



**COLLEGE OF MEDICINE AND HEALTH SCIENCES
SCHOOL OF MEDICINE AND PHARMACY
DEPARTMENT OF PHARMACY**

**QUALITY OF DISPENSING OF CONTROLLED MEDICINES AMONG
COMMUNITY PHARMACIES IN RWANDA**

A thesis submitted in fulfillment of the requirements for the award of a Master of Pharmaceutical Sciences, Quality Assurance and Quality Control at the University of Rwanda.

**Student: RUGAMBA Desire
PG10106841**

Supervisor: Dr. BIENVENU Emile

Huye, June 2016

ABSTRACT

Background: Above 50% of all medicines dispensing procedures in developing countries are inadequate. Lack of knowledge or lack of professionalism among medicines dispensers may result in poor quality of controlled medicines dispensing. **Objectives:** The main objective of this study was to evaluate the quality of dispensing of controlled medicines among community pharmacies and the level of knowledge of dispensers on those medicines. **Methodology:** This study was a cross sectional descriptive study which used both quantitative and qualitative approaches. The study population was formed by 245 community pharmacies, from which a sample of 150 pharmacies was drawn using a random sampling. Data collection was done using a self administered questionnaire containing both open and closed ended questions and through interview. Quantitative data were analyzed using SPSS version 18.0. The chi square test (χ^2) was performed to test the association between the experience of dispensers and their knowledge on controlled medicines at 5% level of significance ($\alpha=0.05$). Qualitative analysis was done using six steps of thematic analysis as it was suggested by Braun and Clarke in 2006. **Findings:** Of all research participants, 79.2% were male, 91.3% being pharmacists and their average working experience in dispensing medicines was 4.2 years. Controlled medicines were handled by 98% of sampled community pharmacies. Only 42.9% of all visited pharmacies had SOPs for controlled medicines dispensing and 96.6% of them had adequate cupboards for the storage of those medicines. 89.3% of community pharmacies were allowing both pharmacists and nurses to dispense controlled medicines to clients. It was found that during the checking of prescriptions for controlled medicines, the refill date was only interesting only 1.4% of all the respondents. The partial dispensing and the oral authorization for refilling prescriptions of controlled medicine were done by dispensers in order help patients reducing unneeded expenses. It was found that 96% of dispensers were writing only the directions for use during the labeling of controlled medicines to be dispensed. All respondents (100%) reported to counsel patients on controlled medicines use. The causes which were declining dispensers from dispensing controlled medicines to patients included prescriptions and patients related problems. Records about dispensed controlled medicine were found in 86.4% of visited community pharmacies and 82.8% of them were keeping those records for a period equal or exceeding 2 years. All community pharmacies were not reporting information concerning controlled medicines to any institution. Research findings showed that 47.3% of dispensers knew clearly the definition of controlled medicines but 9.4 % were able to clearly discuss different schedules of those medicines. Only, 2% of respondents reported to have attended trainings on controlled medicines in their career. Inferential analysis showed that there was no statistically significant association between the working experience of dispensers and their knowledge on controlled medicines. **Conclusion:** Some activities recommended in dispensing controlled medicines were inappropriately performed to ensure quality of controlled medicine dispensing in all community pharmacies that are found in Rwanda.

Key words: Abuse, addiction, community pharmacy, controlled medicines, prescription refill.

LIST OF ACRONYMS

ADR: Adverse Drug Reaction

ASCP: American Society of Consultant Pharmacists

ATS: Amphetamine type stimulants

BINLEA: Bureau for International Narcotics and Law Enforcement Affairs

BOP: Board Of Pharmacy

CDs: Controlled Drugs

CHUK: Centre Hospitalier Universtaire de Kigali

CMs: Controlled Medicines

CMS: Centers for Medicare and Medicaid Services

CPD: Continuous Professional Development

CRS: Congress Research Service

DEA: Drug Enforcement Administration

EMCDDA: European Monitoring Centre for Drugs and Drug Addiction

FDA: Food and Drug Administration

FEFO: First Expire First Out

FIFO: First in First Out

FMHACA: Food, Medicine and Healthcare Administration and Control Authority of Ethiopia

INCB: International Narcotics Control Board

INCSR: International Narcotics Control Strategy Report

IPS: Internee Pharmacy Student

KFH: King Faisal Hospital

NPS: Narcotics and Psychotropic Substances

OTC: Over-The- Counter

RHC: Remedy's Health.com Communities

RMH: Rwanda Military Hospital

SAPC: South African Pharmacy Council

SOPs: Standard Operating Procedures

UN: United Nations

UR: University of Rwanda

USA: United State of America

USP: United States Pharmacopoeia

WHO: World Health Organization

DECLARATION

I hereby declare that "Quality of dispensing of controlled medicines among community pharmacies in Rwanda "is my own work, that it has not been submitted, or part of it, for any degree or examination in any other university, and that all resources I have used or quoted have been indicated and acknowledged by complete references.

RUGAMBA DESIRE

Signature.....

June 2016

Witness:

.....

Dr EMILE BIENVENU

DEDICATION

I dedicate this thesis to my parents for their continuous parenting care, prayers and support. This achievement is the reaping of the seeds you have sown. May God abundantly continue to bless you

ACKNOWLEDGEMENTS

Before all, my grateful thanks to God Almighty for his continuous mercy and blessings. The successful completion of this work has been possible largely due to invaluable assistance extended to me from many people to whom I feel highly indebted;

I would like to express my profound gratitude and appreciation to my thesis supervisor, Dr Emile BIENVENU who despite his tight work schedule was able to read every bit of my work. I see you as a good father; you carry my problems and worries as if they were yours; may God bless you forever;

I feel highly honored to acknowledge the contributions of very respectable personalities from the pharmacy department; Dr Egide KAYITARE, Ass. Prof. Claver KAYUMBA, Prof. NTOKAMUNDA KADIMA, Dr Raymond Muganga, Dr Marnie and Mr. Vedaste KAGISHA who facilitated us throughout class sessions and encouragement during this whole program;

Many thanks to my housemates who facilitated and assisted me throughout the research activities; Also, My sincere thanks go to all research participants and their pharmacies for their information they provided. Without you, this study could not have been possible. I also say thanks to pharmacy department staffs, University of Rwanda staffs and my classmates for your advice, support and love. Thanks to all of you, far or closer, for your minor or major contribution towards the successful accomplishment of this work. May God almighty abundantly bless you.

TABLE OF CONTENT

ABSTRACT.....	i
LIST OF ACRONYMS.....	iii
USA: United State of America	iv
DECLARATION	v
DEDICATION	vi
ACKNOWLEDGEMENTS.....	vii
TABLE OF CONTENT	viii
LIST OF FIGURES.....	xiii
LIST OF TABLES.....	xiv
DEFINITION OF TERMS.....	xv
CHAPTER ONE: INTRODUCTION.....	1
1.1 Background of the study.....	1
1.2 Statement of the problem	4
1.3 Research questions	4
1.4 Research objectives	5
1.4.1 General objective.....	5
1.4.2 Specific objectives.....	5
1.5 Significance of the study.....	5
CHAPTER TWO: LITERATURE REVIEW	7
2.1 Controlled medicines	7
2.2 Controlled medicines classification	7
2.2.1 Classification for controlled medicines in USA	7
2.2.2 Classification of controlled medicines by United Nations	9
2.3 Risk factors for controlled medicines abuse.....	9
2.4 Strategies for preventing the abuse of controlled medicines by patients	9

2.5 Medicines dispensing.....	9
2.5.1 Principles of good medicines dispensing	10
2.5.2 The process for medicines dispensing	10
2.5.3 Refusal to dispense a prescriptions	13
2.5.4 Techniques for quality dispensing of medicines.....	14
2.5.5 Dispensing environment	14
2.5.6 Misuse and abuse of controlled medicines	14
2.5.7 Dispensing of controlled medicines.....	15
2.6 Illicit manufacturing and abuse of controlled drugs worldwide.....	16
2.7 Abuse of controlled medicines in African countries	18
2.8 Conceptual framework for the study.....	19
2.9 Summary of the chapter	20
CHAPTER THREE: METHODOLOGY	21
3.1 Research setting.....	21
3.2 Study design	21
3.3 Study population.....	21
3.4 Sample size determination	21
3.5 Sampling procedure.....	22
3.6 Inclusion and exclusion criteria.....	22
3.6.1 Inclusion criteria.....	22
3.6.2 Exclusion criteria	22
3.7 Data collection methods	23
3.8 Validity and reliability	23
3.9 Data analysis	24
3.9.1 Quantitative data	24
3.9.2 Qualitative data.....	24
3.10 Ethical considerations	24

CHAPTER FOUR: RESULTS AND DISCUSSIONS.....	25
4.1 Demographic characteristics of respondents	25
4.2 The status of management of controlled medicines by community pharmacies	26
4.2.1 Percentage of community pharmacies handling controlled medicines	26
4.2.3 Availability of controlled medicines SOPs among community pharmacies.....	27
4.2.4 Availability of controlled medicines cupboards among community pharmacies.....	29
4.2.5 Storage of expired/patient returned of controlled medicines among community pharmacies.....	30
4.3 Processing of prescriptions for controlled medicines among community pharmacies.....	31
4.3.1 Information checked by dispensers on a prescription prior to dispensing controlled medicines	31
4.4 The status of requirements for dispensing prescriptions of controlled medicines in community pharmacies.....	33
4.4.1 Professions of people allowed to dispense controlled medicines among community pharmacies.....	33
4.4.2 The status of registration and working license certificates for dispensers of controlled medicines	34
Research participants were requested if they are registered or not at the time of data collection. The findings are highlighted in the figure below.	34
4.4.3 Prescribers whose prescriptions for controlled medicines are accepted among community pharmacies.....	36
4.4.4 Status of partial dispensing of controlled medicines among community pharmacies.....	37
4.4.5 The status of controlled medicines refill among community pharmacies.....	38
4.4.6 Status of labeling controlled medicines by dispensers.....	39
4.4.7 Status of patients counseling on controlled medicines among community pharmacies	40
4.4.8 Causes that decline dispensing controlled medicines to clients among community pharmacies.....	43
4.4.9 Status of recording data about dispensed controlled medicines	44
4.4.10 Information that is recorded by community pharmacies on controlled medicines dispensing	45

