keeping the old prescription was not done by more than half of community pharmacies surveyed. Therefore findings of this study indicate ineffective prescription recording system and a poor prescription record keeping in community pharmacies in Rwanda. These could be due to lack of guidelines on the length of time for which the prescriptions would be kept. The same findings were found in a study conducted in Uganda in which lack of appropriate policies was the major factor for not keeping prescription in most community pharmacies (Nina Grøntved 2007). Therefore, appropriate pharmacy software and guidelines need to be developed and implemented in community pharmacies of Rwanda.

#### 4.2.1.2Prescribing recording in use

The aim of this indicator was to know ifprescription recording system was in use. There searcher reaches this objective byverifying if all necessary recording prescription data (date, patient name, prescribers' name, name of medicines) were being recorded.

	Yes	No
Prescribing recording system in use	Frequency (%)	Frequency (%)
The entries are made in last 3 days	80(56.7)	61(43.3)
To all 10 entries the date was recorded	106(75.2)	35(24.8)
To all 10 entries the name of the patient is recorded	33(23.4)	108(76.6)
To all 10 entries the name of medicine is recorded	96(68.1)	45(31.9)
To all 10 entries the name of prescribers is recorded	28(19.9)	113(80.1)

Table 5: Prescribing recording system use

Table 5 shows how prescription recording system is used in visited pharmacies. Only56.7% pharmacies were found to conduct entries in the three days proceeding the day of the survey, but majority of them don't record properly all data namely the name of patient and the name of medicine. This findings indicate a poor data recording system, which could be due to pharmacy staffs ignorance and lack of appropriate materials and equipment. The same results were found in study conducted in India in which poor and ineffective recording system in most community pharmacies of India was at the origin of substandard data recording practice (Srinivasa Reddy Tiyyagura 2014). Therefore, community pharmacy staffs need more training and should build their capacity toward having appropriate materials and equipment for recording accurate patient information which can be retrievable any time for patient care.

# 4.2.1.3Computerization in community pharmacies

The objective was to determine at which extend computerized system was used in stock management, labelling, patient information, Prescription recording and Patient medication profile. The research achieved this goal by verifying which of the dispensing sites operations are computerized.

	Yes	No
Computerization	Frequency (%)	Frequency (%)
The pharmacy is computerized	121(80.7)	29(19.3)
If yes, computerization is used for stock management	55(45.5)	66(54.5)
If yes ,computerization is used to monitor expiry date to ensure FEFO	55 (45.5)	66 (54.5)
If yes ,computerization is used for labeling	11(9.1)	110(90.9)
If yes, computerization is used for patient information	45(37.2)	76(62.8)
If yes, computerization is used for prescription recording	41(33.9)	80(66.1)
If yes, computerization is used for patient medication profile	1(.8)	120(99.2)

 Table 6: Computerization in community pharmacies

Table 6 shows the extent by which the operation computerized system is used in community pharmacies in Rwanda. Normally enhancement of computer technology is essential to assist the community pharmacy in keeping all relevant data in order to provide optimal oversight of drug therapy (WHO 2012). Among community pharmacies surveyed, more than half of pharmacy operation activities are not computerized. This could be due to lack of appropriate cost effectiveness pharmacy computers software and lack of enough knowledge and skills to use those computers software. In addition, other factor is that having appropriate pharmacy computer software before opening community pharmacy to operate in Rwanda was not one of the requirements. Therefore, findings of this study show a poor application of computer in community pharmacy operation; and cost effective pharmacy computer software, new requirements for running a community pharmacy and CPD or C.E are needed for improving pharmacy practice toward using information technology in community pharmacy managements.

#### 4.2.1.4Stock management system

The aim was to verify if the pharmacy has a system to monitor stock levels. In addition, the researcher verified if the implemented computerised stock management system that must include calculation of reorder level values were functioning properly for meeting patient/client needs.

The pharmacy has a formalized stock management system			
	Frequency (%)		
No	109(72.7)		
Yes	41(27.3)		
Total	150(100.0)		

### Table 7: Formalized stock management system

 Table 8: Available types for stock management system among community

 pharmacies that have a formalized stock management system

Types for stock management system	Frequency (%)
Stock card based	1(2.4)
Computerized inventory system	40(97.6)
Total	41(100.0)

Table 9: Implementation of stock management system properly to monitor the stocklevel among community pharmacies that have a formalized stock managementsystem

The pharmacy has implemented the way to monitor the stock level			
Frequency (%)			
No	27(65.9)		
Yes	14(34.1)		
Total	41 (100.0)		

Table 7,8 and 9shows that less than half of community pharmacies surveyed have a formalized stock management, where majority of them have a computerized inventory; and less than half have implemented properly the stock management system that monitors stock levels, e.g. stock card or other quantification based system. These findings show that both the lack of Knowledge, skills and appropriate pharmacy computer software and program could be the main cause's. Therefore, findings of this study reveal a poor pharmacy practice in stock management of health commodities in community pharmacies in Rwanda. The quality of using information technology in community pharmacy stock management system should be improved and C.E or C.P.D should be provided to pharmacy staffs as aiming to improve pharmacy practice toward good stock management of health commodities.

# 4.2.1.5 Reorder level in community pharmacies

The aim was to identify and verify the exiting method utilised by community pharmacies for calculation of records. A memory, consumption and/ or time based daily reordering system must be in place whereby the reorder levels is being calculated or known from records.

Pharmacies with reorder level system in place whereby the reorder levels can be		
calculated or known from records		
Frequency (%)		
No	137(91.3)	
Yes	13(8.7)	
Total	150(100.0)	

### Table 10: The existing reorder level system

#### Table 11: The basis of reorder level

Method	Frequency (%)			
Time based	2(15.4)			
Package based	11(84.6)			
Total	13(100.0)			

Table 10 and 11 shows that among less than half of community pharmacies surveyed who have a reorder level system in place, most of them use the Package based method during calculation of reorder level. These findings indicate that most community pharmacies in Rwanda don't have accurate system for forecasting their health commodities in need. This is a poor pharmacy practice as it may reduce the quality of accessing to health commodities by client/patient. A study conducted in U.S.A revealed that inaccurate stock management produce inaccurate needs estimations and problems of stock outs and expiry(Dobler et al, 1996). These practice could be due to both the lack of Knowledge, skills and appropriate pharmacy computer software and program on stock management of health commodities .However this survey didn't assess at which extend poor health commodities reordering level system affect the outcome of pharmacy practice in community settings. Therefore these results demonstrate that, there is a need to provide C.E or C.P.D to pharmacy staffs on good stock management of health commodities; and pharmacy staffs should build their capacity toward having appropriate materials and equipments.

			Reorder frequency				Total
		Dail	Week	Monthl	When		
			у	ly	У	required	
Prov	SOUTH	Count	0	12	18	0	30
ince		%	0.0%	40.0	60.0%	0.0%	100.0
		within		%			%
		Provinc					
		e					
	NORTH	Count	0	2	7	0	9
		%	0.0%	22.2	77.8%	0.0%	100.0
		within		%			%
		Provinc					
		e					
	EAST	Count	0	5	12	0	17
		%	0.0%	29.4	70.6%	0.0%	100.0
		within		%			%
		Provinc					
		e					
	WEST	Count	0	6	10	0	16
		%	0.0%	37.5	62.5%	0.0%	100.0
		within		%			%
		Provinc					
		e					
	KIGALI	Count	7	66	4	1	78
		%	9.0%	84.6	5.1%	1.3%	100.0
		within		%			%
		Provinc					
		e					
		Count	7	91	51	1	150
Total %		%	4.7	60.7	34.0%	0.7%	100.0
		within	%	%			%
		Provin					
		ce					

 Table 12: Frequency of Reordering of health commodities by community pharmacies per each province

Table 12 shows the frequency of reorder of health commodities by community pharmacies per each province in Rwanda. By examining the table attentively it is clear that in Kigali city, most community pharmacies make order in short time compare to other provinces. It meant that access to health services and commodities by patient in Kigali city as the biggest city of Rwanda is more ease compare to other provinces. This imbalance of access to health service and commodities between Kigali city and other province in community pharmacies and/or patient/clients could be due to many factors

such as geographic limitation and lack of enough pharmaceutical retails and wholesales in rural area compare to Kigali city. As a mother of fact those results were supported by RDB in (2015), where it revealed that all most all operating private pharmaceutical retails and wholesalers were concentrated in Kigali city compare to other provinces. This findings show gap in supply chain management of health commodities in community pharmacies in Rwanda. This challenging pharmacy practice may impinge the quality of life of patients living in that rural area .Therefore, there is a need to increase investments in private pharmacy retails and wholesale in those rural, improve supply chain management in those areas as aiming at increase access to health commodities by patient; as one cofactor of practicing good pharmacy practice.

# 4.2.2 Assessing the pharmacy storage in community pharmacies

The second specific objective of this study was to assess at which extent storage practice is being achieved in community pharmacies in Rwanda. This was achieved by evaluating Cleanliness situation and hygiene condition in the pharmacy, storage condition and the system for storing medicines, and last by verifying the storage practices of medicines.

# 4.2.2.1 Cleanliness and hygienic status of the pharmacy

The objective was to verify the level of cleanliness and tidiness of the pharmacy (dispensary and store room). However the presence of pest in pharmacy must be zero (WHO 2003, 2012).

	Frequency (%)				
Existence of signs of pests in pharmacy area					
No	147(98.0)				
Yes	3(2.0)				
Total	150(100.0)				
Clea	nse level of the dispensary area				
Very clean &tidy	137(91.3)				
Acceptable Clean/tidy 10(6.7)					
Not Clean/Untidy	3(2.0)				
Total	150(100.0)				
Cleanse level of the storage area					
Very clean &tidy	137(91.3)				
Acceptable Clean/tidy	10(6.7)				
Not Clean/Untidy	3(2.0)				
Total	150(100.0)				

 Table 13: The cleanliness and tidiness level of the community pharmacy

The results in table 13 revealed that the level of cleanness and tidiness were good in more than half of community pharmacies visited. It means that most community pharmacies couplied with government policies and measure toward hygiene. However pharmacies could be suspected for doing this to please the customer. This reason was support by the study conducted in Uganda by Nina in (2007), where some community pharmacies visited, instead of reflecting the professional nature of pharmacy and inspiring public confidence; they did it for please the customer. This study also reveals the presence of sing of pest in2.0% of pharmacies surveyed, which show a deviation from WHO recommendation (0.0%) (WHO 2003, 2012). This findings show critical unclear area in few pharmacies. Therefore, regular inspection and audit in community pharmacies and training for pharmacy staff for eradicating all signs of low hygiene in pharmacies should be conducted as intended to optimize a good set of hygiene practices that should be perceived by a community pharmacy setting and be associated with the preservation of health and healthy living.

### 4.2.2.2Hygienic condition of the pharmacy

The objective was to assess the hygienic conditions of the pharmacy by verifying the availability of toilet and hand washing facilities and their operation where applicable.

	Yes	No
Hygiene of the pharmacy	Frequency (%)	Frequency (%)
Availability of toilet facilities	150(100.0)	0.0 (0.0)
Toilet facilities are acceptable, hygienic, and functioning	127(84.7)	23(15.3)
Availability of toilet paper	113(75.3)	37(24.7)
Hand washing facilities are acceptable, hygienic, and functioning	41(27.3)	109(72.7)
There is a soap for hand washing	24(16.0)	126(84.0)

 Table 14: Hygiene condition of the community pharmacy

Table 14 shows that more than half of pharmacies didn't have hand washing facilities that are acceptable, hygienic, and functioning; and they didn't have soap for hand washing. Normally all healthcare care settings should have hygiene and sanitation practice that guaranty the safety not only for patient, but for all people (WHO 2009) .Otherwise poor hand washing may result in increased absenteeism, particularly in time of a potential HINI pandemic, but a limited availability to adequate facilities may lead to poor compliance or poor efficacy of hand washing if performed (Scott Sutton, 2009). Findings of our study reveal a poor hand washing hygiene practice in community pharmacies that could be due to lack of appropriate hand washing facilities and lack of appropriate standard in most community pharmacy settings in Rwanda. Therefore, despite the country effort toward hygiene and sanitation, the national guidelines attempt to address this important issue by focusing on both pharmacy premises, product shortcomings and behavioral shortcomings should be enforced in those settings. Also C.E and C.P.D should be provided where possible.