4.4.11 Duration for the maintenance of controlled medicines records among community pharmacies.....	46
4.4.12 Availability of archives for dispensed controlled medicines.....	48
4.4.13 Status of reporting of information about controlled medicines by community pharmacies	50
4.5 Level of participation of dispensers in trainings related to controlled medicines	51
4.6 Knowledge of community pharmacy dispensers on controlled medicines and their handling .	51
4.6.1 Knowledge of the meaning of controlled medicines	52
4.6.2 The knowledge of dispensers on schedules of controlled of controlled medicines.....	52
4.6.3 Ability of respondents to differentiate abuse and addiction on controlled medicines.....	53
4.6.4 Qualitative findings on the knowledge of dispensers about controlled medicines	54
4.7 The relationship between dispensers' experience and their knowledge on controlled medicines	57
4.8 Limitations of the study	58
CONCLUSION.....	59
RECOMMENDATIONS	61
REFERENCES.....	62
APPENDICES	67
Appendix 1: Research questionnaire	67
Appendix 2: Interview guide	74
Appendix 3: Consent form	75
Appendix 4: Letter for data collection request.....	76
Appendix 5: Number of pharmacies that each district/province contributed to the sample	77

LIST OF FIGURES

Figure 2.1 Dispensing process (FMHACA, 2012).....	11
Figure 2.2 Conceptual framework.....	19
Figure 4.1 Percentage of community pharmacies that handle controlled medicines	26
Figure 4.2 Classes of controlled medicines in community pharmacies.....	27
Figure 4.3 Number of community pharmacies possessing controlled medicines SOPs.....	28
Figure 4.4 Handling of expired controlled medicines in community pharmacies.....	30
Figure 4.5 Information that is evaluated by dispensers prior to CM dispensing	31
Figure 4.6 Controlled medicines dispensers among community pharmacies.....	33
Figure 4.7 Dispensers' registration status in their council	34
Figure 4.8 Status of working licenses for dispensers of controlled medicines.....	35
Figure 4.9 Prescribers accepted by CM dispensers among community pharmacies	36
Figure 4.10 Information that is written on a label that is put on a pharmacy made CM package	39
Figure 4.11 Crucial information given the patient during the counseling process	41
Figure 4.12 Causes for declining the dispensing of controlled medicines	43
Figure 4.13 Information from the dispensed CM prescription that is recorded	46
Figure 4.14 Duration for which controlled medicines records are kept	47
Figure 4.15 Availability of archives of dispensed CM prescriptions among community pharmacies.....	48
Figure 4.16 Reporting of information on controlled medicines dispensing.....	50
Figure 4.17 Knowledge of the meaning of CM by dispensers	52
Figure 4.18 Respondents' knowledge on CMs schedules.....	53

LIST OF TABLES

Table 4.1 Demographic characteristics of respondents	25
Table 4.2 Availability of cupboards for Controlled medicines in community pharmacies.....	29
Table 4.3 Partial dispensing controlled medicines among community pharmacies	37
Table 4.4 Controlled medicine prescriptions refill status.....	38
Table 4.5 Status of patients counseling on CMs use among community pharmacies	40
Table 4.6 Evaluation of information retained by the patient after the counseling	41
Table 4.7 Status of recording controlled medicines dispensing data.....	44
Table 4.8 Availability of archives for CM inventory and disposal documents among community pharmacies	49
Table 4.9 The number of CM related trainings attended by medicines dispensers	51
Table 4.10 Respondents knowledge on CM associated risks	53

DEFINITION OF TERMS

Abuse: is a persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice.

Adverse drug reaction: A noxious and unintended effect of medicine that occurs in doses normally used in humans or animals for the diagnosis, prophylaxis or treatment of disease.

Agonist: is a substance that binds to a receptor of a cell and triggers a response by that cell. Agonists often mimic the action of a naturally occurring substance.

Analgesic: is a medicine that reduces pain.

Availability: is the degree to which a medicine is present at distribution points in a defined area for the population living in that area at the moment of need.

Controlled medicines or controlled drugs: are medicines containing controlled substances. These have some potential for abuse or dependence.

Controlled substances: are the substances listed in the international drug control conventions.

Dependence: is defined by the WHO Expert Committee on Drug Dependence as “A cluster of physiological, behavioral and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority.

Dispenser: Any person who is licensed or authorized by the appropriate body to dispense medicines and/or medical supplies.

Dispensing: The act of preparing medicines and/or medical supplies and distributing to users with adequate information, counseling and appropriate follow up.

Label: Any material which is printed or affixed to a packing material which provides the necessary information about medicine, and includes an insert.

Medicine: Any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in human and includes narcotic drugs, psychotropic substances and precursor chemicals, traditional medicines, complementary or alternative medicine; poisons, blood and blood products, vaccine, radioactive pharmaceuticals, cosmetics and sanitary items and medical instruments.

Misuse (of a controlled substance) : is defined as the non-medical and non-scientific use of substances controlled under the international drug control treaties or under national law.

Narcotic drug: is a legal term that refers to all those substances listed in the Single Convention.

Opioid: Pharmacological: chemical substances having similar pharmacological activity as morphine and codeine, i.e. analgesic properties. They can stem from the poppy plant, be synthetic or even made by the body itself (endorphins), and they may be

structurally related to morphine or not. An example of a synthetic opioid not structurally related to morphine is methadone.

Over-the-counter medicines: Medicines that can be dispensed without prescription

Packing material: means any article that may be used for filling, inserting or wrapping or packing medicine and includes immediate container and other materials for wrapping the product.

Patient/client: A person presenting to an authorized health care provider to promote health, prevent or treat disease.

Prepacking: Repackaging of medicines into usable quantities before they are requested by of patients (users)

Prescriber: Any medical practitioner who is licensed or authorized by the appropriate body to write a prescription.

Prescription only medicines: medicines dispensed only with prescription

Prescription: Any order for medicine written and signed by a duly licensed or authorized practitioner issued to a patient in order to collect medicine from dispensing outlet.

Psychotropic substance: is a legal term that refers to all those substances listed in the Convention on Psychotropic Substances.

Rational medicine use: it is the appropriate use of a medicine by both health professionals and consumers in their respective roles. Rational medical use aims at meeting the clinical needs of the individual patient by prescribing, dispensing, and administering effective medicines for the medical condition of the patient, at the adequate dose, within the required time schedule and for the required amount of time to treat or cure the patient's medical condition; it should also enable the patient to adhere to such treatment.

Repacking: Packing of any processed or semi-processed medicine by a different manufacturing company in any other way.

Single Convention: refers to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 protocol amending the Single Convention on Narcotic Drugs.

CHAPTER ONE: INTRODUCTION

This chapter presents the background of the study. An overview on controlled medicines, the problem statement, research questions and objectives the study as well as the significance are also highlighted in this chapter.

1.1 Background of the study

Controlled medicines are drugs that have a potential for abuse and psychological and physical dependence. These medicines include opioids, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances (DEA, 2016). Controlled medicines are listed in the international drug control conventions because of their potential for abuse. Several drug treaties have been adopted by the League of Nations prior to World War II, specifying uniform controls on addictive drugs such as cocaine and opium, and its derivatives. However, the lists of substances to be controlled were fixed in the treaties and it is continuously updated (UN, 1961).

In 1961, the UN Economic and Social Council convened a plenipotentiary conference of 73 nations for the adoption of a single convention on narcotic drugs. That meeting was known as the United Nations Conference on Narcotic Drugs (UN, 1961). The Single Convention created four schedules of controlled substances and a process for adding new substances to the schedules without amending the treaty. The single convention entered into force on 13 December 1964 (INCSR, 2013). On 21 May 1971, the UN economic and social council called a conference of plenipotentiaries to consider amendments to the single convention. The conference met at the United Nations office at Geneva from 6 to 24 March 1972, producing the 1972 protocol amending the single convention on narcotic drugs. The amendments entered into force on 8 August 1975 (UN, 1961).

On 11 November 1990, mechanisms for enforcing the single convention on controlled substances were expanded significantly by the entry into force of the United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances, which had been signed at Vienna on 20 December 1988. The new treaty focuses on stopping organized crime by providing for international cooperation in apprehending and convicting gangsters and starving them of funds through forfeiture, asset freezing, and other methods. All countries were assigned a dual obligation with regard to controlled medicines based on legal, political, public health and moral grounds. The dual obligation was to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence (UNODC, 2012).

The single convention repeatedly affirmed the importance of medical use of controlled substances. This convention confirmed that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be

made to ensure the availability of narcotic drugs for such purposes (UN, 1961). Countries were permitted to allow dispensation and use of controlled substances under a prescription, subject to record-keeping requirements and other restrictions (UN, 1961). The Single Convention unambiguously condemns drug addiction; however, stating that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind (UNODC, 2014).

The majority of substances controlled under the international drug control treaties, notably narcotic drugs and psychotropic substances, have a variety of medical uses. Opioid analgesics, such as codeine and morphine, and antiepileptics, such as lorazepam and phenobarbital, are considered as essential medicines by the World Health Organization (INCB, 2011). Concern about abuse and dependence is a major factor in limiting access to opioids and other controlled medicines that are used in treating important health conditions. In practice, most patients, who are appropriately prescribed controlled medicines, do not become dependent from rational use of these medicines (Noble, 2008).

Some 250 substances were listed in the Schedules annexed to the United Nations single convention on narcotic drugs, the convention on psychotropic substances (Vienna, 1971) and the convention against illicit traffic in narcotic drugs and psychotropic substances (Vienna, 1988). The purpose of this listing was to control and limit the use of these drugs according to a classification of their therapeutic value, risk of abuse and health dangers, and to minimize the diversion of precursor chemicals to illegal drug manufacturers (UN, 1961).

At the fifth session of the African union conference of Ministers for drug control and crime prevention, held in Addis Ababa in October 2012, participants endorsed the African union plan of action on drug control and crime prevention (2013-2017). This conference adopted the African union common position on controlled substances and pain management (INCB, 2012). This summit adopted strategies for ensuring adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs were established as the obligations for Governments in the Single United Nations convention on narcotic drugs of 1961 as amended by the 1972 protocol and the 1971 convention on psychotropic substances (UN, 1971).