# . 4.2.2.3Storage conditions

The aim was to ascertain storage conditions. It mean that the researcher verify the level of good storage practices at the pharmacy/dispensary thought these indicators.(WHO 2003,2012)

	Yes	No
Storage conditions	Frequency (%)	Frequency (%)
The medicines are protected from direct sunlight	141(94.0)	9(6.0)
The temperature of the storage room is monitored	34(22.7)	116(77.3)
The temperature of the store room is regulated	20(13.3)	130(86.7)
There is a functioning system for cold storage	59(39.3)	91(60.7)
If yes, only medicines are stored in the refrigerator – no food or beverage	50(84.7)	9(15.3)
If yes, the vaccines are placed in center of the refrigerator (not in the door)	52(88.1)	7(11.9)
If yes, the temperature of refrigerator is recorded	17(28.8)	42(71.2)
The roof is appropriate and there is no leakage	147(98.0)	3(2.0)
The storage space is sufficient and adequate	102(68.0)	48(32.0)

 Table 15: Good Storage Practice in community pharmacies – Level of Storage conditions

Table 15 shows that more than half of visited pharmacies didn't regularly monitor regulate and record the temperature of pharmacy dispensing/ storage room. Also less than half of pharmacies have a functioning system for cold storage, but most of them didn't record the temperature of refrigerator. Basically proper storage of pharmaceuticals products in pharmacy premises should be maintained until it reaches the last consumer(i.e., proper temperature, light, and humidity, conditions of sanitation, ventilation, and segregation)(WHO 2003, 2012). These findings implied that most community pharmacies in Rwanda were grossly compromised to good storage condition;

because there are some health commodities that their quality could not be assured as their stability studies is exposed to a certain extent of modifications and may not be detected early. This poor storage condition could be due to lack of knowledge and skills related good storage condition and lack of adequate national standard; however lack of appropriate equipments is another cofactor in poor storage condition. Similarly results was revealed in Tanzania , where lack of appropriate equipments contribute to inappropriate controlling of storage condition in health facilities; and end by requesting that the equipment used should be capable of controlling the storage conditions within the ranges (TFDA, 2008). Also other similarly result found that good storage practice was found to be undermined by storage condition tolerance which is usually defined as the acceptable variations in temperature and relative humidity of storage facilities for stability studies (Taylor, 2001)

Therefore, there is a need to elaborate the national standard of storage of health commodities and provide C.E or C.P.D to different health provider for achieving good storage practice in Pharmacies.

### 4.2.2.4 System for storage of health commodities

The objective was to ascertain if the pharmacy is well organised and practice good storage practices. The researcher asked to be shown around the pharmacy and observe the following conditions:

A well examined stars a system	Yes	No	
A wen organised storage system	Frequency (%)	Frequency (%)	
Medicines are stored in shelves or in cupboards	149(99.3)	1(.7)	
Medicines stored on shelves or in cupboards are stored in systematic manner (alphabetic, therapeutic, etc.)	149(99.3)	1(.7)	
Shelves are labeled	8(5.3)	142(94.7)	
There is a separate lockable cupboards for narcotic drugs	111(74.0)	39(26.0)	
The store room is lockable	15(10.0)	135(90.0)	

 Table 16: Good Storage Practice in community pharmacies –A well organised storage system

Table 16 that all most all pharmacies didn't label their shelves and their store room was not lockable. Normally practice of good labeling of shelves improve basic operations in the pharmacy such as easily identifying medicines on shelves and avoid fatal errors that are in relation to medication storage whereas locking store room help in good inventory management (WHO 2003, 2012). However, the findings of this study indicate that this practice is no longer applicable in more than half of community pharmacies. Therefore, findings indicate a gap in organizingand practice of good storage practice in most community pharmacies of Rwanda; which has a negative consequence to pharmacist staff in meeting pharmacy professional standards. Otherwise further research studies should be conducted to assess the cause of this poor practice as aiming at taking appropriate decisions.

### 4.2.2.5 Storage practices of health commodities

The objective was to ascertain if good storage practices were maintained and implemented in community pharmacies in Rwanda.

Stone as muching of modicing	Yes	No	
Storage practices of medicine	Frequency (%)	Frequency (%)	
Opened bottles are labeled with opening date	2(1.3)	148(98.7)	
All Opened tins/ bottles have a lid on	146(97.3)	4(2.7)	
Boxes are on the floor of the dispensary area	143 (95.3)	7 (4.7)	
Expired drugs are recorded	99(66.0)	51(34.0)	
Expired medicines are kept separate from other medicines until disposal	111(74.0)	39(26.0)	
There is a procedure for disposal of expired medicines	3(2.0)	147(98.0)	
FEFO method was being complied	105(70.0)	45(30.0)	

 Table 17: Storage practices of medicines in community pharmacies- its

 implementation and maintenance

Table 17 show that all most all community pharmacies surveyed were found to have opened bottles that were not labeled with opening date; and also more than half of community pharmacies surveyed didn't have procedure for disposal of expired medicines. Normally once a bottle that contained medicine is opened; it should be labeled with opening date for assuring the quality of medicines that are stored there. In addition, all practices pharmacy should implement FEFO, recorded Expired drugs and have procedures for disposal of expired medicines; otherwise improper disposal of unused and expired medicines can affect the environment and health (WHO 2003, 2012). However, findings of this study indicate that community pharmacies operate privately in Rwanda are below standard in maintaining and implementing good storage practice as they didn't comply to those guidelines. Therefore, result from table 16 and 17 show that there is a dire need to improve the storage practices in community pharmacies by complying with

the regulatory standards/laws as specified by the drug regulatory Authority of Rwanda; and implement training program directed towards pharmacy staff.

# 4.2.3Assessing the pharmacy services in community pharmacies

This is considered as the third specific objective of this study. The researcher was willingly to know the extent by which community pharmacy services are offered to customers/patients. Here the researcher considered the opening hours in the whole week, qualification of staffs, services offered, tests offered, and participation in health promotion activities.

# 4.2.3.1Openinghoursin community pharmacies

The aim of this point was to know if community pharmacies are able to serve patients long time as possible and if the patient can find the right health commodities at any time.

Opening hours in normal working days				
Number of hours	Frequency (%)			
12-16h	141 (94.0)			
16-20h	6(4.0)			
20-24h	3(2.0)			
Total	150(100.0)			
0	pening hours on Saturday			
<8h	2(1.3)			
8-12h	141(94.0)			
12-16h	4(2.7)			
16-20h	3(2.0)			
Total	150(100.0)			
	Opening hours on Sunday			
<8h	2(1.3)			
8-12h	146(97.3)			
12-16h	2(1.3)			
Total	150(100.0)			

Table 18: Opening hours per day of community pharmacies

Table 18 shows that more than half of community pharmacies work between 12-16hours per day in normal working days whereas in weekend days all most all pharmacies surveyed work between 8-12hours only .This implied that the attitude of working 24 hours for any day for delivering good pharmaceutical services was not applicable by most community pharmacies in Rwanda. Indeed, despite the availability of Pharmacy duty roster in different community pharmacy settings (MoH 2016); a poor community pharmacy practice was revealed in all most all community pharmacy settings in Rwanda as it reduces the quality of accessing to pharmaceutical service by customers at any time.

It mean that there are some patient who don't get their medicine Therefore further research to ascertain at which extent this poor pharmacy practice affect patients in need, should be conducted and different health stakeholders are requested to elaborate a cost effective strategies for resolving permanently this problem in the country.

### 4.2.3.2 Number and qualification of staff

The aim was to determine the competence of dispensing site/pharmacy personnel. The researcher ascertained the community pharmacies that have responsible pharmacists, the number, the qualifications, years of experience and working hours of the staff in the pharmacy. Also the researcher ended by verifying how much time (hours) does a pharmacist spend in the pharmacy on an average on a daily basis.

			Having re	Total	
			/head pha	/head pharmacists	
			No	Yes	
Province	SOUTH	Count	5	25	30
		% within Province	16.7%	83.3%	100.0%
	NORTH	Count	1	8	9
		% within Province	11.1%	88.9%	100.0%
	EAST	Count	5	12	17
		% within Province	29.4%	70.6%	100.0%
	WEST	Count	2	14	16
		% within Province	12.5%	87.5%	100.0%
	KIGALI	Count	0	78	78
		% within Province	0.0%	100.0%	100.0%
Total		Count	13	137	150
		% within Province	8.7%	91.3%	100.0%

 Table 19: Number of community pharmacies with pharmacists

Table 19 shows that 8.7% of community pharmacies didn't have responsible pharmacist, the one who is at the heart of community pharmacies operations and ensuring good pharmaceutical services delivery (FIP, 1998). This findings indicated that the main contributing region was Eastern and South province. Even if this study didn't ascertain the cause of lacking responsible pharmacist in those provinces at the day of visit, finding of this study indicate a poor pharmaceutical service delivery in 8.7% of community pharmacies mostly located in Eastern and South province in Rwanda. This poor practice could be due to many factors which need to be investigated as intended to elaborate new strategies to eradicate this issue.

		-	N	Number of pharmacists			
			0	1	2	3	
Provin	SOUTH	Count	5	23	2	0	30
ce		%	16.7	76.7%	6.7%	0.0	100.0
		withinProvinc	%			%	%
		e					
	NORTH	Count	1	7	1	0	9
		% within	11.1	77.8%	11.1%	0.0	100.0
		Province	%			%	%
	EAST	Count	5	12	0	0	17
		%	29.4	70.6%	0.0%	0.0	100.0
		withinProvinc	%			%	%
		e					
	WEST	Count	2	11	3	0	16
		% within	12.5	68.8%	18.8%	0.0	100.0
		Province	%			%	%
	KIGALI	Count	0	65	8	5	78
		% within	0.0%	83.3%	10.3%	6.4	100.0
		Province				%	%
Total		Count	13	118	14	5	150
		% within	8.7%	78.7%	9.3%	3.3	100.0
		Province				%	%

 Table 20: Number of pharmacists in community pharmacies

# Table 21: Number of nurses in community pharmacies

			Number of nurses					Total	
			0	1	2	3	5	8	
Pr	SOUT	Count	1	19	10	0	0	0	30
ovi	Н	% within	3.3	63.3	33.3	0.0	0.0	0.0	100.0
nc		Province	%	%	%	%	%	%	%
e	NORT	Count	0	5	4	0	0	0	9
	Н	% within	0.0	55.6	44.4	0.0	0.0	0.0	100.0
		Province	%	%	%	%	%	%	%
	EAST	Count	0	12	5	0	0	0	17
		% within	0.0	70.6	29.4	0.0	0.0	0.0	100.0
		Province	%	%	%	%	%	%	%
	WEST	Count	0	6	9	1	0	0	16
		% within	0.0	37.5	56.2	6.2	0.0	0.0	100.0
		Province	%	%	%	%	%	%	%
	KIGA	Count	3	30	40	3	1	1	78
	LI	% within	3.8	38.5	51.3	3.8	1.3	1.3	100.0
		Province	%	%	%	%	%	%	%
Total Co		Count	4	72	68	4	1	1	150
% with		% within	2.7	48.0	45.3	2.7	0.7	0.7	100.0
		Province	%	%	%	%	%	%	%

The table 20 and 21 show that more than half of community pharmacies use one pharmacist as well as one to two nurse(s) in providing pharmaceutical service. This finding indicated that all most all community pharmacies are concentrated by nurses, whom their duties and competency in community pharmacy practice remain uncertain. It means that most pharmacists were working with more nurses .This is similar to the study conducted in Ambo Town, West Shewa in Ethiopia where dispensing medicine by nursing professionals was also observed (Jimma Likisa Lenjisa, et al. 2015). In addition, one pharmacist may be overloaded by too much tasks in which he/she could be tired and be subjected to ineffective work production. Therefore there is a need to study if service offered by one pharmacist compare to their tasks and working hour contributes to good pharmaceutical service delivery in community pharmacies; otherwise more pharmacy staffs with pharmaceutical background are need in those community pharmacy settings and where possible C.E or C.P.D should be provided to those health provider.

		•	Others pat	Total		
			0	1	2	
Provinc	SOUTH	Count	15	14	1	30
e		% within Province	50.0%	46.7	3.3%	100.0%
				%		
	NORTH	Count	8	1	0	9
		% within Province	88.9%	11.1	0.0%	100.0%
				%		
	EAST	Count	8	8	1	17
		% within Province	47.1%	47.1	5.9%	100.0%
				%		
	WEST	Count	3	12	1	16
		% within Province	18.8%	75.0	6.2%	100.0%
				%		
	KIGALI	Count	43	29	6	78
		% within Province	55.1%	37.2	7.7%	100.0%
				%		
Total		Count	77	64	9	150
		% within Province	51.3%	42.7	6.0%	100.0%
				%		

 Table 22: Other personnel in community pharmacies who use to be in direct contact with patient/client (Neither pharmacist nor nurses)

Table 22 shows a number of people (48.7%) who are neither nurses nor pharmacists who use to be in direct contact with patient/clients during community pharmacy operation in all provinces and city of Rwanda. This finding indicates unqualified personnel who carry

out pharmaceutical service operation in community pharmacy in Rwanda. This is similar to the study conducted in Ambo Town, West Shewa in Ethiopia where about 28% of the dispensers working in community pharmacy settings were neither pharmacy professionals nor persons with any sorts of qualification. This is one of the cofactors that contributing to poor pharmaceutical service delivery such as inappropriate medicine dose dispensing in community pharmacies in Rwanda. Jimma Likisa Lenjisa, et al. (2015). If this situation continues there will be significant economic and life loss in the future in Rwanda pertaining to irrational use medicines. Therefore, special inspections and regular audit should be conducted by regulatory bodies and join hand with client/patient for eradicating all cause of such mal practice in community pharmacies in Rwanda.

			Other not	Other not in contact with clients		
			0	1	2	
Provinc	SOUTH	Count	4	21	5	30
e		% within	13.3%	70.0%	16.7%	100.0%
		Province				
	NORT	Count	1	8	0	9
	Н	% within	11.1%	88.9%	0.0%	100.0%
		Province				
	EAST	Count	2	11	4	17
		% within	11.8%	64.7%	23.5%	100.0%
		Province				
	WEST	Count	1	10	5	16
		% within	6.2%	62.5%	31.2%	100.0%
		Province				
	KIGAL	Count	11	51	16	78
	Ι	% within	14.1%	65.4%	20.5%	100.0%
		Province				
Total		Count	19	101	30	150
		% within	12.7%	67.3%	20.0%	100.0%
		Province				

Table 23: Others not in contact with clients in community pharmacies

Table 23 shows more than half of community pharmacies use to have one staff not in direct contact with client/patient. These findings indicate that there are other job attributions in community pharmacies. However the qualification, skills and knowledge of these personnel to accomplish their tasks in community pharmacy should be determined, otherwise their practice toward fulfilling good pharmacy practice guideline

will remain critical. In addition, where possible more training about pharmacy practice should be provided to these personnel.

			Exp	Experience of pharmacists			
			Below	5-10	Above 10		
			5 years	years	years		
Provin	SOUTH	Count	18	4	3	25	
ce		% within	72.0%	16.0%	12.0%	100.0%	
		Province					
	NORTH	Count	6	2	0	8	
		%	75.0%	25.0%	0.0%	100.0%	
		withinProv					
		ince					
	EAST	Count	12	0	0	12	
		% within	100.0	0.0%	0.0%	100.0%	
		Province	%				
	WEST	Count	13	1	0	14	
		% within	92.9%	7.1%	0.0%	100.0%	
		Province					
	KIGALI	Count	67	5	6	78	
		% within	85.9%	6.4%	7.7%	100.0%	
		Province					
Total		Count	116	12	9	137	
		% within	84.7%	8.8%	6.6%	100.0%	
		Province					

Table 24: Range of experience of licensed pharmacists in community pharmacies
			Expe	Total		
			Below 5	5-10	Above 10	
			years	years	years	
Provi	SOUT	Count	21	6	2	29
nce	Н	% within	72.4%	20.7%	6.9%	100.0
		Province				%
	NORT	Count	9	0	0	9
	Н	% within	100.0%	0.0%	0.0%	100.0
		Province				%
	EAST	Count	16	1	0	17
		% within	94.1%	5.9%	0.0%	100.0
		Province				%
	WEST	Count	12	0	4	16
		% within	75.0%	0.0%	25.0%	100.0
		Province				%
	KIGA	Count	68	5	2	75
	LI	% within	90.7%	6.7%	2.7%	100.0
		Province				%
Total		Count	126	12	8	146
		% within	86.3%	8.2%	5.5%	100.0
		Province				%

Table 25: Experience of licensed nurses in community pharmacies

Table 24 and table 25 shows that majority of community pharmacies surveyed reported that their pharmacists and their nurses have less than 5 years of working experience in community pharmacy. This finding indicates that working experience will remain critical compare to current community pharmacy practice trends in Rwanda. Therefore capacity building and more training are need for broadening pharmacy staff skills and knowledge toward community pharmacy practice.

Full time pharmacists					
Number of Pharmacist	Frequency (%)				
1	120(87.6)				
2	15(10.9)				
3	2(1.5)				
Total	137(100.0)				
Part time pharmacists					
0	132(96.4)				
1	5(3.6)				
Total	137(100.0)				

 Table 26: Number of full and part time pharmacists

Tuble 27. Rumber of full a	
	Frequency (%)
	Full time nurses
1	90(61.6)
2	53(36.3)
3	2(1.4)
5	1(.7)
Total	146(100.0)
	Part time nurses
0	125 (85.6)
1	21 (14.4)
Total	146 (100 0)

Table 27: Number of full and part time nurses

Table 26 and 27shows that majority of community pharmacies use one fulltime pharmacist as well as one fulltime nurse, whereas using part time staff was not applicable in most community pharmacies visited. This could be due to eithereconomic status of those community pharmacies or lack of appropriate national guideline. This finding indicates that the rational of using par time staff remain uncertain. Therefore, new strategies should be put into place for promoting the rational of employing fulltime qualified personnel in pharmacy.

#### 4.2.3.3 Particular services offered by community pharmacies to customer

The aim was to ascertain the availability of services at the dispensing site in order to make sure that patient is fully satisfied.

Coursions offered	Yes	No	
Services offered	Frequency (%)	Frequency (%)	
The privacy of the patient is respected	18(12.0)	132(88.0)	
There is a chairs or benches for customers while waiting	144(96.0)	6(4.0)	
Availability of weighing scale to the clients	20(13.3)	130(86.7)	
Availability of drinking water for customers	143(95.3)	7(4.7)	
Availability of facilities for washing hands	11(7.3)	139(92.7)	
Availability of soaps for customers	10(6.7)	140(93.3)	
Availability of toilet for customers	142(94.7)	8(5.3)	
Availability of toilet paper for customers	102(68.0)	48(32.0)	

-	• •	-	•		-	• ·	-	•		
Tahle	78.	Particular	Services	offered	hv	community	nhg	rmacies '	tn.	customer
Lanc	40.	I al ticular	SCI VICCS	untru	IJУ	community	pne	macics	w	customer

Table 28 shows that more than half of community pharmacies visited didn't respected the privacy of the patient; it mean that most pharmacies didn't dispense medicines without other customers/clients listening to the conversation in a separate room with only the patient and the dispenser or by having other patients kept away from the dispensing area

by at least 2 meter. This poor practice this world health Organization recommendation, as it stipulated that every patient must be treated with respect especially when explaining the use of some types of medicine (WHO 1996).A 2001 pharmacy- led intervention in The Netherlands focused on pharmacies as sources of information, reporting lack of pharmacy privacy led to reluctance to ask questions(H Laetitia Hattingh et al 2015).Similarly, in the UK, research to enhance the utilization of community pharmacy services identified lack of privacy and confidentiality as crucial obstacles that could inhibit service utilization. H Laetitia Hattingh et al (2015).Also more than half of community pharmacies visited didn't have a weighting scale, facilities and soaps for hands washing to the clients. Therefore this study reveals a poor service that was offered to patient/clients in community pharmacy setting of Rwanda; which could be to lack of adequate community pharmacy standard that deal with premises and services offered and to improve all rules and requirements for set up a community pharmacy.

#### 4.2.3.4 Test conducted by community pharmacies

The objective was to assess the type of available tests offered by the dispensing site/pharmacy.

Tracks and the stad has a based on the	Yes	No
lests conducted by pharmacy	Frequency (%)	Frequency (%)
The pharmacy conducts cholesterol test	3(2.0)	147(98.0)
The pharmacy helps patients to monitor blood pressure	3(2.0)	147(98.0)
The pharmacy conducts pregnancy test	1(.7)	149(99.3)
The pharmacy conducts glucose test	3(2.0)	147(98.0)
The pharmacy has asthma peak flow meter	0(0.0)	150(100.0)
The pharmacy offers prescription glasses	0(0.0)	150(100.0)

Table 29: Tests offered by community pharmacies

Table 29 show that all most all community pharmacies visited didn't offering different tests to patients in need. This implied that community pharmacies intervention as a point of care testing is still at a lower level of pharmacy practice. These findings could be due to both academic training of pharmacist and the lack of adequate regulation and rules and scope of community pharmacy practice. The finding of this study was supported by a study conducted in six cities of Amhara regional state of Ethiopia , where most community pharmacies reported as being either "not at all involved" or "little involved" in counseling on smoking cessation (79.3%), and screening for hypertension (86.9%),

diabetes (89.5%), and dyslipidemia (88.9%).However, the lack of knowledge or clinical skills and lack of personnel or resources were the most commonly reported barrier for expanding such services (Daniel Asfaw Erku et al 2017). Therefore, this survey reveals a low level of community pharmacies 'involvement in point-of-care testing, including rapid diagnostic testing in Rwanda. In order to have community pharmacies of Rwanda that meet good pharmacy practice guidelines, further research studies should focus on the applicability and sustainability of community pharmacy involvements in a point-of care testing program.

#### 4.2.3.4Participation of community pharmacies in health promotion

The aim was to ascertain the type of health promotion/public health activities the pharmacy/pharmacist has been engaged in during the last year.

Table 30: Participation of community pharmacies/pharmacist in Health promotion	n
activity / public health activitiesduring last year	

Health promotion activity / public health	Yes	No
activities	Frequency (%)	Frequency (%)
Participation in health promotion activities	12(8.0)	138(92.0)
The pharmacy has participated in anti-smoking activities	0(0.0)	12(100.0)
The pharmacy has participated in anti-obesity	4(33.3)	8(66.7)
The pharmacy takes participation in fighting against HIV-AIDS, TB	2(16.7)	10(83.3)
The pharmacy participates in activities of family planning	4(33.3)	8(66.7)
The pharmacy participates in actions regarding fighting diabetes	3(25.0)	9(75.0)
The pharmacy participates in school education on health related topics	0(0.0)	12(100.0)
The pharmacy/pharmacist has participated in fighting against-STI	6(50.0)	6(50.0)
The pharmacy/pharmacist has participated in educating people on good nutrition	2(16.7)	10(83.3)

Table 30 shows that all most all community pharmacies responded that they didn't participation in health promotion activities. A study conducted in Uganda by Nina (2007), revealed that none of the pharmacies had been engaged in any health promotion/public health activity during the last year (Nina 2007). Despite that this survey didn't determined the reason behind this poor pharmacy practice, a study conducted in Australia (Tasmanian and Victorian pharmacists) revealed that the lack of understanding

of the knowledge and skills a pharmacist could offer as the main cause ( Howarth, Helen Dorice 2005). Another study conducted in Community pharmacies in Kuwait showed that the 58% of pharmacist respondent that lack of pharmacists' time was reported by about of respondents as the major barrier limiting pharmacists' provision of health promotion (Awad A et al 2010). Therefore, our study demonstrates that community pharmacies involvement in public health services is low particularly in lifestyle . However further studies on a national scale regarding identifying barriers and application of a health education and health promotion model to selected populations in community pharmacies are recommended. Also the provision of public health activities following appropriate training and reduction or removal of various more barriers as aiming at complying to good pharmacy practice guidelines and inform regulatory bodies should be implemented.

#### 4.2.4 Dispensing practices in community pharmacies

The objective was to evaluate at which extent good dispensing practice is performed by community pharmacies in Rwanda. This aim was achieved by verifying the availability of information source available to the dispensary /pharmacy staff, Product range – medicines in stock, dispensing time, health commodities package materials and equipment, dispensing procedure and prescriber contact.

#### 4.2.4.1 Information available to dispenser/pharmacy staff

The aim was to determine the number and type of health information sources available to the dispensary /pharmacy staff.