Once controlled medicines are in community pharmacies, different documentations suggested that those medicines should be stored in safe cupboards that limits their accessibility to people so as to reduce the risks of stealing or abusing them (O'Brien, 2014). The DEA policy for controlled substances states that controlled medicines must never be disposed or thrown out in the regular garbage. Its policy request community pharmacies to

clearly label expired controlled drugs as expired and keep them in a separate place from non-expired drugs within the securely locked cabinet until they can be disposed of properly.

Studies showed that people abuse controlled medicines as a way to manage the daily demands of academics, work and social pressures. It was found that the non-medical use of prescription stimulants is higher among college students who are male, white, members of fraternities and sororities and earned lower grade point averages. It was also shown that young adults generally misuse and abuse prescription stimulants for functional reasons (McCabe, 2005).

Controlled medicines have the potential to be diverted to the illicit market. Different guidelines require medicine dispensers to check against patient information and possible over ordering of controlled medicines before dispensing any controlled drug (Tennessee, 2015). The DEA and the Rwandan MOH guidelines require dispensers of controlled medicines to be registered by their professional councils and to have renewed working licenses. The American Society of Consultant Pharmacists (ASCP) recognizes nurses as agents of support for pharmacists to dispense controlled substances (ASCP, 2016).

The partial and repeat dispensing of prescriptions for controlled medicines are accepted in USA, England and in many other countries (Bradley, et al., 2013). Controlled medicines labeling has been identified to be of great importance in medication safety and one of the factors contributing to safe use of those medications (Jennings J, 2007). A study conducted in the State of Penang, Malaysia showed that compliance to medication labeling standards determines the safe use of medications by patients.

The counseling of patients on controlled medicines is a part of the dispensing process and the dispenser should provide the patient clear and complete instructions on how to take or use those medicines (Nasir T Wabe, 2011). The Arizona guidelines for controlled medicines require pharmacists to educate their patients about proper use, storage and proper disposal prior to dispensing controlled substances during the counseling session (DrugFreeAZ, 2016).

Different studies mentioned different causes that may prevent dispensers to give controlled medicines to the patient. A study conducted on the management of medicines by pharmacists showed that patients without prescriptions were not given controlled medicines (El-Sakka, 2012). Another study conducted in New Mexico on availability of narcotics and pharmacists' attitudes toward narcotic prescriptions for cancer patients showed that suspecting the patient to abuse controlled medicines was among the causes that prevent pharmacists to dispense controlled substances.

The DEA require community pharmacies to record controlled medicines data while dispensing them and report those data to its offices located in different states. The DEA also require community pharmacies to keep archives for controlled medicines for inspection and

audit purposes (DEA, 2012). A number of studies mentioned that dispensers lack knowledge on rules and regulations governing controlled medicines. A study conducted by Joranson and Gilson on pharmacists' knowledge of and attitudes toward controlled medicines for pain in relation to federal and state policies showed that only few dispensers had adequate knowledge on controlled substances and their schedules.

1.2 Statement of the problem

In a WHO report on the world medicines situation in 2011, it was stated that patient adherence to treatment regimes is about 50% worldwide and lower in developing and transitional countries because above 50% of all dispensing procedures are inadequate (WHO, 2011). In the UNODC report of 2013 on patterns and trends of amphetamine-type stimulants and other drugs, it was shown that the abuse of prescription medicines, such as slimming tablets containing controlled substances, analgesics and benzodiazepines, continues to be a problem in many African countries. Controlled medicines abuser may get them from pharmacies using prescriptions acquired through corruption or fake prescriptions. It was also reported that CMs abusers can access them through illegal sales by pharmacies, misuse within families, illegal patient-to-patient sales or through counterfeit medications (INCB, 2012).

According to the 5th edition list of essential medicines used in Rwanda, there are many controlled medicines that are being used in the Rwandan healthcare system in caring for patient having different types of diseases. Currently, most of community pharmacies have only one pharmacist and this is making them to be overloaded by other tasks of their pharmacies. Those tasks are not allowing them to be the only dispensers of controlled medicines even though they are supposed to be most knowledgeable in medicines handling and dispensing. Usually lack of knowledge or professionalism among medicines dispensers may result in poor quality of services offered to pharmacy clients. However, no study investigated the quality of controlled medicines dispensing processes that are taking place among Rwanda community pharmacies. Thus, the present study intends to provide that information.

1.3 Research questions

- How are controlled medicines managed among community pharmacies?
- What is checked by dispensers during the processing of prescriptions for controlled medicines among community pharmacies?
- How is the status of the requirements for dispensing controlled medicines in community pharmacies?

- Which is the level of participation of dispensers in trainings related to controlled medicines?
- What is the level of knowledge of dispensers on controlled medicines and their handling?
- Is there any association between the experience of dispensers and their knowledge on controlled medicines?

1.4 Research objectives

1.4.1 General objective

The general objective for this study is to evaluate the quality of dispensing processes and the knowledge of dispensers in relation to controlled medicines among community pharmacies in Rwanda.

1.4.2 Specific objectives

- To assess the status of management of controlled medicines by community pharmacies.
- To appraise the processing of prescriptions for controlled medicines among community pharmacies.
- To evaluate the status of the requirements for dispensing prescriptions of controlled medicines in community pharmacies.
- To determine the level of participation of dispensers in trainings related to controlled medicines.
- To assess the knowledge of dispensers on controlled medicines and their handling.
- To study the association between experience of dispensers in dispensing medicines and their knowledge on controlled medicines.

1.5 Significance of the study

- The results of this study will help many pharmacy professionals in Rwanda to be aware about the gaps found in the dispensing practice of controlled medicines among community pharmacies. This study could also help the Pharmacy council and the Ministry of health to strengthen the pharmacy system through the enforcement of standard operating procedures and this can positively impact the quality of services provided by community pharmacies.

- This study is also expected to help pharmacy academicians to address controlled medicines associated risks while teaching students. This might improve the quality of dispensing and handling of controlled medicines among different health facilities in future.

CHAPTER TWO: LITERATURE REVIEW

A review of literature regarding principles of medicines dispensing is presented in this chapter. Dispensing activities, conditions for the dispensing environment, and other relevant information about medicines dispensing are highlighted in the chapter. An overview on controlled medicines, their misuse and their abuse risk factors and the empirical studies on controlled medicines dispensing are provided in this chapter. Finally, the conceptual framework and the summary for the chapter are provided at the end of the current chapter.

2.1 Controlled medicines

Some medicines used to treat important health conditions are listed in the UN list of controlled substances. Those are like opioid analgesics, such as morphine for the treatment of moderate to severe pain; opioid agonists used for treatment of opioid dependence, such as methadone; ergometrine and ephedrine used in emergency obstetric care (DEA, 2015). Concern about abuse and dependence is a major factor in limiting access to opioids and other controlled medicines that are used in treating important health conditions. In practice, most patients, who are appropriately prescribed controlled medicines; do not become dependent if they rationally use them (Milani, 2011).

Narcotics are abused by people because they can produce intense pleasure and general calmness, drowsiness, tranquilization, or sleep, feeling of well-being, pain relief (analgesia) and temporary euphoria (RHC, 2016). In addition to the risks of dependency, non-medical use of stimulants may lead to heartbeat irregularities, elevated body temperature or even cardiovascular failure and seizures (INCB, 2012). In South America, in particular, stimulant use is often linked to weight loss efforts (UNODC, 2013).

2.2 Controlled medicines classification

2.2.1 Classification for controlled medicines in USA

In USA, controlled medicines are placed in their respective schedules based on whether they have a currently accepted medical use in treatment, their relative abuse potential, and likelihood of causing dependence when abused (DEA, 2015). Drugs and other substances that are considered controlled substances under the USA Controlled Substances Act are divided into five schedules.

a. Schedule I controlled medicines

This schedule contains substances with no currently accepted medical use because of a lack of accepted safety for use under medical supervision, and they have a high potential for abuse. In this schedule, examples are including: lysergic acid diethylamide (LSD), heroin, marijuana, peyote, methaqualone, and ecstasy.

b. Schedule II controlled medicines

This schedule contains drugs having a high potential for abuse. These medicines can lead to severe psychological or physical dependence. Medicines classified in this schedule have many medical uses. Their prescriptions are not refillable. Examples of medicines of this schedule include narcotics like: hydromorphone, methadone, meperidine, oxycodone, fentanyl, morphine, opium, and codeine. This schedule also contains stimulants like amphetamine, methamphetamine and methylphenidate. Also, amobarbital, glutethimide, and pentobarbital are classified in the schedule II.

c. Schedule III controlled medicines

Medicines from this schedule can also be abused but the risk for their abuse is less than substances in Schedules I or II. The drug in this schedule must be having an accepted medical use in USA. The abuse of a controlled medicine in this schedule may lead to a moderate or low physical dependence. It might also lead to high psychological dependence. Some dosage forms containing narcotics can be classified in this schedule. An example is like dosage forms containing less than 15 milligrams of hydrocodone per dosage unit. The schedule also contains non-narcotics drugs like benzphetamine, phendimetrazine, ketamine, and anabolic steroids such as Depo –Testosterone (FDA, 2015).

d. Schedule IV controlled medicines

Substances in this schedule have a low potential for abuse relative to substances in Schedule III. As defined by the USA controlled medicines act, drugs in this schedule must be having an accepted medical use. They are associated with a limited risk of physical dependence or psychological dependence compared to the one of those in schedule III. Examples of these medicines are including alprazolam, clonazepam, carisoprodol, lorazepam, clorazepate, diazepam, midazolam, temazepam and triazolam etc (FDA, 2015).

e. Schedule V controlled medicines

The USA controlled substance act specifies that medicines of this schedule have a low potential for abuse. They are even associated with a limited physical psychological dependence compared with that of schedule IV. They consist primarily of preparations containing limited quantities of certain narcotics. Cough suppressants containing small

amounts of codeine and those having small amounts of opium or diphenoxylate are classified in this schedule (FDA, 2015).

2.2.2 Classification of controlled medicines by United Nations

Narcotic drugs are classified and placed under international control by the 1961 UN Single convention on narcotic drugs, as amended in 1972. The 1961 UN single convention classifies narcotic drugs in four schedules from schedule I up to schedule IV. Psychotropic substances are internationally controlled by the 1971 United Nations convention on psychotropic substances. The 1971 UN single convention classifies psychotropic drugs in four schedules which are from schedule I up to schedule IV.

2.3 Risk factors for controlled medicines abuse

Drug abuse includes any inappropriate use of controlled medicines and use of illicit drugs. It can attack people of any age, sex or economic status. Some factors can lead to controlled medicines abuse and speed up the addiction to them. These are including family history of addiction, being male, having another mental health disorder, peer pressure, lack of family involvement, anxiety, depression and loneliness, using a highly addictive drug, anxiety, depression and loneliness (Clinic, 2015)

2.4 Strategies for preventing the abuse of controlled medicines by patients

According to FDA, the controlled medicines abuse by patients can be prevented using different strategies and requirements. To reduce the risks of controlled medicines abuse, health care providers who prescribe and dispense controlled medications should be having a particular training, experience, or special certifications. Medications have to be dispensed only to patients for whom safe-use conditions are verified. Also, each patient using controlled medicines has to be specially monitored (FDA, 2015). Patients using controlled medications have to be enrolled in a registry before dispensing a specific those medications (Barnes, et al., 2010)

2.5 Medicines dispensing

The dispensing of controlled substances in compliance with regulations is a function that is critical to the day-to-day activities of pharmacists. Since the dispenser is often the last person to see the patient before the medicine is used, it is important that the dispensing process be efficient, as it affects medicine use. Good dispensing of medicines is an important component of rational medicine therapy. In order to maximize the benefits and minimize the risks to end users, pharmacy professionals bridge the gap between the prescriber and the patient and serve as the gate-keepers of medicine supply system (FMHACA, 2012).

2.5.1 Principles of good medicines dispensing

Rational use of medicines is a complex issue demanding mainly an integrated action of prescribers, health administrators, policy makers, dispensers and users. Dispensing refers to the process of preparing medicines and distributing to users with provision of an appropriate information, counseling and follow up. Good medicine dispensing practice refers to the delivery of the correct medicine to the right patient, in the required dosage and quantities, in the package that maintains acceptable potency and quality for the specified period, clear medicine information counseling and appropriate follow up. This practice is a key step for effective treatment outcome (FMHACA, 2012).

The pharmacist is responsible for assessing the appropriateness of the medications in relation to the full medication history (or medication profile if available), the final check of dispensed medicines, and the counseling of the patient (PSA, 2010). Dispensing includes all the activities that occur between the time the prescription or oral request of the patient or care provider is presented and the medicine or other items are issued to them. This process may take place in health institutions and community medicines retail outlets. No matter where dispensing takes place or who does it, any error or failure in the dispensing process can seriously affect the care of the patient mainly with medical and economical consequences. Therefore, the dispenser plays a crucial role in the therapeutic process (FMHACA, 2012).

A shortage of dispensing materials and insufficient dispensing time due to heavy patients load may also have adverse impacts on dispensing. One good way to reduce the dispensing time and potential error is to pre-pack and label commonly used medicines. A way to prevent staff from making errors when working under pressure is to organize the work so that more than one individual is involved in the dispensing process for each prescription. Medicine dispensers should be adequately equipped with up-to-date medicine information. Lack of knowledge and information by patients about the medicines they take leads to incorrect use which in turn results in loss of efficacy or occurrence of adverse effects. Application of the professional code of ethics by pharmacy professionals is an important issue during medicines dispensing (FMHACA, 2012).

2.5.2 The process for medicines dispensing

Dispensing refers to the process of preparing and giving medicine to named person on basis of a prescription. It involves the correct interpretation of the wishes of the prescriber and accurate preparation and labeling of medicine for use by the patient. The dispensing process has different steps which are including the reception of a prescription, its evaluation and interpretation, the selection and manipulation of prescribed medicine accompanied by its labeling and packaging. After this, the following step is the provision of information and instruction to the medicine user. The last step of the dispensing process is the recording of

the transaction done during the process followed by the filing of the copy of the prescription (PSA, 2010).

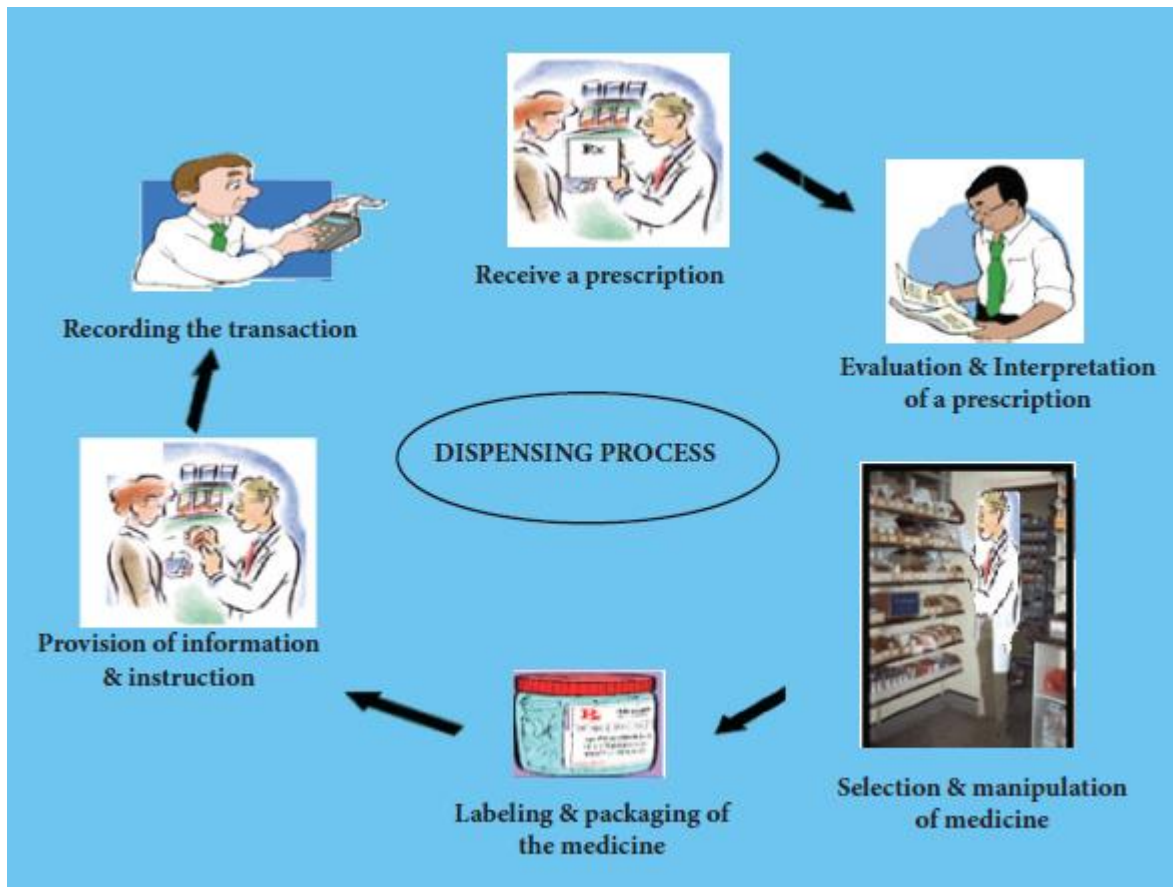


Figure 2.3 Dispensing process (FMHACA, 2012)

a. Interpretation and evaluation of the prescription

After the reception of a prescription, pharmacy professionals should confirm and identify its legality and legibility. They have also to identify the patient's condition, completeness of the prescription, correctness of the prescription, therapeutic aspects and the appropriateness of the individual (PSA, 2010). A prescription is considered to be legal if it is written and signed by an authorized prescriber. Medicines that are prescribed have to be written on the right prescription like the normal prescription or NPS prescription for controlled drugs. A prescription for these drugs has to contain the date of issue not exceeding 15 days for narcotic drugs and psychotropic substances (FMHACA, 2012).

As forgers and fraudulent prescriptions showing up in pharmacies, pharmacy dispensers must be careful while checking and accepting a controlled-substance prescription. These prescriptions require extra attention because of their potential to be abused. According to the US federal law, a prescription for a controlled medicine must contain the date of issue, patient's name and physical address, practitioner's name, address and registration number, drug name, drug strength, dosage form, quantity prescribed, number of refills authorized, if any, and manual signature of prescriber (O'Brien, 2014).

A complete prescription has to contain the name, address, telephone of prescriber, the date of prescription, the generic name of the drug, the strength, dosage form and the total amount of the drug. It has also to be equipped by label instructions and warnings, the name, address, age of patient and signature or initials of prescriber (WHO, 2015). A brief examination of each prescription should be made immediately upon receiving it from the patient to ascertain its legibility. Any doubt regarding the reading of the prescription, should be examined closely and, if necessary discussed/ consulted with other pharmacists or the prescriber himself/herself without arousing doubts or fears in the patient (FMHACA, 2012).