Table	31:	Available	health	information	source	to	dispensers	in	community
pharm	acies	1							

	Yes	No
Information available to dispenser	Frequency (%)	Frequency (%)
Availability of drug catalogues	66(44.0)	84(56.0)
Existence of drug formulary	47(31.3)	103(68.7)
Existence of essential drugs list with standard treatment	23(15.3)	127(84.7)
Access to computers with drug information or internet access	112(74.7)	38(25.3)
Existence of medicines handbooks such as Martindale	21(14.0)	129(86.0)

Table 31 show that more than half of community pharmacies visited didn't have drug catalogues, drug formulary, essential drugs list with standard treatment and medicines handbooks such as Martindale or drug index whereas majority have access to computer

and internet as source of health information for quickly accessing to health information. Compare to a study conducted in OMAR by Saif Mohammed Al-Farsi et al.(2013), where it found that all pharmacies had at least one reference but most were books like the Oman National Formulary (ONF) and British National Formulary (BNF) were the most commonly found (n=56, 79%) whereas only 10% of community pharmacists had internet access. That comparison indicates that availability of health information source to dispensers/pharmacy staffs vary according to each nation. Therefore, this study reveals an overall poor access to paper based health information resources in community pharmacy staffs of Rwanda by dispenser/pharmacy staffs. This will affect the quality of information provided to patients and other healthcare providers, and have an adverse effect on the role that dispenser/pharmacy staff can play in the health care system in Rwanda. Therefore, intervention aimed at improving dispensers/pharmacy staffs' access to and evaluation of drug information is urgently needed.

#### **4.2.4.2 Product range – medicines in stock**

The objective was to o ascertain the average of items (different brands, strength and formulations) kept in stock.





The above figure shows that more than half of community pharmacies visited have a more than1000 items in their stock. This implied that community pharmacies try to respond to patient fundamental right of having access to medicine at a certain point. However, this study didn't outlined at which extent the essential medicine are accessible compare to their brand medicines in community pharmacies. The implication of this, is that patient should get cost effective health medicines that respond to their need.

#### 4.2.4.3. Dispensing time

The aim was to determine the time used for dispensing of medicines which must including provision of information to the patient. Normally the study verified the time it takes for the staff to dispense the medicines after having been informed what need to be dispensed and after having obtained the medicines to be dispensed. *Note: Receiving the prescription and finding the medicines are not included only the actual dispensing and time and the time talking to the patient while dispensing including the process of payment of the medicines.* The ideal dispensing time that should be used by the dispenser should be above 61 seconds for every community pharmacy (HV Hogerzeil 1993)





Figure 3 shows that only 62.7% of community pharmacies surveyed use more than one minute as dispensing time while that time should be used by all community pharmacies surveyed. This indicate a poor dispensing practice in 37.3% of community pharmacies visited as they used to spend less than a minute while dispensing medicine. These findings generally indicated that there is a national problem regarding the time spent to dispensing medicines at community pharmacy settings. However, the causes of this problem remain uncertain. In Ethiopian scenario, inadequate dispensing time could be because of the fact that community pharmacy settings are more of business oriented and rush to accommodate more patients rather than applying the standard principles of dispensing. Beside this, study showed that lack of adequate knowledge on drugs and up-to-date drug information was major factor that prevent dispensers from not taking time to counsel patients (Jimma Likisa Lenjisa, et al. 2015). This in turn could lead to lack of time for prescription processing, labelling medications, and counselling the patient which might make the time to be somewhat shorter (Jimma Likisa Lenjisa, et al.2015).

Therefore, there is a poor dispensing practice which should be assessed in all community pharmacy in Rwanda.

## 4.2.4.3Packagingand repackaging material

The aim was to determine how medicines are packed by Observing and verifying the packaging material available and in use. The ideal packaging and repackaging material to be used should not affect the quality of the health commodities in any way until their use or allow other contaminants to do so. It must be the best compromise between cost and risk of waste, with regard to maintaining standard of cleanliness or international standards (FIP, 1998).

De alco ain a con d'aconce alco ain a motorial	Yes	No	
Packaging and repackaging material	Frequency (%)	Frequency (%)	
Pharmacy supplies new bottles	3(2.0)	147(98.0)	
Pharmacy use dispensing envelope	150(100.0)	0(0.0)	
Pharmacy reuses old but cleaned bottles	55(36.7)	95(63.3)	
Pharmacy uses original manufactured containers	1(.7)	149(99.3)	
Pharmacy only use new or washable bottles/the patient do not bring own container	28(18.7)	122(81.3)	
Only appropriate packaging and repackaging material are used	0(0.0)	150(100.0)	

Table 32: Packaging and repackaging material in community pharmacies

Table 32 shows that all community pharmacies use dispensing envelope; but the use of other packaging and repackaging material remain uncertain. However, this study didn't quantify the imbalance of using these materials .Therefore, a study is needed toaccess if these materials comply with international standardFIP (1998). Otherwise a national standard of appropriate packaging and repacking materials should be available in all community pharmacies in Rwanda.

### 4.2.4.4 Dispensing equipment

The objective was to determine if the pharmacy has appropriate equipment for dispensing medicines. The ideal dispensing equipment should avoid any cross contamination (WHO 2012).

Dian anging a guinmant	Yes	No Frequency (%)	
Dispensing equipment	Frequency (%)		
A spatula or spoon	144(96.0)	6(4.0)	
Non-filled labels	12(8.0)	138(92.0)	
Tablet counting tray or similar	9(6.0)	141(94.0)	
Tablets counted by use of tray or similar instrument but not bare hand	12(8.0)	138(92.0)	
Graduated measuring flask	6(4.0)	144(96.0)	

 Table 33: Dispensing materials in community pharmacies

Tables 33 shows that more than half of community pharmacies visited use to have a spatula or spoon as dispensing equipments. However their rational use for avoiding cross contamination remains uncertain. This finding implied that other dispensing equipments are likely unavailable in most pharmacies surveyedand where these equipments are in need by pharmacy staffs, it is reasonable that poor dispensing practice will be detected as soon as their need was ignorant by the pharmacy. Perhaps the lack of these materials is due to that some medicines are dispensed in their manufacturer's container, no counting or measuring equipment is needed. The same finding was foundin Ethiopia, where in all community pharmacies surveyed, they found that dispensing spoon was the only dispensing aid available (Jimma Likisa Lenjisa, et al. 2015). This study confirms the unavailability of essential dispensing-equipments. So there is a need for urgent managerial and educational intervention to improve dispensing practices in all community pharmacies Rwanda.

### 4.2.4.5 Dispensing procedure

The objective was to ascertain if the pharmacy has a system for controlling dispensing of prescribed medicines and the pharmacist is responsible for undertaking that control. Normally all community pharmacies should have appropriate procedure in place for dispensing prescribed medicines

	Frequency (%)
There	is a control before dispensing the medicines
No 137(91.3)	
Yes	13(8.7)
Total	150(100.0)
	Responsible for control
Nurse	8(61.5)
Pharmacist	5(38.5)
Total	13(100.0)

**Table 34: Dispensing procedure in community pharmacies** 

Table 34 shows that all most all community pharmacies didn't have appropriate procedures in place to control dispensing of medicines; and where it found to be feasible, more than half of nurses were observed to undertake that control .i.e. countercheck . This is completely different of what should be done in assuring the quality of dispensing practice. This poor practice could be due to lack of national dispensing standard or guidelines in community pharmacies. Findings from this research study were supported by Nina (2007) in study conducted in Uganda, where no countercheck was undertaken before dispensing the medicines in all community pharmacy surveyed. Our study confirms a lack of appropriate medicine dispensing procedures in community pharmacy of Rwanda, which imply a poor dispensing practice. Therefore appropriate national dispensing procedures should be developed and implemented in community pharmacies of Rwanda (FIP/WHO 2011).

#### 4.2.4.6Prescriber contact

The aim was to ascertain if records of prescriber contacts related to pharmacy initiated changes in prescriptions are kept. It helps to determine the influence that the prescriber could play in good dispensing practice if dug dispensed differ from the one prescribed. The ideal requirement is to record update prescriber contact in all community pharmacies.

	Yes	No
Prescriber contact	Frequency (%)	Frequency (%)
The pharmacy takes contacts to health prescriber in case of prescription error	122(81.3)	28(18.7)
The pharmacy has a record or file for recording of health prescriber contacts	50(33.3)	100(66.7)
If yes the last entry is less than 3 months old	2(4.0)	48(96.0)

#### Table 35: Health Prescriber contact in community pharmacies

Tablet 35 show that less all most all community pharmacies surveyed didn't have the update contacts records of the prescribe as the only 2% pharmacies were observed to do so. This implied that majority of community pharmacies didn't kept update prescriber contact; which is indicating a poor collaboration between pharmacy staffs and prescribers. These findings from this research study were supported in by Nina (2007) in a study conducted in Uganda, where no retail pharmacy was found to document prescriber' contact. Therefore, new strategies should be addressed for improving professional collaboration of community pharmacies as a health provider with different health prescribers.

#### 4.2.5 Rational use of medicines in community pharmacies

This is the fifth specific objective of this study where the intention was to know how compliance to rational use of medicines by community pharmacies was fulfilled. This was scaled in terms of the availability of information sources to patient /client, patient care with regard to medicines use, labelling practices in dispensing medicines, rational prescribing, dispensing of "pharmacist only medicines" initiated by patients, dispensing of antibiotics without prescription and ascertained if generic substitution was implemented in community pharmacy practice.

### 4.2.5.1 Availability of patient information sources

The objective was to ascertain the availability of information sources to the patient/client. Normally access to health information by patient/client should be easy and is their right; and access to health information sources by patient/client is integral part for using medicine rationally (FIP 998).

Availability of patient information	Yes	No
resources	Frequency (%)	Frequency (%)
Patient leaflets	143(95.3)	7(4.7)
Computer printouts	4(2.7)	146(97.3)
Access to computers with drug information	1(.7)	149(99.3)
Medicines' handbooks	1(.7)	149(99.3)

Table 36: Availability of patient information sources in community pharmacies

Table 36show that in all most all community pharmacy surveyed, patient leaflets was available as the main source of patient information whereas other sources of patient information remain scarce. These findings were confirmed by those found by Nina (2017) in a study conduct in retail pharmacy in Uganda; where all pharmacy surveyed, the source for written patient information were scare. This finding confirms that the availability of insufficient patient information sources is common in community pharmacies of Rwanda. Community pharmacies should improve this poor practice for helping patient/client access to other reliable medicine information.

#### 4.2.5.2 Patient care

The aim was to ascertain the knowledge of the patient with regard to medicines use. The ideal situation for this outcome indicator stands that: Clear and correct patient care should be provided by health providers and being understood by patient/ client 100% to ensure the rational use of medicine (FIP, 1998, WHO 2001).

Patient care	Yes	No
	Frequency (%)	Frequency (%)
Discrepancy	19(1.3)	1481(98.7)
Number of doses to take	1147(76.5)	353(23.5)
Frequency to take	316(21.1)	1184(78.9)
Duration of how long to take medicine	993(66.2)	507(33.8)
Treatment cause	481(32.1)	1019(67.9)
Other information	561(37.4)	939(62.6)

Table 37: Patient care provided by community pharmacies

Table 34 shows that more than half of patients/clients living community pharmacies were interviewed and respondent that they didn't clearly understood the frequency, the cause and other necessary information of their medicines. This implied a poor patient care at community pharmacy level in Rwanda. The findings of this study were confirmed by those revealed in a study conducted in health facility from Ethiopia (2003), where only

67% instead of 100% of patient/client understood well how to take their dispensed drugs (Assessment of the Pharmaceutical Sector in Ethiopia2003). The results showed that the types and intensity of patient care provided incommunity pharmacy settings is still poor. The pharmacist and/or their assistants should improve their practice toward provide quality patient care with regard to understanding the patients' comprehension levels.

#### 4.2.5.3 Labeling

The objective was to access labelling practices in dispensing medicines. It means that to verify that good labelling practice is used when dispensing medicines. The ideal guideline is to buy/receive the medicine labelled 100% with all essential elements of good labelling practice (FIP, 1998).

Elements of good Labeling	Yes	No
practices	Frequency (%)	Frequency (%)
Medicine name	1034 (68.9)	466(31.1)
Strength	950(63.3)	550(36.7)
Quantity	214(14.3)	1286(85.7)
Expiry date	114(7.6)	1386(92.4)
Dose	397(26.5)	1102(73.5)
Patient name	96(6.4)	1404(93.6)
Facility name	15(1.0)	1485(99.0)

 Table 38: Labeling practices in community pharmacies

Table 35 show that all medicine bought/received by patient from community pharmacies surveyed weren't 100% conform to good labeling practice (not adequately labeled with quantity; Expiry date; Dose; Patient name and Facility name). This implied a poor labeling practice of medicine. These findings were supported by those found in Ethiopia (2003), where 43% of drugs dispensed to patients in health facilities were inadequately labeled (Assessment of the Pharmaceutical Sector in Ethiopia2003). Another research study conducted in Lao People's Democratic Republic in 2011, demonstrated that 47 % of drugs dispensed to patients in health facilities were inadequately labeled (Real world pharmacy, 2001). In Uganda, only 5% of medicines dispensed to patients in health facilities were adequately labeled (at least having name of the medicine and how to take it) (Nina, 2017). Dispensing drugs without label or labeling drug without full information could increase the chance of drug toxicity, and therapeutic failure. Therefore inadequate labeling of medicines remains a concern in community pharmacies of Rwanda. It needs

immediate response by regulatory bodies to support Good Pharmacy Practices guidelines implementation and enforce pharmacy staff to put label on each and every dispensed medicine to patients; and also more training are needed to address sub-optimal labeling practices.

# 4.2.5.4 Rational prescribing

The aim was to determine if pharmacy staffs encounter factors that undermine pharmacy practice by assessing poly pharmacy, use of generic prescribing and antibiotics in community pharmacy of Rwanda. Note: antibiotic doesn't include antihelminitics, TB, antifungal, antiamoebic or anti malaria medicines, but should include penicillin and tetracycline eye ointments.

Descriptives						
		Ν	Mean	Std.	Minim	Maximu
				Deviation	um	m
Number of	SOUTH	600	1.92	1.085	1	4
medicines	NORTH	180	1.49	.918	1	4
per	EAST	340	1.53	.966	1	4
prescription	WEST	320	1.75	1.083	1	4
	KIGALI	1560	2.12	1.084	1	4
	Total	3000	1.94	1.086	1	4
Number of	SOUTH	600	.46	.499	0	1
generics per	NORTH	180	.55	.499	0	1
prescription	EAST	340	.46	.499	0	1
	WEST	320	.51	.501	0	1
	KIGALI	1560	.56	.632	0	2
	Total	3000	.52	.573	0	2
Number of	SOUTH	600	.46	.499	0	1
antibiotics	NORTH	180	.55	.499	0	1
per	EAST	340	.46	.499	0	1
prescription	WEST	320	.51	.501	0	1
	KIGALI	1560	.53	.519	0	2
	Total	3000	.51	.511	0	2

 Table 39: Rational prescription found in community pharmacies

ANOVA						
		Sum of	df	Mean	F	Sig.
		Squares		Square		
Number of	Between	156.797	4	39.199	34.74	.000
medicines	Groups				3	
	Within Groups	3379.17	2995	1.128		
		0				
	Total	3535.96	2999			
		7				
Number of	Between	6.469	4	1.617	4.943	.001
generics	Groups					
	Within Groups	979.850	2995	.327		
	Total	986.320	2999			
Number of	Between	3.676	4	.919	3.537	.007
antibiotics	Groups					
	Within Groups	778.081	2995	.260		
	Total	781.757	2999			

 Table 40: Analysis of variance regarding rational prescribing by province

Table 39 and 40 shows that a poly pharmacy was prescribed in all community pharmacies visited, and was statistically significant (p=0.000<0.05) all provinces and Kigali city. These findings were confirmed by World Health Organization (2004), where worldwide statistic, estimated that half of all medicines are inappropriately prescribed. Therefore, these findings confirm that irrational medicine prescribing is a common challenge to all community pharmacies of Rwanda while they are promoting rational use of medicine. Therefore there is a need to elaborate strategies for preventing irrational prescribing.

### 4.2.5.5 Dispensing of "pharmacist only medicines" initiated by patients

The objective was to assess the quality of dispensing and counselling of pharmacist only medicines (POM) or pharmacist initiated drugs (PIM). The guideline indicates the pharmacist should be responsible for the quality of dispensing and counselling those medicines at 100% (FIP, 1998).

 Table 41: The the quality of dispensing of pharmacist only medicines (POM) or

 pharmacist initiated drugs (PIM)

Dispensing pharmacist only medicines (POM)	Yes	No
or pharmacist initiated drugs (PIM)	Frequency (%)	Frequency (%)
Tablets are kept in shelves	150(100.0)	0(0.0)
The pharmacist is involved in dispensing medicines	73(48.7)	77(51.3)

Table 41, show that more than half of community pharmacies visited didn't effectively involved in dispensing' pharmacist only medicines (POM) 'initiated by patient or

pharmacist initiated medicine (PIM). These findings illustrate irrational us of medicines, that could be due to lack of appropriate national guidelines on rational use of medicines. The findings were confirmed in a study conducted in in Pakistan, where only 5.9 % of community pharmacies visited were aware of POM(Azhar Hussain et al 2012). This finding indicate illegal sale of a wide range of pharmacist only medicines (POM) initiated by patient or pharmacist initiated medicine (PIM) in most community pharmacies of Rwanda . This poor practice contributes to irrational use of medicines, therefore national guidelines and more awareness are needed for promote rational use of medicines.

#### 4.2.5.6 Dispensing of antibiotics without prescription

The objective was to assess if antibiotics can be obtained without prescription. The guideline recommends that all antibiotics should be dispensed with authentic medical prescription (FIP, 1998).

Dismonsing on tiblicating with out program tion	Yes	No	
Dispensing antibiotics without prescription	Frequency (%)	Frequency (%)	
The pharmacy would sell the antibiotic without prescription	143(95.3)	7(4.7)	

 Table 42: The quality of dispensing antibiotic in community pharmacies

Table 39 show that all most all community pharmacies surveyed sold antibiotics without prescription; however this study didn't ascertain the cause of this irrational antibiotic use. These finding were confirmed by those found worldwide, where it is estimated that more than 50% of antibiotics worldwide are purchased privately without a prescription, from pharmacies or street vendors in the informal sector (Cars O, Nordberg P 2005). Another study conducted in Ghana revealed that at least 60% of the chemical shops were found to sell various antibiotics to the public outside the remit of their license (Sixtus B. Bayaa Martin Saana, et .al 2014). Indeed, a study conducted in Spanish pharmacies revealed that attitudes such as patient complacency, external responsibility, indifference and insufficient knowledge were shown to be the cause of irrational antibiotics dispensing and sales(Maruxa Zapata-Cachafeiro et al 2014).Our study confirms that irrational dispensing of antibiotic in most community pharmacies is a need to change this bad practice within community pharmacies by complying with pharmacy ethic, rule and regulation.

#### 4.2.5.6 Generic substitution

The main objective was to assess if generic substitution is implemented.Normally generic substitution means that prescribed medicine is substituted by a cheaper medicine with the same qualitative and quantitative composition in active substances, same dosage form, and same route of administration as the reference drug, with bioavailability demonstrated by appropriate studies (Trost et al., 2012); and the reason for substitution should be provide to the patient/client 100%.

 Table 43: the level of implementation of generic substitution in community pharmacies

Conquia substitution	Yes	No
Generic substitution	Frequency (%)	Frequency (%)
The generic substitution is offered	81(54.0)	69(46.0)
The substitution is explained	33 (40.7)	48 (59.3)

Table 43 reveal that more than half of community pharmacies offer generic substitution; among them, more than half of community pharmacies did not explain that substitution. The findings of this study was supported in a study conducted in Lebanon, where majority of community pharmacies visited(64%) were in favour of generic drug substitution; however, less than half (40%) indicated they have substituted brand drugs for generic equivalents(Fadi El-Jardal et al. 2017).Our research study didn't assess the cause of that malpractice but Rathe et al., (2014) conduct a study and found that it was due to unclear impact of cost containment policies on quality of care.Fadi El-Jardal et al. (2017) found that57% of visited Lebanon pharmacies indicated that the existing pricing system discourages them from performing generic drug substitution.Therefore finding from our study confirms general that generic drug substitution is not yet implemented in community pharmacies of Rwanda. However, the real cause of this poor practice should be examiner.

All in all, the current rational use of medicine in community pharmacy of Rwanda underscores the urgency need for national community pharmacy practice reform.

# **CHAPTER FIVE: GENERAL CONCLUSION**

The pharmacy practice in community pharmacies in Rwanda was assessed thought its prominent five components which are the system, the storage, the service, the dispensing and the rational use of medicine. This assessment was vital in order to know at which extent community pharmacies in Rwanda are meeting the guideline of Good Pharmacy Practice. However general conclusion was drown from partial conclusions of each specific objective as follow:

#### Conclusions

More than half of community pharmacies in Rwanda didn't have appropriate pharmacy system because of lacking national community pharmacy standard and training and appropriate material such as appropriate pharmacy software that help them to comply with guideline of Good Pharmacy Practice.

Regarding good storage practice, storage condition was undermined by poor monitoring and regulator of store room and cold storage temperature and humidity and lack of hygienic and functioning hand washing facilities in more than half of community pharmacies in Rwanda.

The quality of pharmacy service offered in most community pharmacies was undermined by lack of sufficient trained pharmacy staffs; lack of national premise standard that guarantee the privacy of the patient in the dispensing site/pharmacy as well as lack of community pharmacy contribution as a point of care testing and participate in health promotion activities.

Good dispensing practice was undermined in most community pharmacies by not having dispensing procedure in place and weak professional collaboration of medicine prescribers and community pharmacy staffs.

Dispensing antibiotics without prescription, inaccurate patient care, inappropriate labeling and generic substitution practice were the core indicators of irrational use of medicine in most community pharmacies in Rwanda;

Briefly majority of community pharmacies in Rwanda were not meeting good pharmacy practice guidelines. This implies the poor quality of community pharmacy practice in Rwanda. Therefore it underscores the urgency need for national community pharmacy practice reform.

#### Recommendations

The output of this research study should be bring a lot off fruitful to community pharmacies and their staffs, to the Rwanda pharmacy council, to pharmacy academician and to the Ministry of health, however their input is needed by every stakeholder through the following partial recommendations that were down from every objectives as follow :

- Regarding the system, there are urgent to develop appropriate national community pharmacy guidelines and standards by community pharmacies in collaboration with pharmacy regulatory Authorities, institutes or and others; providing C.E or C.P.D to pharmacy staffs about the use and utility of information technology in community pharmacies operations; and trainings in good inventory management. In addition community pharmacies should increase the investment in the community pharmacy toward information technology and recognizing essential, advanced and enhanced pharmacy services.
- According to good storage practice, community pharmacy staffs should comply with all requirements of hygiene and stock conditions of pharmacy. However the Ministry of Health in collaboration with different pharmaceutical related agencies or bodies should carry out audits and inspections as intended to protect people from any harm result from bad storage practice in pharmacies of community settings. Also trainings are one of the solutions to eradicate this poor practice.
- > Regarding the service offered, Minister of Education, the National pharmacy council and the Ministry of Health in collaboration with different pharmaceutical related intuitions or Authorities should increase the number of trained and qualified personnel in pharmacies of community settings, and should also revise and implement pharmacy academic curriculum to help pharmacy students to be knowledgeable and skilled about new pharmacy trends such as screening test. They should also collaborate for developing national pharmacy scope of practice and develop and implement national guidelines and standard of community pharmacy premises as intended not only to respect the privacy of the patient but also comply with international guidelines of good pharmacy practice. Briefly they should revising criteria for establishing community pharmacies. Modernizing the education in pharmacy practice using information and health assessment technologies, introducing inter-professional training and training of trainers for pharmacy practice, increasing awareness of the necessity of basic and

specialist competences. Offering more educational, training and innovative programs and multiple CPD activities. Promoting pharmacists role in the health care system and encouraging development of individual educational portfolios.

According to good dispensing practice, most community pharmacies should improve their practice toward good dispensing practice for responding to patient needs. The National Pharmacy council and the Ministry of Health in collaboration with different pharmaceutical related agencies or bodies should set and avail national standard of good dispensing and be able to conduct audits and inspections for the implementation of those standards and procedure.

Lastly, community pharmacy staffs should change their practice as aiming at promoting rational use of medicines. However the Ministry of Health and National pharmacy council in collaboration with different pharmaceutical related agencies or bodies should promote any activity that improve knowledge and skills of community pharmacy staff toward rational use of medicine and should be able to conduct audits and inspections for ensuring the rational use of medicine. All in all pharmacies should moving from commercial to patient care model, investing in pharmacy structure and processes, raising basic and specialist competences and skills, establishing better relationship with other health care providers, and continuing assessment of Pharmacy Practice status and quality of Pharmaceutical care services.