During the prescription correctness evaluation, checking double medications (same medicine or different medicine with same pharmaco-therapeutic effect) and the appropriateness of the individual have to be done. Also the history of overuse, under use or misuse of medicines by the patient, the overwriting of medication which can be done by the patient especially in case of medicines of abuse and fake/false prescription have to be checked. Therapeutic aspects to be checked include: The safety of the medicine, possible contra-indications, drug/drug interactions, drug/food interactions, drug/disease interactions and treatment duplications (FMHACA, 2012).

b. Selection of a medicine to be dispensed

When the evaluation of a prescription is over, the step which follows is the selection and the manipulation of the prescribed medicine. This step involves the selection of stock container of pre-pack reading the label and cross matching the medicine name and strength against the prescription. After this, the dispenser has to read the container label at least twice in order to prevent possible dispensing errors (FMHACA, 2012)

c. Labeling and packaging of the medicine

Containers used for dispensing must be appropriate for the product to be dispensed. All containers intended for medicinal products must be protected and kept free from contamination. The main functions of a label on a dispensed medicine are to uniquely identify the contents of the container and to ensure that patients have clear and concise information about the use of the medicine. The minimum information to put on a label include the patient name, the generic name, strength and dosage form of the medicine, the dose, frequency, quantity and duration of use of dispensed medicine. The label has also to provide information about how to take or administer the medicine and the storage condition. If the medicine has been prepared extemporaneously, a batch number may be also provided (FMHACA, 2012).

d. Provision of information to the client

Medicines have to be dispensed with adequate information and counseling. The information to give a patient must be structured to meet the needs and questions of that patient. Written information on the label should be provided to supplement verbal communication. Counseling should cover matters that will enhance or optimize medicine therapy. The way to administer dispensed medicines and an instruction of not stopping the treatment when side effects occur or in the absence of response without consulting the prescriber or dispenser have to be clearly explained to the receiver of medicines. After all these things, The patient or the person who has received medicines has to answer questions asked by the dispenser to verify if he/she has retained what has been said (FMHACA, 2012).

e. Recording the transaction

After the dispensation of medicines to the patient, the prescription should be recorded and documented as proof of the transaction between the patient and the dispenser. All dispensing units should have a standardized prescription registration book for recording every pharmaceutical issued to a patient. A computerized dispensing and registration system may also be used, but should always be supported by paper back up. After the time the dispensing process or at the close of the working day, the registration book should be completed (FMHACA, 2012).

f. Prescription filing

For the correctness of the dispensing process and confirming that the medicine was given to the patient, each prescription should be signed and accountability accepted by the dispenser or other authorized person. At the close of each day all dispensed prescriptions should be organized, filed sequentially by day in a single container and carton for each month. Normal prescriptions should be filed securely for two years and special prescriptions like NPS prescriptions should be filed for 5 years. Recorded information about prescriptions, patient and medication should be documented and kept in a secure place that is easily accessible only to the authorized personnel (FMHACA, 2012).

2.5.3 Refusal to dispense a prescriptions

The medicine dispenser should politely refuse to give out a prescription in case essential information is missing or unsure, and the prescriber cannot be contacted in case of prescription problem. Also, when the safety of the medicines is doubtful or in case of forged or illegitimate alteration of the prescription the dispensing can be stopped (FMHACA, 2012).

2.5.4 Techniques for quality dispensing of medicines

The Purpose of quality dispensing is to maintain the quality of the dispensed medicines for their specified shelf-life and ensure appropriate and rational use of the medicine by the patients. They are main techniques that help in improving the quality of medicines dispensing. These are including the conservation by the pharmacy department of a daily list of medicines in stock to inform prescriber about medicines to prescribe and the maintenance of records on what medicines were dispensed. A system whereby two different prescriptions are written one for medicines available in the pharmacy and the other for those that are not present, the adherence to specifications for storage conditions and repackaging are also useful in ensuring the quality of dispensing (FMHACA, 2012).

The dispensing of only one prescription at a time and the double checking of the name, dosage form, strength and amount of controlled medicine to be dispensed were proven to be of big value during the dispensing process. Other techniques to improve the quality of dispensing are including the maintenance of procedures for compounding when dealing with extemporaneous preparations, the checking of all information on the label of the original medicine container. Finally, the avoidance of dispensing when dizzy or in stress help to ensure the quality of medicines dispensing (FMHACA, 2012)

2.5.5 Dispensing environment

The quality of premises plays a big role in the reflection of the quality of services to be offered in a given pharmacy. They also inspire confidence on patients in the nature of pharmaceutical service delivered. An appropriate dispensing environment should possess sufficient lighting, appropriate temperature, optimum humidity control, cold storage facilities, adequate number and type of shelves, patient/care provider waiting area, dispensing aids and lockable cabinet for narcotic medicines, psychotropic drugs and poisons. All medicines dispensing should fit with high standards of personal cleanliness and they have to wear protective cloths that should be washed on a regular basis (FMHACA, 2012).

2.5.6 Misuse and abuse of controlled medicines

Non-medical use of controlled medicines includes use by the person the drug was prescribed for but not in the prescribed manner or dosage, as well as use by another person. Diversion takes place using various means, such as prescriptions acquired through corruption, fake prescriptions, illegal sales by pharmacies, misuse within families, illegal patient-to-patient sales and counterfeit medication, sometimes bought via the internet. Illicit drug use is not a static phenomenon. Drug users may change to new substances. But they may also use different drug combinations or various consumption modes and/or use licit substances, including prescription drugs, for non-medical purposes (INCB, 2012).

2.5.7 Dispensing of controlled medicines

a. General requirements for dispensing controlled medicines

In developing countries, 50% of all dispensing processes are inadequate (WHO, 2011). A prescription for a controlled medicine must include relevant approval particulars before it can be legally dispensed by a pharmacist. The pharmacist dispensing a controlled medicine prescription has to affix to the package a label showing date of filling, the pharmacy name and address, the name and address of the prescriber, the prescription number, the name and address of the patient, and instructions for use and caution statements (DEA, 2010). Also, dispensers have to check the registration number of the prescriber, his/her signature, the drug name, its strength, its dosage form, the quantity prescribed as well as the number of refills (Retailing, 2016).

Controlled medicine prescriptions may be issued by physicians, podiatrist, dentists, mid-level practitioner or any other registered practitioner who is allowed by the law to prescribe controlled medicines (DEA, 2010). Information on controlled medicines dispensed by pharmacies has to be reported each month to the chief health officer. This information is used by the chief health officer to monitor and regulate the public health risks of controlled medicines supply (Kelly, 2016). The USA Drug Enforcement Administration (DEA) requires records of controlled medicines to be maintained for two years separated from other records. Also DEA regulations require that records for controlled medicines listed under schedule II have to be separated with other controlled medicines records. About what is related to the stock of controlled medicines, it may be dispersed throughout the stock of non-controlled medicines to prevent theft (DEA, 2010).

Faxed prescriptions containing schedule II narcotics drugs can be dispensed in case they contain drugs to be compounded and directly administered intravenously, intramuscular, subcutaneously or through intraspinal infusion. Also faxed prescriptions can be accepted for those undergoing a long-term care in an authorized facility or those in a hospice licensed by the state (DEA, 2010). Apart from reading, writing, counting, and pouring, the dispenser needs further knowledge, skills, and attitudes to complete the dispensing process. These include the knowledge about the controlled medicines being dispensed, good calculation and arithmetic skills, ability to assess the quality of preparations, attributes of cleanliness, accuracy, and honesty and skills required to communicate efficiently with patients.

b. Requirements for dispensing schedule II controlled medicines

The US federal law stipulates that there is no time limit for dispensing a prescription having a schedule II controlled medicine. This law says that it is upon a pharmacist to determine the legitimate medical purpose and decide whether the prescription is still needed by the patient (DEA, 2010). No controlled medicine on schedule II has to be dispensed without a prescription except in emergency situation or when it is directly dispensed by the prescriber.

No schedule II prescription refill is accepted (FDA, 2015). Pharmacists can partially dispense prescriptions containing a schedule II controlled drug in case the remaining portion can be dispensed within 72 hours. Those prescriptions for terminally ill patients or for patients undergoing long term care can be partially filled up to 60 days from the time the prescription was issued (DEA, 2010).

c. Requirements for dispensing schedule III-V controlled medicines

No schedule III or schedule IV prescription can be dispensed without a written or oral prescription unless if it is directly dispensed by another practitioner to an ultimate user. Schedule III and schedule IV prescriptions may not be refilled more than five times within six months after they are issued by the prescriber. The documentation on this refills have to be done by the dispensing practitioner (FDA, 2015). The prescriptions for controlled medicines on schedule III and IV may be partially filled provided that each partial filling is considered as a refill. Prescriptions containing schedule V drugs can be refilled as it was authorized by the prescriber (DEA, 2010).

2.6 Illicit manufacturing and abuse of controlled drugs worldwide

Drug users may still have a preferred drug, but at the same time they are often capable of switching to other drugs if need be. Ecstasy users, for example, have adapted by consuming fake ecstasy tablets which may contain methamphetamine, ketamine or piperazines. MDMA, and opiate users often consume synthetic opioids or benzodiazepines when faced with heroin shortages (EMCDDA, 2011). Opioids are the most commonly misused prescription drugs and non-medical use is a concern for most countries. The non-medical use of any psychotherapeutic drug may have major negative health implications. In addition to the risk of dependency, the misuse of opioid pain killers, in particular, has led to large numbers of deaths (INCB, 2012).

Central nervous system depressants are usually prescribed as sedatives or anxiolytics for the treatment of anxiety disorders. Benzodiazepines are currently the main substances of concern in this class of drugs, having largely replaced barbiturates because barbiturates carry a higher risk of lethal overdose. Some of the commonly misused benzodiazepines are flunitrazepam and diazepam (INCB, 2012). In some countries, including Australia and the United States, the non-medical use of pharmaceutical drugs is more prevalent than that of any illegal drug except cannabis. Drug use and addiction have the potential to negatively affect the social fabric of communities, hinder economic development, and place an additional burden on national public health infrastructures (Rosen, 2015).

The illicit manufacture of ATS used to be heavily concentrated in a certain area, has gradually become more dispersed worldwide. In Europe, illicit manufacture of ATS mostly amphetamine and ecstasy used to be largely concentrated in the Netherlands, and to a lesser extent Belgium and Poland, but is nowadays found in many European countries, including Bulgaria, countries of the western Balkans, the Baltic countries and Germany. In East Asia, illicit manufacture of ATS was concentrated in Japan in the 1940s and 1950s, but subsequently moved to the Republic of Korea, Taiwan Province of China and Thailand. Nowadays, ATS manufacture is concentrated mainly in China, Myanmar and the Philippines (UNODC, 2013).

A study conducted in USA in 2001 has found that young adults and students misuse and abuse prescription stimulants as a way to manage the daily demands of academics, work and social pressures. The results for this research showed that the life-time prevalence of non-medical prescription stimulants use was 6.9%. It was found that 1 in 5 college students (20%) reported to have abused prescription stimulants at least once in their lifetime, compared to 1 in 7 non-students (15 %). The non-medical use prescription stimulants were higher among college students who were male, white, members of fraternities and sororities and earned lower grade point averages. It was also shown in this study that young adults generally misuse and abuse prescription stimulants for functional reasons (McCabe, 2005).

A study conducted in Australia between 2011 and 2012 on drug use among people attending nighttime entertainments in five major Australian cities during Australia's warmer months has shown that approximately 9% of participants had consumed illicit or non-prescribed pharmaceutical drugs and 81% of drugs those abused were psychostimulants drugs. In this study, five hundred and three participants were invited randomly to be tested for the use of cannabis, meth/amphetamine, benzodiazepines, cocaine and opiates, via drug saliva swab. Results showed that 20% drug swabs gave a positive result, where psychostimulants the most commonly detected drugs at the level of 15% (Miller, 2015).

In recent years the strongest increases have been reported in countries in East and South-East Asia and the near and Middle east. On the Arabian Peninsula, illicit demand for drugs has been mainly for tablets containing amphetamine and caffeine referred to as Captagon. A number of drug use surveys have indicated that prescription stimulants are frequently misused in the America (UNODC, 2013). The abuse of prescription drugs between 2007 and 2009 was also reported in Argentina, Brazil, Mexico and Chile (INCB, 2010).

2.7 Abuse of controlled medicines in African countries

While cannabis remains the most widely cultivated, trafficked and abused drug in Africa, new threats have emerged, in particular, the illicit manufacture, trafficking and abuse of amphetamine-type stimulants. Until a few years ago, illicit manufacture and abuse of methamphetamine and methcathinone appeared to be largely confined to Southern Africa. Kenyan authorities have been reporting significant thefts and/or losses of ephedrine and pseudoephedrine since 2009, and in 2010. Tanzanian authorities started to report thefts of pseudoephedrine. Between September 2009 and December 2011, the thefts of ephedrine and pseudoephedrine in Kenya and the United Republic of Tanzania combined totalled over 3.2 tons, 2,062 kg of pseudoephedrine and 1,183 kg of ephedrine (INCB, 2012).

The annual prevalence of amphetamine-type stimulants abuse in Africa is estimated at between 0.2 per cent and 1.4 per cent of the population aged 15-64. This wide range reflects the fact that there is either limited or no recent or reliable data available for most parts of Africa. Abuse of tramadol, a synthetic opioid not under international control, has also become a serious problem in a number of African countries, notably in North Africa. In Mauritius, psychotropic substances such as diazepam and clonazepam are abused by drug-dependent persons who get them from dealers. The diversion of sedatives and tranquillizers from local distribution channels has increased, mainly through purchases without medical prescription from rogue pharmacies (INCB, 2012).

There continue to be attempts to divert precursor chemicals in Africa, predominantly precursors used in the illicit manufacture of amphetamine-type stimulants. Recent reports of significant thefts or losses of ephedrine and pseudoephedrine in countries in East Africa might be an indication that precursors of amphetamine-type stimulants are being diverted from licit domestic distribution channels into the illicit manufacture of amphetamine-type stimulants in other parts of Africa. Nigeria, South Africa and Egypt, in that order, seem to have the highest annual prevalence rates of abuse of such stimulants. The chart below is showing how some controlled medicines were abused in Africa from 2000 to 2010 (INCB, 2012).

2.8 Conceptual framework for the study

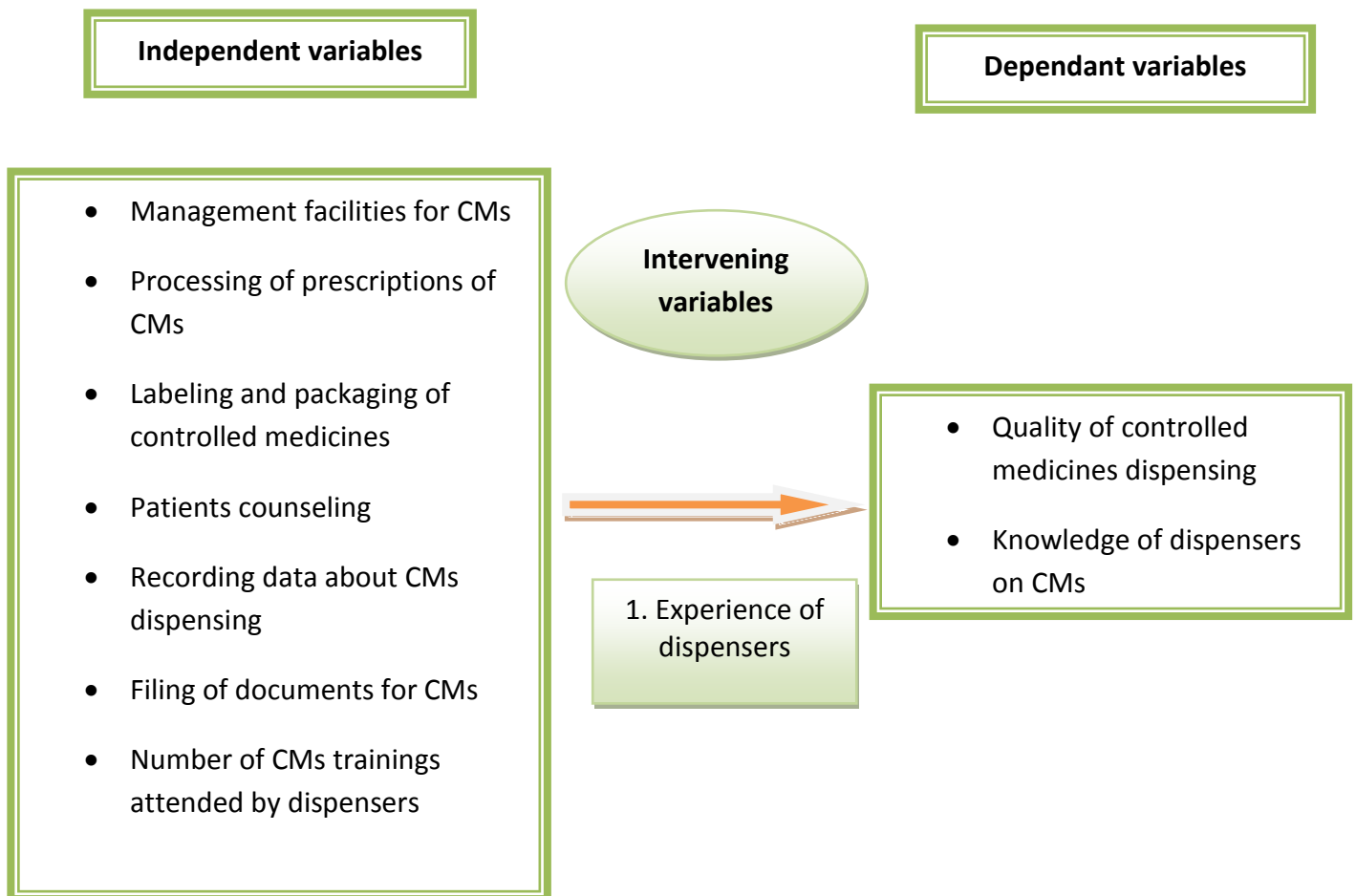


Figure 2.4 Conceptual framework

This conceptual framework presents independent, dependent and intervening variables for this study. Different literatures mentioned that the quality of controlled medicines dispensing may depend on facilities for the management of CMs available in the pharmacy and the processing of prescriptions and the labeling of controlled medicines by dispensers. Also the counseling of patients, the recording of data on controlled medicines and the filing of their documents influence the quality of controlled medicines dispensing. Literatures showed that the knowledge of dispensers on controlled medicines may be associated with the number of CMs trainings attended by those dispensers. The relationship between independent and dependent variables which is discussed above can be influenced by the experience of dispensers, and this is considered as an intervening variable for the current study.

2.9 Summary of the chapter

Controlled medicines are drugs that have a potential for abuse and psychological and physical dependence. These risks may arise from inadequate dispensing of those medicines in case dispensers lack knowledge or professionalism. Regulations on controlled medicines handling vary according to their classification. In USA, controlled drugs are classified in five schedules but only schedule II to schedule V controlled medicines can be used in medicine. The level of controlled medicines monitoring decreases from schedule II to schedule V. Abuse of controlled medicines can attack people of any age, sex or economic status. The dispensing of only one prescription at a time and the double checking of the name, dosage form, strength and amount of controlled medicine to be dispensed improve the quality of their dispensing. A prescription for a controlled medicine must include relevant approval particulars before it can be legally dispensed. Prescriptions for schedule II controlled medicines are not refillable. Schedule III and schedule IV prescriptions may not be refilled more than five times within six months while schedule V drugs can be refilled as it was authorized by the prescriber.

Opioids are the most commonly misused prescription drugs and non-medical use is a concern for most countries. Several studies conducted worldwide have shown that addiction and abuse cases of opioid pain killers, psychotropic drugs and other controlled medicines, has been resulting most of the times from the inappropriate dispensing or from the need of increased performance. Most of the times, people who were abusing controlled medicines included students and people attending nighttime entertainments. Studies showed that inappropriately dispensed controlled medicines can be diverted to illicit manufacturing of controlled drugs for abuse. Nowadays it was found that in many European countries, including Netherlands, Bulgaria, Baltic countries and Germany, there are many illicit manufacturers of controlled drugs. Also different cases of illicit manufacture of controlled medicines were found in Asia, America and in Africa.

In the East African region where Rwanda is located, Kenya and the United Republic of Tanzania reported between 2009 and December 2011 many cases of inappropriate handling of controlled medicines which facilitate the diversion of controlled medicines from licit domestic distribution channels to illicit manufacture. In these countries it was reported that enormous quantities of ephedrine and pseudoephedrine were stolen and put in illicit manufacturing of controlled drugs. Community pharmacies, are among health facilities that handle controlled medicines. As they are financially independent, inappropriate handling and dispensing of controlled medicines can take place in order to get money in case nothing is done to monitor the handling of those medicines. There was no research which has provided information about the management and dispensing of controlled medicines by community pharmacies in Rwanda. This is why the researcher was interested by this study.

CHAPTER THREE: METHODOLOGY

This chapter explores the methods and procedures that were used to collect and analyze data for the study. It describes the research setting, study population, study sample, study design and the procedures used while collecting data. Finally, data analysis method and ethical issues used in this study are provided in this chapter.