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**APPENDICES** 

**Appendix 1: Research questionnaire** 

# REASEARCH TOPIC: ASSESSMENT OF PHARMACY PRACTICE IN COMMUNITY PHARMACIES TOOL FOR MEASURING GOOD PHARMACY PRACTICE

**Researcher**: Jean d'Amour HABUMUGISHA BPhrm PG: 10103196 Surpervisor: Emile Bienvenu ,Bphrm, MScPhrm, PhD Code of Community/Retail Pharmacy: District:

# Indicators:

A. S	YSTEM	95
1.	Prescribing recording system availability	95
2.	Prescribing recording system use	
3.	Computerisation	96
4.	Stock management system	96
5.	Reorder level	97
<b>B.</b> S'	TORAGE	
6.	Cleanliness of the store (15 A & 15 B)	
7.	Hygiene of the pharmacy	
	Storage conditions	
9.	System for storage of medicines	99
10.	Storage practices of medicines (19A & 19B)	100
C.SI	ERVICES	
11.	Prescription turnover/load	
12.	Opening hours	
13.	Number and qualifications of staff	
14.	Services offered	
16.	Tests offered	103
17.	Health promotion activities	103
D.D	ISPENSING	104
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# A. SYSTEM

# 1. Prescribing recording system availability

a) Is a prescription book/ computerized system available for recording prescription data: (Yes/No): \_\_\_\_\_

If yes:

b) Does the system provide recording of <u>all</u> the following data: (Yes/No if one or more is no): \_\_\_\_\_

	Yes	No
Date		
Patient name		
Medicines name		
Prescriber name		
Prescriber name		

c) Are old prescriptions kept (Yes/No) (Check): \_\_\_\_\_

If yes, for how long: \_\_\_\_\_ years

Data source:

Prescription recording system

# 2. Prescribing recording system use

- a) Check if there are entries during the last 3 days (Yes/No): \_\_\_\_\_
- b) Record from last 10 entries what information have been entered in the system (Yes/No) (1/0): \_\_\_\_\_

Dispensing Operation	Date	Patient name	Medicines Name	Prescribers name	Sum	%
1.						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Sum						
%						

Data source: Prescription recording system.

## 3. Computerisation

Ask to see the computerized system and see how it is used

Is the pharmacy computerised? Yes/No: \_\_\_\_\_

If yes

- a) Is it used in stock management?: Yes/No: \_\_\_\_\_
- b) Are expiry dates monitored to ensure FEFO Yes/No:
- c) Is it used for labelling? Yes/No: \_\_\_\_\_
- d) Is it used for patient information? Yes/No: \_\_\_\_\_
- e) Is it used for prescription recording? Yes/No: \_\_\_\_\_
- f) Is it used for patient medication profile? Yes/No: \_\_\_\_\_

Data source:

Computer

#### 4. Stock management system

a) Does the pharmacy have a formalised stock management system e.g. stock cards, computerised stock management system including calculation of reorder level values: Yes/No: \_\_\_\_\_

If yes, which:

Stock card based	
Computerised inventory system	

b) Have the pharmacy implemented a stock management system that monitors stock levels, e.g. stock card or other quantification based system: Yes/No: \_\_\_\_\_

Data source: Documentation of the stock management system/Pharmacy staff

#### 5. **Reorder level**

a) Is a reorder system in place whereby the reorder levels can be calculated or known from records, stock cards or similar? (Y/N): \_\_\_\_ (No: if memory based)

Describe the system:

If yes:

b) Is the reorder system in use consumption or time based

Yes No

Time based (3 month consumption):	
Package based e.g. 5 packages left:	

Describe the system: \_\_\_\_\_

c) Reorder frequency (Y/N): daily: \_\_\_\_\_, weekly: \_\_\_\_\_, Monthly: \_\_\_\_\_ When required: \_\_\_\_; emergency orders: \_\_\_\_\_

Data source:

Pharmacy staff/Documentation of the stock management system
# **B. STORAGE**

# 6. Cleanliness of the store (15 A & 15 B)

Ask to be shown around the pharmacy, in particular the dispensing and storage area

<b>15 A</b> . <b>Criteria</b> (Yes = 1 / No = 0):	Yes	No
Are there or have there been signs of pests seen in the area?		

15 B.	Very clean & tidy	Acceptable clean/tidy	Not clean/untidy	Very dirty/untidy
The dispensary is: (Tick only one)				
The storage area is: (Tick only one)				

Data source: Observation of storeroom and dispensary

# 7. Hygiene of the pharmacy

Ask to be shown the toilet and hand washing facilities in the pharmacy.

	Yes	No/Na
<ul> <li>a) Are toilet facilities available?</li> </ul>		
<ul> <li>b) Are the toilet facilities acceptable, hygienic and functioning?</li> </ul>		
c) Are there toilet paper		
<ul> <li>d) Is the hand washing facilities acceptable, hygienic and functioning?</li> </ul>	?	
<ul><li>e) Is there soap for hand washing?</li></ul>		

Data source: Observation of facilities

# 8. Storage conditions

Ask to be shown the pharmacy and tick the following:

<b>Criteria</b> (Yes = 1 / No = 0):	Yes	No/Na
<ul> <li>Are the medicines protected from direct sunlight (Painted glass, curtains or blinds – or no windows)?</li> </ul>		
b) Is the temperature of the storage room monitored?		
<ul> <li>c) Can the temperature of the storeroom be regulated (Ventilation, heater, air-condition)?</li> </ul>		
<ul> <li>d) Is there a functioning system for cold storage (Refrigerator)?</li> </ul>		
<ul> <li>e. If yes, are only medicines is stored in the refrigerator – no food or beverage?</li> </ul>		
f. Are vaccines placed in the center of refrigerator (not in the door)?		
g) Is the temperature of the refrigerator recorded?		
h) Is the roof appropriate with no leakages?		
i) Is the storage space sufficient and adequate?		
Overall score: sum of a-i yes (1) divided by 9 minus NA's		

Data source: Observation of storage facilities

# 9. System for storage of medicines

Ask to be shown around the pharmacy and observe the following conditions:

<b>Criteria</b> (Yes = 1 / No = 0):	Yes	No
a) Are medicines stored on shelves and /or in cupboards?		
b) Are medicines stored on shelves or in cupboards stored in a systematic manner (alphabetic, therapeutic etc)?		
c) Are the shelves labelled?		
d) Is there a separate lockable cupboard for narcotic drugs?		
e) Is the storeroom lockable?		
Overall score: sum of a-e yes (1) divided by 5		

Data source: Observation of storage facilities

# 10. Storage practices of medicines (19A & 19B)

Ask to be shown around the pharmacy and observe the following conditions:

<b>Criteria</b> (Yes = 1 / No = 0):	Yes	No
a) Are opened bottles labelled with the opening date?		
b) Do all tins/bottles that have been opened have a lid on?		
c) Are there boxes on the floor in the dispensary?		
d) Is there a record for expired drugs (Check)?		
<ul> <li>e) Are expired medicines kept separate from other medicines until disposal? (Check)?</li> </ul>	S	
<ul> <li>f) Is there a procedure for disposal of expired medicines (Check)</li> </ul>		
<ul> <li>g) Is FEFO adhered to? (Check 20 randomly selected medicines in the storeroom for FEFO)</li> </ul>	Number	:
h) Record the number of medicines that does not adhere to FEFO:		

Data source: Observation of storage facilities

# **C.SERVICES**

# 11. Prescription turnover/load

	b) Cl prese from prese	neck in the presc criptions stored b computerized re criptions supplied	ription system (if by random selecti cords and record d:	available) or fr ing three differe I the number of	om ent days or
	•	Day 1	Day 2	Day 3	Average
Number of prescriptions f	lled				
Data source:	Pres	cription system c	or prescriptions s	tored	
12. Opening hours					
	Ob pre	tain information of ferably from a w	on the opening h ritten source. From	ours per day To	
	M	onday			
	Τι	lesday			
	W	ednesday			
	Tł	nursday			
	Fr	iday			
	Sa	aturday			
	Su	unday			

Data source: Pharmacy staff

# 13. Number and qualifications of staff

a) Record the staffing in the pharmacy at the day of survey

Category of staff	Number	Full time	Part- time	Year expe	s of p rience	oractio e	ce
				reco	rd for	each	staff
Pharmacist(s)							
Pharmacy technician(s)							
Nurse(s)							
Other in contact with clients							
Other not in contact with the clients							
							-

What training/education has the "Others in contact with clients" had? E.g. dispensary assistance, in-service training:

- a) What time do you / the chief pharmacist normally arrive at the dispensing site on a week day: \_\_\_\_\_(Time)
- b) What time do you normally leave on a week day: \_\_\_\_\_ (Time)

Data source: Pharmacy staff or written source.

# 14. Services offered

- a) Check if privacy can be achieved in dispensing so that it is possible to talk and dispense medicines without other customers/clients listening to the conversation (Yes=1/No=0): \_\_\_\_\_
- b) Check if there are chairs or benches for the customers to use while waiting, (Yes/No): \_\_\_\_\_
- c) Check if a weighing scale is available to the clients(Yes/No): \_\_\_\_\_
- d) Check if drinking water (to take tablets) is available to the customers (Yes/No) : \_\_\_\_\_
- e) Check if facilities to wash hands is available to the customers (Yes/No) : \_\_\_\_\_
- f) Check if soap is available to the customers (Yes/No) : \_\_\_\_\_
- g) Check if toilet is available to the customers (Yes/No) : \_\_\_\_\_
- h) Check if toilet paper is available to the customers (Yes/No) : \_\_\_\_\_

Data source: Dispensary site

# 16. Tests offered

Ask what tests are available – check their availability (Yes = 1 / No = 0):

	Yes	No
a) Cholesterol test		
b) Blood pressure monitoring		
c) Pregnancy test		
d) Glucose test		
e) Asthma peak flow meter		
f) Prescription glasses		

Data source: Dispensary site/Pharmacy

# 17. Health promotion activities

Ask if the pharmacy/pharmacist has been engaged in any health promotion/public health activities during the last year (Yes/No):\_\_\_\_\_

If yes, record the type of activities:

(Yes = 1 / No = 0):	Yes	No
Smoking		
Obesity		
HIV/AIDS ; TB		
Family planning		
Diabetes		
School education on health related topics		
Others : (Specify) :		

Data source:

Pharmacy staff

# **D.DISPENSING**

# 18. Information available to dispenser/pharmacy staff

Ask what information source are available – check their availability (Yes /No ):

		Yes	No
a)	Drug catalogues e.g. MIMS, BNF		
b)	(National) Drug Formulary, WHO Drug formulary		
c)	Essential drugs list with Standard treatment guidelines		
d)	Access to computers with drug information or internet access		
e)	Medicines handbooks such as Martidale etc		

Data source: Information sources

# **19.** Product range – medicines in stock

What is the total number of items in stock (different brands, strength and formulations): \_\_\_\_\_

If precise number is not available, estimate number of items: (Tick)

a)<100:\_\_\_\_, b) 100-200: \_\_\_\_, c) 201-500:\_\_\_\_ d)501-1000:\_\_\_\_ e) >1000:\_\_\_\_

Data source Stock management system/Pharmacy staff

# 20. Product range – alternative per brand

amoxicilline in the form of t	tablets or capsules
1.	6.
2.	
3.	
4.	
5.	

List all brands stored containing the active ingredient amoxicilline in the form of tablets or capsules

Data source: Stock management system/Pharmacy staff

# 22. Dispensing time

Measures the time it takes for the staff to dispense the medicines after having been informed what needs to be dispensed and after the medicines have been assembled.Observe the dispensing process without being noticed and record the dispensing time for 6 patients

Patient number	1	2	3	4	5	6	Average
Dispensing time in seconds							

Data source: Observation of dispensing process

# 23. Packaging material

Observe and verify the packaging material available and in use:

Type of packaging material used	Yes	No/Na
a) Pharmacy supply new bottles		
b) Dispensing envelope		
c) Pharmacy reuse old but cleaned bottles		
d) Use of manufacturers original containers		
<ul> <li>e) Pharmacy only use new or washed bottles the patients do not bring own containers/bottles</li> </ul>		
f) Only-appropriate packaging material is used		
In-appropriate packaging material seen was (describe	e):	

Data source:

Pharmacy

# 24. Dispensing equipment

Verify that the pharmacy has the following equipment in the dispensing area:

Equip	<b>ment</b> (Yes = 1 / No = 0):	Yes	No
a)	A spatula or spoon		
b)	Non-filled (empty) labels		
c)	Tablet counting tray or similar		
d)	Tablets counted by use of tray or similar instrument but not by bare hand		
e)	Graduated measuring flask		

Data Source: Observation/pharmacy staff

#### 25. Dispensing procedure

a) Observe the dispensing process. Is there a control carried out of the prescriptions and the medicines before dispensing, i.e. is it counterchecked? (Yes/No): \_\_\_\_\_

b) If yes, who undertakes the control:

Data source: Observation of dispensing.