3.1 Research setting

This study was conducted among 150 community pharmacies that were chosen from all those registered in Rwanda. Four provinces and the city of Kigali containing a total of 30 districts are found in Rwanda. Those four provinces are the Eastern, Northern, Southern and Western provinces. Most community pharmacies are located mainly in cities where the city of Kigali, has 64 % of all community pharmacies that are located in Rwanda.

3.2 Study design

This study was about the evaluation of controlled medicines dispensing among community pharmacies in Rwanda. It was conducted between June 2015 & June 2016. This research was concerning all controlled medicines that are found on National list of essential medicines. This was sectional and descriptive study which used quantitative and qualitative approaches. The reason for combining those approaches was to assess different research objectives with optimal possibilities to generalize the results and generate a more rigorous methodologically sound study as it was stated by Creswell in 2009. Dispensing activities and dispensers' knowledge on controlled medicines were evaluated in this study. The research took inspiration from the pharmacist check list for dispensing controlled substances as it is stated in the DEA guidelines on controlled medicines dispensing (DEA, 2010).

3.3 Study population

The research population was formed by 245 community pharmacies which were found in Rwanda in 2015 as it was reported by the Rwandan Ministry of Health. Of those pharmacies, 150 were sampled to participate in this study. According to the number of community pharmacies which were sampled from each province, 97 were taken from the city of Kigali, 21 from the Southern province and 13 were sampled from Western provinces. The Eastern and the Northern provinces contributed 10 community pharmacies each (Appendix 5). During this study, the researcher worked with people who were dispensing medicines in selected community pharmacies.

3.4 Sample size determination

The sample size of pharmacies to use in this study was determined using Cochran's formula.

$$n_o = Z^2_{\alpha/2} P(1-P) / W^2$$
$$n_o = 1.96^2 \times 0.5(1-0.5) / 0.05^2 = 384$$

Where “ n_0 ” is the sample size gotten when using the non finite population, “ p ” equals to 50 %, “ W ” being the margin of error and it was considered to be 5%. In this study and “ Z ” = 1.96, being the confidence interval of 95%. Then, the calculated sample size was adjusted to the finite population which is 245 pharmacies using the finite population correction factor

$$n = \frac{n_0 N}{n_0 + (N - 1)}$$

Where “ n_0 ” is the sample size gotten using the non-finite population, “ N ” being the finite population size and “ n ” is the adjusted sample size.

$$n = 384 \times 245 / 384 + (245 - 1) = 149.8 \approx 150 \text{ pharmacies.}$$

This means that 150 pharmacies was the calculated sample size.

3.5 Sampling procedure

A random sampling was used to select pharmacies to work with from the whole study population. The number of community pharmacies which were randomly selected from each district (N_i) was determined using the probability proportional to size (PPS) as it is shown in the formula below.

$$N_i = N_d \times 150 / N$$

N : Population size

N_d : Total number of pharmacy in each district

N_i : Number of pharmacies to select from each district

3.6 Inclusion and exclusion criteria

3.6.1 Inclusion criteria

For any person to participate in this study he/she had:

1. To be a health professional who was working in a private pharmacy located in Rwanda
2. To be dispensing controlled medicines to patients
3. To have signed the consent form

3.6.2 Exclusion criteria

Criteria for excluding people from participating in this research were as follow:

1. People who were working in other pharmacies rather than community pharmacies were excluded from this study.

2. Those who were working for community pharmacies that were not found in Rwanda were excluded from the current research.
3. Any person who was working for community pharmacy but who was not dispensing medicines to patients was excluded

3.7 Data collection methods

Data collection was done through interview and by using a self administered and structured questionnaire formed by both closed and open ended questions. That questionnaire had three parts. The first one was made by questions asking demographic information and the second one was formed by questions that were answering the first specific objective. The third part of the questionnaire was an interview guide which was mainly addressing the second specific objective of this study. Open ended questions were included in the questionnaire in order to facilitate respondents to freely express their views about the controlled medicines dispensing practice. During the time of interview, the researcher used to summarize and record information which was being provided by the respondent.

The data collection tool was designed by the researcher referring to the DEA guidelines for controlled medicines dispensing. From each visited pharmacy, one among the persons who said they were dispensing controlled medicines the time of the visit, was requested to fill the questionnaire and to do an interview with the researcher. In order to reduce the risks of interfering with clients, the researcher was visiting community pharmacies between 9h30-11h30 and between 2h30-4h30, which were the times when clients workload is usually reduced in community pharmacies. The study respondents was given a questionnaire and requested to answer it in the presence of the researcher for consultation if need be. This strategy was very useful because it was allowing the respondent to write what he/she knows about CMs.

3.8 Validity and reliability

To ensure that the data collection tool is reliable, a pilot study was conducted in 3 hospital pharmacies of Masaka, Kibagabaga and Muhima district hospitals. The same instrument had been re-administered to the same group of people two weeks later to check the consistency of the answers. The Spearman's correlation coefficient was determined and it was .914. This score was strong enough to ensure the reliability of the instrument used in data collection. Apart from assessing the reliability of data collection tool, this pilot study helped to assess the time to be taken by research participants to fill it.

3.9 Data analysis

3.9.1 Quantitative data

Collected quantitative data were entered using the CPro 6.2 software, then after they were transferred to SPSS software version 18.0 for analysis. Univariate analysis was used to describe collected data. The chi square test (χ^2) was performed to test the association between the experience of dispensers and their knowledge on controlled medicines at 5% level of significance ($\alpha=0.05$). The presentation of quantitative results was done in form of pie charts, bar charts, histograms and tables where frequencies, central tendency and dispersion measures were provided.

3.9.2 Qualitative data

Qualitative data collected from open ended questions and interviews were analyzed using the six steps of thematic analysis as suggested by Braun and Clarke (2006). Themes were generated then after, grouped into broader categories to make sure that there is no respondent's opinion omitted. In order to reduce the number of themes that were formed by the researcher, similar categories were conflated to produce headings. The distinct categories but internally conveying the same opinions were grouped together as it was recommended by Marshall (1995). To ensure validity and reliability of the categorizing, the independent researchers from Mount Kenya University, school of health sciences, were requested to read through the answers from open ended questions and generate their themes. Both the researcher and independent researchers' developed themes were compared in the absence of the independent researchers in order to make final themes.

3.10 Ethical considerations

Prior to data collection, a letter requesting community pharmacies to participate in the study was sent to each selected pharmacy. In order to take into account ethical values, the researcher presented the proposal to UR pharmacy department team for its approval. The researcher was given a letter by the college of medicine and health sciences requesting community pharmacies to facilitate him in collecting research data. Before participating in the research, participants were explained about the study and its objectives, then after they were requested to sign consent forms. Selected pharmacies and research respondents were anonymously presented by attributing them reference codes. This helped to ensure the confidentiality of information that those respondents had provided.

CHAPTER FOUR: RESULTS AND DISCUSSIONS

This chapter presents the results of this study. It critically reviews the findings of this research in relation to its objective. It discusses data related to general requirements for managing controlled medicines in community pharmacies, the processing of prescriptions for controlled medicines, evaluation of the requirements for dispensing controlled medicines and the knowledge of dispensers on those medicines. Limitations encountered during this study are also clarified at the end of this chapter.

4.1 Demographic characteristics of respondents

Demographic data for respondents of this study including the age, gender, profession and the working experience of respondents were evaluated and they are presented in the table below.

Table 4.1 Demographic characteristics of respondents

Respondent's age		N (%)
Less than 25 years		2 (1.6%)
25 - 30 years		92 (73%)
30-40 years		29 (23%)
Above 40 years		3 (2.3%)
Respondent's gender		N (%)
Male		114 (79.2%)
Female		30 (20.8%)
Respondent's profession		N (%)
Pharmacist		137 (91.3%)
Nurse		11 (7.3%)
Internee pharmacy student		2 (1.3%)
Respondent's working experience (years)		
Mean		4.2
Std. Deviation		3.4
Minimum		0.3
Maximum		15

A total of 150 medicine dispensers from community pharmacies participated in this study. Most of these respondents (73%) were aged between 25 to 30 years. The big proportion of them was formed by males who represented 79.2% of the whole study sample. According to

the profession of study participants, pharmacists, nurses and internee pharmacy students participated in this study but the big number of them was formed by pharmacists (91.3%). Finally, 4.2 years was the average experience of respondents in medicines dispensing. The respondent who had the highest experience had 15 years and the one who had the smallest experience had four months (0.3 years) of experience. The details are provided in table 4.1.

4.2 The status of management of controlled medicines by community pharmacies

4.2.1 Percentage of community pharmacies handling controlled medicines

Study participants were asked if they were dispensing controlled medicines to patients. This was done in order to determine the percentage of community pharmacies, which were handling controlled medicines. The figure below presents findings which were gotten.

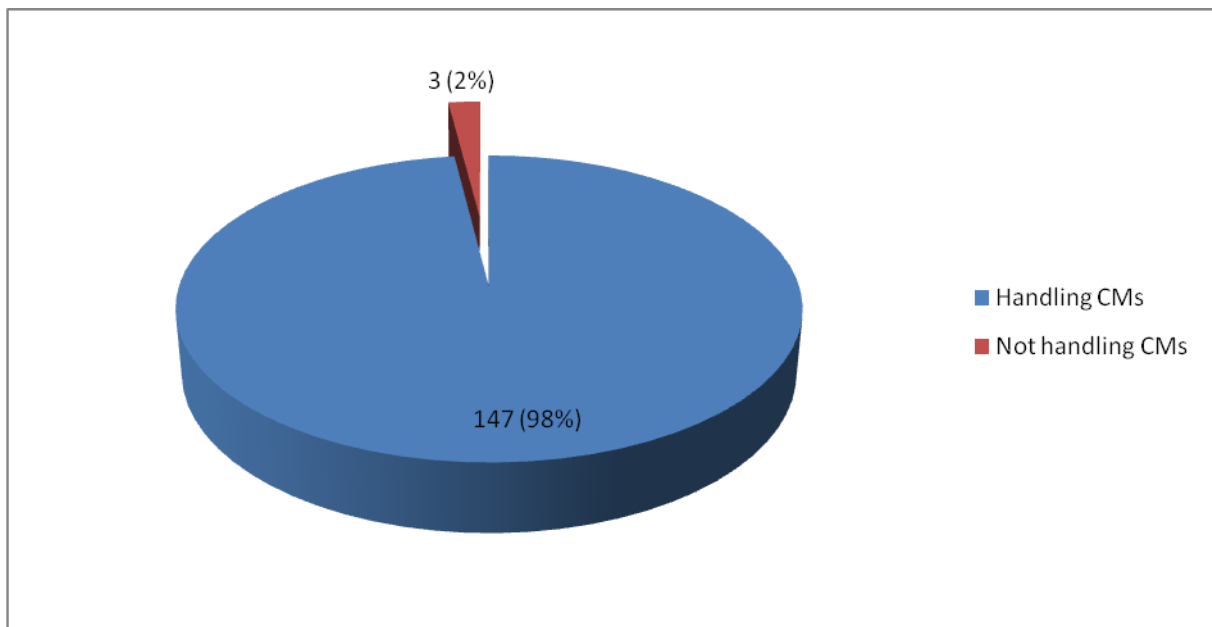


Figure 4.1 Percentage of community pharmacies that handle controlled medicines

It was found that 147 community pharmacies representing 98% of those, which were visited, were handling controlled medicines while only 2% of them did not (Figure 4.1).