# 26. Prescriber contact

Ask and check if the pharmacy keeps a record or file for recording of contacts to the prescriber regarding pharmacy initiated changes in prescriptions

a) Does the pharmacy take contact to prescriber in case of prescription error (Yes/No):\_\_\_\_\_

b) Does the pharmacy have a record or file for recording of contacts to the prescriber (Yes/No): \_\_\_\_\_ and

c) Is the last entry less than 3 month old (Yes/No):\_\_\_\_\_

Data source: Pharmacy staff and documents

# **E.RATIONAL USE OF MEDICINE**

# 27. Availability of patient information sources

Ask what information source are offered – check their availability (Yes = 1 / No = 0):

		Yes	No
a)	Patient leaflets		
b)	Computer printouts		
c)	Access to computers with drug information or goggle/similar		
d)	Medicines handbooks		

Data source: Information sources

# 28. Patient care

Interview 10 patients leaving the pharmacy and ask to see the medicines they have received and if possible their prescription: Select one of the medicines to check patient knowledge. Record the following (Yes = 1, No =0)

				Does the				
Pt. no	No. medi cine s pres crib ed	No of medici nes dispen sed	a) Discre- pancy (1/0)	b) Dose How many /much to take (1/0)	c) Frequenc y How often to take (1/0)	d) Duration How long to take the medicine (1/0)	e) Treatment cause: Do you know why you are getting the treatment (1/0)	f) Other information given: Adverse reactions, how to take etc) (1/0)-record which
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
	S	um of 1:						
% (s	sum / tot	al no. of						
patie	ənt							
inter	viewed)	*100						

Data source: Patient interviewed

# 29. Labelling

Interview 10 patients leaving the pharmacy and ask each patient to see the medicines they have bought/received. Select one medicine to check for labelling. (The first given to you by the patient). Use Yes = 1 / No = 0 to indicate if the information appears on the label

Medicine no	a. Medicine name*	b. Strength	c. Quantity	d. Date	e. Dose	f. Patient name	g. Facility name
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
Total (1)							
%							

\*Note: The medicine name appears by generic name or by brand and generic name

Data source: Patient interview

# 30. Rational prescribing

If retrospective prescribing information is available: Select by random 20 prescriptions covering a period of 3 month and record what has been prescribed in below table:

If retrospective information is not available: Select prescription information from the day of the survey in below table:

\* Note: Antibiotics does not include antihelmintics, TB, antifungal, antiamoebic or anti malaria medicines, but should include penicillins and tetracycline eye ointments.

Prescription	Number of	Number of generics	Number of
No.	medicines	-	antibiotics
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
Total			
Average			% of encounters:
		% of total medicines:	% of medicines:

Data source: Prescriptions.

# 31. Appropriateness of dosage and use of amoxicillin

Select the last 20 prescriptions for a moxicillin from prescription records or prescriptions and record the following:

Prescription no	1	2	3	4	5	6	7	8	9	10
Is duration >2½ days (Yes=1/No=0)										

Prescription no	11	12	13	14	15	16	17	18	19	20
Is duration >2½ days (Yes=1/No=0)										

Data source: Prescriptions

# 32. Dispensing of "pharmacist only medicines" initiated by patients

Enter the pharmacy as a surrogate patient and ask the counter for some POM e.g. 30 ibuprofen tablets. Only offer more information if you are asked for it. If asked say that they are for your mother who uses them for backache. She normally takes e.g. 200 mg tablets

a) Where were the tablets kept: \_\_\_\_\_

b) Was the pharmacist involved in the dispensing (did the counter staff consult the pharmacist)? (Yes/No):\_\_\_\_\_

Data source: Surrogate patient records

#### 33. Dispensing of antibiotics without prescription

Enter the pharmacy as a surrogate patient and ask for a course of Amoxyl tablets/capsules. Your husband has a cold and needs some antibiotics. Last time he was given Amoxyl and it helped. Be a bit persistent talk about unavailability of medicine in public sector. If offered ask how much they cost, say you haven't enough money and will come back with money later to buy them.The pharmacy would not sell you the antibiotic tablets/capsules as you did not have a prescription? (Yes/No): \_\_\_\_\_

Data source: Surrogate patient records

Note: One surrogate patient can combine indicator 29 and 30.

# 34. Generic substitution

Enter the pharmacy as a surrogate patient and present a prescription in brand name (e.g. Ciprobay 500 mg) Ask for the price first. Wait for their answer. Then react: Uh! that is expensive. Wait and see if an alternative is suggested. If not, then ask if there is a cheaper drug that you can have.

The price of the medicines first offered:\_\_\_\_\_

The name of the medicines first offered :\_\_\_\_\_

a) Was a generic substitution offered (Y/N):\_\_\_\_\_

What was offered after you asked for a cheaper drug :

Name of medicines suggested :\_\_\_\_\_ Price :\_\_\_\_\_

b) Was the substitution explained (Y/N) :\_\_\_\_\_

Surrogate patient record

Data source:

#### **Appendix 2: Approval from University of Rwanda**



**COLLEGE OF MEDICINE AND HEALTH SCIENCES** 

School of Medicine and Pharmacy

Huye, 30th March 2017

-

To: The Responsible Pharmacist

.....Pharmacy

Dear Sir/ Madam,

Re: Recommendation for Data collection

Within the frame of collaboration between your institution and the University of Rwanda, I have the pleasure, on behalf of the Department of Pharmacy at the School of Medicine and Pharmacy, to request your agreement in accepting, HABUMUGISHA Jean D' Amour, to collect data in your institution. According to the postgraduate Pharmacy program, student has to perform a research project in final year. His project is entitled" ASSESSMENT OF PHARMACY PRACTICE IN COMMUNITY PHARMACIES." supervised by Dr. Emile BIENVENU.

Any assistance rendered, facilitating him to collect data is highly appreciated.

WERC Yours faithfully Dr. HAHIRWA Innocent Head of Pharmack Department School of Medicine and Pharmacy HEALTH Tel: +250786006010

P.O.Box 3286 Kigali – RWANDA

WEBSITE: www.ur.ac.rw

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#### Appendix 3: Request Permission for Data Collect UNIVERSITY OF RWANDA

#### SCHOOL OF MEDICINE AND HEALTH SCIENCES

#### **DEPARTMENT OF PHARMACY**

# MASTER OF PHARMACEUTICAL QUALITY ASSURANCE AND QUALITY CONTROL

Dear Sir/Madam

#### **<u>RE</u>: REQUEST PERMISSION FOR DATA COLLECT**

My name is Jean d'Amour HABUMUGISHA, Postgraduate student from University of Rwanda as mentioned above. For fulfillment of Student's academic requirements for the award of a Master's degree in Pharmaceutical quality assurance and quality control by University of Rwanda, I am conducting a research study entitled *"assessment of pharmacy practice in community pharmacy in Rwanda"*.

# Therefore, I write to request your permission to collect data from your community

pharmacy.

I will use the attached data collection tools (structured questionnaire and a checklist for vital essential Medicine).

The information provided will be treated as confidential and used only for the purpose of this research unless with your direct permission to use it elsewhere for the interest of the public. No name(s) of informant or institutions will be mentioned on the final report (findings) of this research study.

I shall be highly grateful for your support and cooperation.

Yours sincerely

Jean D'amour HABUMUGISHA Researcher, 0783284720

Noted by:

Emile Bienvenue, Bphrm, MScPhrm, PhD The Research supervisor Nyakubahwa muyobozi,

# <u>IMPAMVU</u>: GUSABA URUHUSHYA RWO GUKUSANYA AMAKURU AZIFASHISHWA MU BUSHAKASHATSI

Nitwa HABUMUGISHA Jean D'amour, ndi umunyeshuri muri kaminuza y'u Rwanda.

Mu rwego rwo kurangiza icyiciriro cya gatatu cya kaminuza (Master) mu bijyanye no kubungabunga ubuziranenge bw'imiti, ndimo nkora ubushakashatsi mu gihugu cyose bufite umutwe ugira uti"kugenzura imikorera ya farumasi mu maguriro y'igenga atanga imiti y'abantu nibindi bijyanye nayo mu Rwanda".

Kubwibyo,mbandikiye mbasaba uruhushya rwo gukusanya amakuru azifashishwa muri ub'ubushakashatsi mu kigo mubereye umuyoboyi.

Ku mugereka wiyi baruwa hari ibizakorehwa mugukusanya amakuru y'ubu bushakashatsi.

Ub'ubushakashatsi nta zindi nyungu bugamije, amakuru muzatanga azakoreshwa mu rwego rw' ub'ubushakashatsi gusa kandi mw'ibanga; keretse nyiri ugutanga uru ruhushya abishatse nabwo mu nyungu zabaturage .Nta zina ry'umuntu cyangwa ikigo runaka rizagaragaragazwa nki byavuye muri ub' ubushakashatsi.

Murakoze mbaye mbashimiye.

Umushakashatsi 0783284720 HABUMUGISHA Jean D'amour.

Uyobora cyangwa uhagarariye ubu bushakashatsi Emile Bienvenue, Bphrm, MScPhrm, PhD

# Appendix 4: General Consent Form AMASEZERANO YO KWINJIRA MU BUSHAKASHATSI

# Umutwe w'ubushakashatsi:

KUGENZURA IMIKORERE YA FARUMASI MU MAGURIRO Y'IGENGA ATANGA IMITI Y'ABANTU N'IBINDI BIJYANYE NAYO MU RWANDA.

Abashakashatsi: Phn. HABUMUGISHA Jean d'Amour, Dr Emile BIENVENU, PhD

**Aho buzakorerwa**: Mu Rwanda hose hibandwa cyane cyane mu maguriro y'igenga atanga imiti y'abantu n'ibindi bijyanye nayo.

Aderesi: Mu gihe ugize ikibazo ku bijyanye n'ubu bushakashatsi cyangwa impungenge izo ari zo zose, wakwiyambaza:

1. Umugenzuzi mukuru uhagarariye ubushakashatsi: Dr Emile BIENVENU, PhD

- Telefoni: +250 (0) 788309765
- Imeri: ebienvenu3@gmail.com

2. Umushakashatsi: Phn HABUMUGISHA Jean d'Amour:

- Telefoni: +250783284720,
- Imeri: <u>damoukhan@yahoo.fr</u> cyangwa <u>damoukhan@gmail.com</u>

# AMAKURU AGENEWE ABAZABAZWA

# Iriburiro

Twishimiye kubatumira muri ubu bushakashatsi. Ubu bushakashatsi buzadufasha kumenya IMIKORERE YA FARUMASI MU MAGURIRO Y'IGENGA ATANGA IMITI Y'ABANTU N'IBINDI BIJYANYE NAYO MU RWANDA, bityo bigatuma hagaragazwa ahakenewe inyunganizi mu rwego rw'iterambere maze abafata ibyemezo bakaba bahera kubyagaragajwe muri ubu bushakashatsi bagakomeza inzira nziza yogushira mu bikorwa ingamba z'imbitse mu guteza imbere ibirebana n'imikorere myiza mu maguriro y' imiti y'abantu n'ibindi bijyanye nayo.

# Ibyerekeranye no kujya muri ubu bushakashatsi

Kujya muri ubu bushakashatsi si itegeko, biterwa nubushake bwawe umaze kubusobanurirwa.Iyi nyandiko igamije kugusobanurira byimazeyo iby'ubu bushakashatsi:uko buzakorwa, Impamvu yabwo ibyiza cyangwa ingaruka ushobora kugirira mugihe ubwinjiyemo. Kugirango ujye muri ubu bushakashatsi, nta kindi bisaba uretse kuba ubishaka, hanyuma ukabanza ugasinya aya masezerano. Amazina yawe

cyangwa y'ikigo ukoreramo bizagirwa ibanga;nta na hamwe bizagaragara muri ubu bushakashatsi. Mu gihe uri muri ubu bushakashatsi, biremewe ko hari ibibazo utasubiza cyangwa ugafata umwanzuro wo kubuvamo igihe icyo aricyo cyose ntankurikizi cyangwa ngo usabwe ibisobanuro .Gusa twifuzaga ko waba muri ubu bushakakashatsi.

# Ni nde ugiye gukora ubu ubushakashatsi?

Ubu bushakashatsi bugiye gukorwa n'umuhanga mu by'imiti y'abantu akaba n'umunyeshuri mucyiciro cya kabiri cya kaminuza y'u Rwanda ishami rya Farumasi.

## Uko bizagenda

Turaganira, turebe ndetse tukubaze ibibazo bigendanye :

- N'umurongo mugari ngenderwaho mu maguriro y'igenga atanga imiti y'abantu n'ibindi bijyanye nayo
- 2. Uburyo bukwiye mu kubika imiti y'abantu n'ibindi bijyanye nayo
- 3. Serivise ikwiye kuba itangwa mu maguriro y'igenga atanga imiti y'abantu n'ibindi bijyanye nayo
- 4. Uko Itangwa ry' imiti y'abantu n'ibindi bijyanye nayo bikwiye kuba bikorwa
- **5.** Uko ikoreshwa neza ry' imiti y'abantu n'ibindi bijyanye nayo bikwiye kuba bikorwa.

# Dore ishusho y'ubu bushakashatsi muri make

## Urupapuro rwo gusubirizaho

Turaganira, turebe ndetse tunagusomere ibibazo byateguwe kandi bigendanye n'ub' ubushakashatsi .Bishobora kugufata hafi iminota itatu (3) mu kudusubiza.

## Ibyago byabonekamo

Turamutse tubonye ikibazo gikeneye kwitabwaho dushingiye kubyo twabonye cg ku bisubizo watanze (urugero nko kuba wabura akazi kawe cyanga wananizwa, ugatotezwa), twabimenyesha inzegozose zibishinzwe aho ukorera cyangwa ahisumbuyeho kugira ngo bagufashe.

## Inyungu wakuramo

Kwinjira muri ubu bushakashatsi ntibisobanuye ko uzahabwa ibihembo. Nta nyungu itaziguye irimo gusa uzabonamo inyungu iziguye yoku wafashije abantu bagana amaguriro y'igenga atanga imiti y'abantu n'ibindi bijyanye nayo gukomeza kugira ubuzima n'imibereho myiza.

## Kugirirwa ibanga

Ub'ubushakashatsi nta zindi nyungu bugamije, amakuru muzatanga azakoreshwa mu rwego rw' ub'ubushakashatsi gusa kandi mw'ibanga; keretse nyiri ugutanga uru ruhushya abishatse nabwo mu nyungu zabaturage .Nta zina ry'umuntu cyangwa ikigo runaka rizagaragaragazwa nk' ibyavuye muri ub' ubushakashatsi.

#### Gutanga uburenganzira

Turagusobanurira ubu bushakashatsi ndetse ubaze nibibazo byose wifuza.Ukeneye ibindi bisobanuro wabaza umushakashatsi mukuru ariwe umuhanga mu by'imiti Habumugisha Jean d'Amour.

#### Ibyo kugira uruhare no kuva muri ubu bushakashatsi

Kujya muri ubu bushakashatsi ni ubushake.Ushobora kwemera kubugiramo uruhare cg ukabyanga ntakibazo .Ushobora kandi kuva muri ubu bushakashatsi igihe ubishakiye ntankurikizi cyangwa ibisobanuro usabwe. Igihe uvuyemo kandi amakuru yawe yaramaze kuboneka akomeza kugirwa ibanga kandi aguma mubushakashatsi, gusa twaguha copi yayo.

Usinye aya masezerano ntacyo bihindura kuburenganzira asanganywe. Ntibinahindura uburenganzira n'inshingano z'abashakashatsi.

- Ndemeye ko numvise, nasomye nanasobanuriwe iby'aya masezerano
- Nabonye umwanya uhagije wo gutekereza kuri aya makuru no kugisha inama
- Nahawe umwanya wo kubaza ibibazo mpabwa n'ibisubizo nahawe byanyuze
- Nasobanukiwe ko amakuru yose azagirwa ibanga kandi ibizava muri ubu bushakashatsi bizakoreshwa ku guteza imbere ubumenyi.

• Nasobanukiwe ko kubujyamo ari ubushake kandi ko mfite uburenganzira bwo kutabujyamo no kubuvamo igihe nshakiye cyose, ntibingireho ingaruka.

• Nsobanukiwe ko gusinya aya masezerano bidahindura nagato uburenganzira mpabwa n'amategeko.

• Nihitiyemo nta gahato kujya muri ubu bushakashatsi.

Amazina y'ugiye mu bushakashatsi:..... Isinya cyangwa igikumwe cy'ugiye mu bushakashatsi: ...... Ahantu n'Itariki,.....

Amazina y'ugusobanuriye ubu bushakashatsi(niba atari umushkashatsi mukuru)

Isinya cyangwa igikumwe cy'ugusobanuriye ubu bushakashatsi: ...... Ahantu n'Itariki, Amazina y'umushakashatsi..... Isinya cyangwa igikumwe cy'umushakashatsi: .....Ahantu n'Itariki

# MURAKOZE

# **CONSENT FORM (ENGLISH FORMAT)**

#### **Principal investigators**:

Phn. HABUMUGISHA Jean d'Amour, Dr Emile BIENVENU, PhD

#### Title of the research Study:

ASSESSMENT OF PHARMACY PRACTICE IN COMMUNITY PHARMACY IN RWANDA

**Site**: In Rwanda, mainly by focusing on pharmaceutical sector particularity in Retails/community pharmacies.

## If any problem concerning this study feel free to contact:

1. The supervision of this research project: Dr Emile BIENVENU, PhD Contact: - phone: +250 (0) 788309765

-Email: ebienvenu3@gmail.com

2. Investigator: Phn HABUMUGISHA Jean d'Amour:

Contact: Tel: +25 0783284720

Email: damoukhan@yahoo.fr or damoukhan@gmail.com

## I.INFORMATION FOR STUDY PARTICIPANTS

## Introduction

Dear Participant

You have been invited to take part in this research study. The study aimed at assessing the current pharmacy practice in community pharmacy in Rwanda and to identify areas of improvement for further appropriate policies development and implementation.

## Participation in the study

Study participation is on voluntary basis. After you have read carefully this consent form, understand well the objectives and how the study will be conducted, benefits and the risks you may get as a study participant. You will be enrolled after you sign this consent form. All the information about you will only be used for the purpose of this study and will be kept anonymous. 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.

Therefore we humbly request you to participate in this research study.

## Who is conducting this research?

This study is run by a postgraduate student from University of Rwanda in Pharmaceutical quality assurance and quality control under direct supervision of his lecture.

# Procedure

# We will ask question related to

- 6. The system that is being used in community pharmacy
- 7. The storage practice in community pharmacy
- 8. The service delivery in community pharmacy
- 9. The dispensing practice in community pharmacy
- 10. The rational use of medicines in community pharmacy

## Summary of the study

# Data collection sheet

We will read and explain to you the paper; it will take approximately 3minutes to answer all structured questions.

## Risks

In case we encounter or observe any problems that may put a research subject in risk during and/or after providing the requested research information or checking the data, (such as lose their job or may be harassed by their superior Authority, etc), we will informed all responsible personnel or institutions for handling your case.

## Benefit

There isn't any incentive for participate in this research study .There isn't also a direct benefit from this study but the only indirect benefit is your contribution to the health and well-being of patient/client

## Confidentiality

The information provided will be treated as confidential and used only for the purpose of this research unless with your direct permission to use it elsewhere for the interest of the public. No name(s) of informant or institutions will be mentioned or revealed on the final report (findings) of this research study.

#### **II. STATEMENT OF CONSENT**

By signing the above, I acknowledge that:

- I have read the information sheet or data collection sheet and the consent form, for this study,

- I had the opportunity to ask questions and provide answers as I am satisfied

- I took time to discuss with others to all about my concerned information in this study

And decide to take my concerned part in this research study as I was satisfied.

- I will receive a dated and signed copy of the consent form,

- I agree to take my concerned part in this research study

.....

Names of the subject (in capital letters)

.....

Date and Signature of the subject

.....

Name of the person requiring the consent (If not the researcher)

.....

Names of the researcher (in capital letters)

.....

Date and Signature of the Researcher

.....

Name of the witness (in capital letters)

.....

Date and Signature of the witness

#### THANK

Appendix 5: Research ethic training curriculum



# Appendix 6: Sample of "Mystery Client /patient "or" surrogate client/patient" Consent Form

The following is sample form to highlighting what key points to ask when asking for informed consent from men / women in the community to perform as mystery clients

I want to thank you for taking the time to meet with me today. My name is

\_\_\_\_\_ and I would like to talk to you about serving as a mystery client for

retails/community pharmacy.

The purpose of this work is to assess retail /community pharmacy practice in Rwanda.

Your participation would include the following:

- Training on how to conduct a mystery client visit
- > A visit to one or more community pharmacy as a mystery client
- Completion of an interview regarding the community pharmacy and the visit

I want to note that you will not receive any services during the community pharmacy visit (such as tests or exams), but may receive information and counseling on dispensing of antibiotics without prescription or generic substitution implementation or information on the quality of dispensing of pharmacist only medicines (POM) or pharmacist initiated

drugs (PIM).

All interview responses will be kept confidential and the interview should take less than an hour.

Are there any questions about what I have just explained?

Is your pharmacy willing to participate as a mystery client?

Interviewee

Witness

Date

# Appendix 7: Scenario Examples '' surrogate patient''

# 1. Dispensing of "pharmacist only medicines" initiated by patients

Assessment area:	Dispensing and care quality/RDU					
Question :	Enter the pharmacy as a surrogate patient					
	Ask the counter for some POM e.g. 30 ibuprofen tablets. Only offer more information if you are asked for it.					
	If asked say that they are for your mother who uses them for backache. She normally takes e.g. 200 mg tablets					
	➢ If offered , pay 10 tablets only					
	And ask the name and telephone number of the pharmacist saying that your mother will call her/him for further pharmaceutical advices.					

# 2. Dispensing of antibiotics without prescription

Assessment area:	Dispensing and care quality/RDU
Question :	Enter the pharmacy as a surrogate patient and
	Ask for a course of Amoxylline tablets/capsules by saying your relative (e.g. husband/wife) has a cold and needs some antibiotics. Last time he was given Amoxylline and it helped.
	Be a bit persistent talk about unavailability of medicine in public sector.
	➢ If offered ask how much they cost?
	Say you haven't enough money and will come back

with money later to buy them.

# 3. Generic substitution

Assessment area:	Dispensing and care quality/RDU
Question :	Enter the pharmacy as a surrogate patient and present a prescription in brand name (e.g. ORACEFAL 500 mg)
	> Ask for the price first.
	➢ Wait for their answer.
	> Then react: Uh! That is expensive.
	➢ Wait and see if an alternative is suggested.
	> If not, then ask if there is a cheaper drug that you

can have.

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Assessment area:	Dispensing and care quality/RDU					
Туре:	Outcome					
Objective:	To assess the quality of dispensing of pharmacist only medicines (POM) or pharmacist initiated drugs (PIM)					
Definition:	To verify the quality of dispensing and counselling in relation to POM					
Question :	a) Where were the tablets kept:					
	b) Was the pharmacist involved in the dispensing (did the counter staff consult the pharmacist)? (Yes/No):					
2. Dispensing of ant	ibiotics without prescription					
Assessment area:	Dispensing and care quality/RDU					
Туре:	Outcome					
Objective:	To assess if antibiotics can be obtained without prescription					
Definition:	To verify if antibiotics can be obtained without prescription					
Question :	The pharmacy would not sell you the antibiotic tablets/capsules as you did not have a prescription? (Yes/No):					

Surrogate patient records

# 1. Dispensing of "pharmacist only medicines" initiated by patients

Data source:

# **3.** Generic substitution

Assessment area:	Dispensing and care quality/RDU					
Type:	Outcome					
Objective:	To assess if generic substitution is implemented					
Definition:	To verify if generic substitution is implemented					
Question	The price of the medicines first offered:					
	The name of the medicines first offered :					
	a) Was a generic substitution offered (Y/N):					
	What was offered after you asked for a cheaper drug :					
	Name of medicines suggested : Price :					
	b) Was the substitution explained (Y/N) :					
Data source:	Surrogate patient record					

### **Appendix 9: Mystery Client assessment score according to their test performance**

This checklist provides an example of the components of pharmacy practice to collect from the mystery clients following their community pharmacy visit. Mystery clients are either given a copy of the interview guide to self administer and make notes on, or they can be interviewed shortly after the visit.

The mystery client is required to give a score by ticking to each of the observation factors, between 0 and 4, whereby:

 $0 = \text{not present}, \square$   $1 = \text{present but needs improvement}, \square$  $2 = \text{satisfactory}, \square$ 

3 = good,

4 = excellent.

Each retail/community pharmacy can be then assigned a total score as part of the ongoing monitoring

Name of retail/community pharmacy / provider: \_\_\_\_\_

Address: \_\_\_\_\_

Date: \_\_\_\_\_ Mystery Client Name:

Scenario enacted (circle)

- 1. Dispensing of "pharmacist only medicines" initiated by patient
- 2. Dispensing antibiotic without prescription
- 3. Generic substitution is implemented