According to the Drug Enforcement Administration (DEA) regulations for controlled substances, all community pharmacies registered in USA are not allowed to handle and dispense controlled substances. Only those, which are given an authorization by the DEA for controlled substance handling, are allowed to dispense them to patients. The findings of the current study showed that all community pharmacies that were registered in Rwanda were allowed to handle and dispense controlled medicines even though all of them did not have them.

4.2.2 Classes of controlled medicines managed by community pharmacies

Respondents were asked about the schedules of controlled medicines they were dispensing. The purpose of this was to get general information on controlled medicines that are mostly found among sampled community pharmacies. The results are presented below.

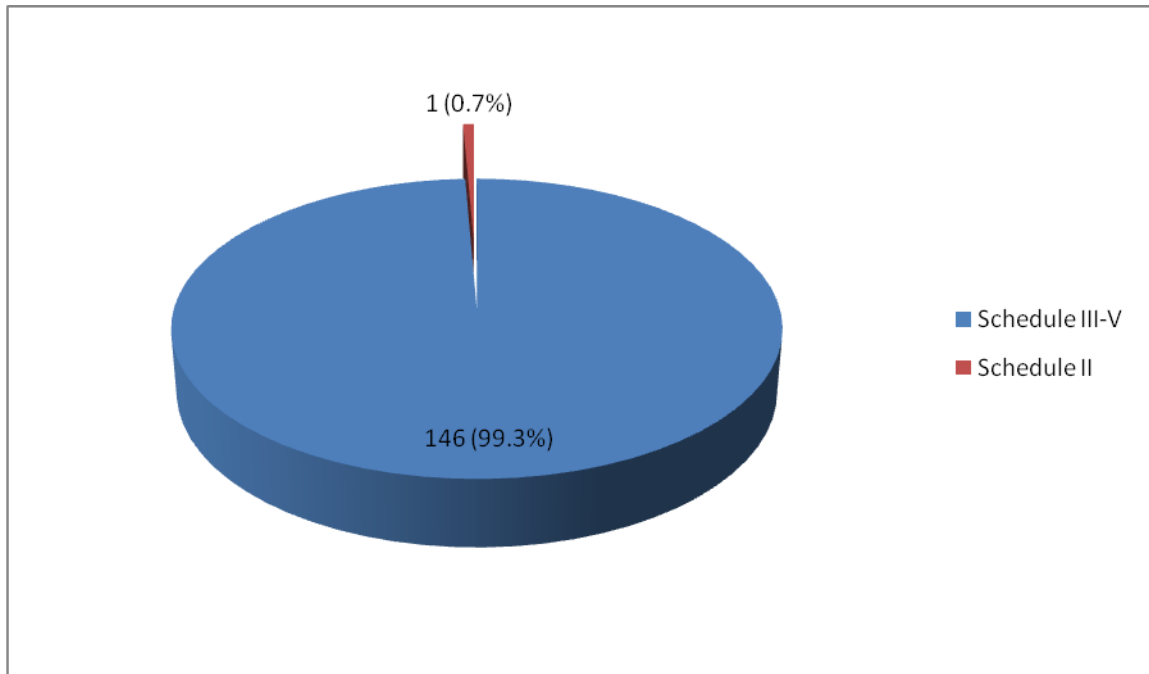


Figure 4.2 Classes of controlled medicines in community pharmacies

The findings showed that 99.3% of controlled medicines which were found in community pharmacies were schedule III-V controlled medicines. Only one community pharmacy had schedule II controlled medicines (Figure 4.2).

Community pharmacies that have an authorization for controlled medicines handling are allowed to dispense controlled medicines classified from schedule II to those in schedule V (DEA, 2012). The current study showed that all community pharmacies were allowed to dispense schedule II to schedule V controlled medicines even though most of them prefer not to handle controlled medicines classified in schedule II because of their increased risk of abuse and a reduced number of clients who need them.

4.2.3 Availability of controlled medicines SOPs among community pharmacies

In order to get information about the availability of controlled medicines standard operating procedures for among community pharmacies, research participants were requested to show a copy of those documents to the researcher. The figure 4.3 highlights the findings which were gotten.

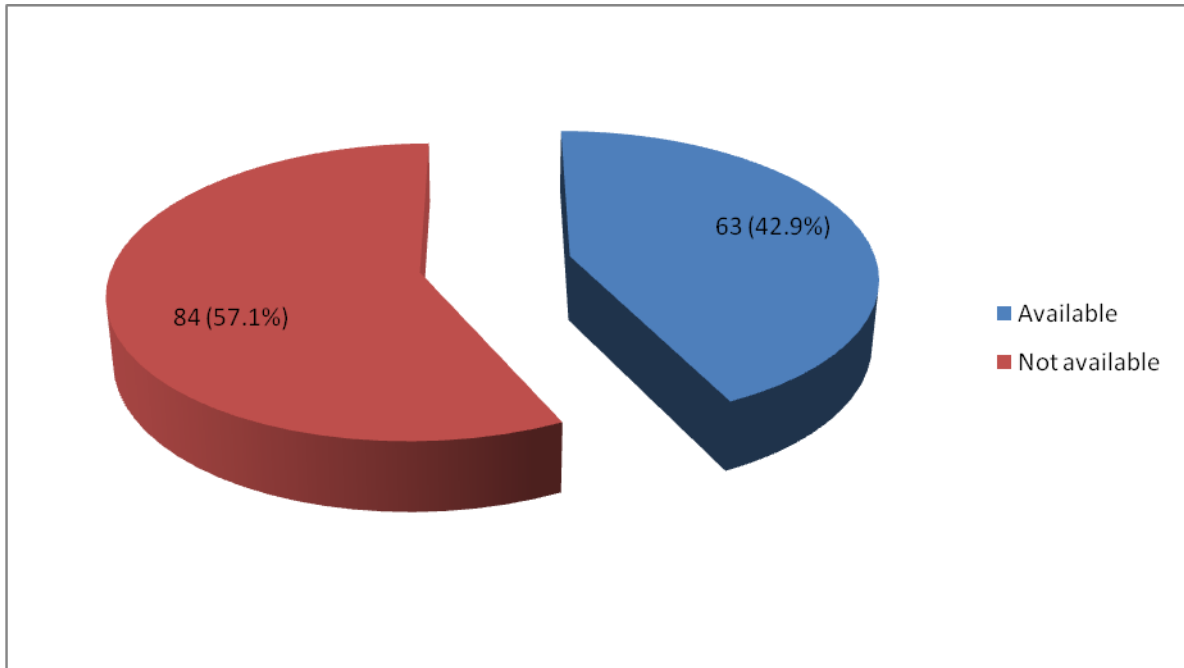


Figure 4.3 Number of community pharmacies possessing controlled medicines SOPs

Research findings showed that only 42.9% of visited community pharmacies had SOPs which were related to controlled medicines dispensing while 57% of community pharmacies did not have them.

Policies and procedures must be developed for the provision of, or access to a pharmacy service on a twenty-four hour basis (SAPC,2010). Regulations introduced standard operating procedures (SOPs) for the use and management of controlled medicines (Siler, 2001). The current study showed that 98% of community pharmacies were dispensing controlled medicines but only 42.9 % of all pharmacies had CMs handling SOPs. Comparable findings are in a supervision report done on community pharmacies in United Kingdom in 2013. In this report, 53.3% pharmacists reported that they had controlled medicines SOPs that they were following while dispensing those medicines (Bradley, et al., 2013). The percentage of community pharmacies which follow SOPs while dispensing controlled medicines is small to ensure that all steps for a quality process for dispensing those medicines are implemented in all community pharmacies that are found in Rwanda. The MOH needs to request all community pharmacies handling controlled medicines to elaborate and implent SOPs for these medines.

4.2.4 Availability of controlled medicines cupboards among community pharmacies

Community pharmacies that handle controlled medicines are supposed to have special cupboards for controlled medicines. The availability of them among visited pharmacies was evaluated by requesting respondents to show them to the data collector at the time of the visit. Respondents were also requested about what they store in those cupboards. The table 4.2 provides details of the findings which gotten.

Table 4.2 Availability of cupboards for Controlled medicines in community pharmacies

Is the pharmacy having a secured cupboard for CM?		N (%)
Yes		142 (96.6%)
No		5 (3.4%)

Is the CM cupboard reserved only for the storage of medicines not other items?		N (%)
Yes		112 (77.2%)
No		33 (22.8%)

Research findings showed that 96.6% of all visited pharmacies had appropriate cupboard which were used to store controlled medicines if need be. According to what was found to be stored in CM cupboards, 22.8% of community pharmacies were mixing controlled medicines with other items (Table 4.2).

As controlled medicines might be associated with a risk of abuse, they have to be stored in a safe environment that limits their accessibility to some people. It is a requirement for every pharmacy handling controlled medicines to have a cupboard designed for keeping those medicines (O'Brien, 2014). The findings of the present study showed that 96.6 % of visited pharmacies had lockable controlled medicine cabinets as planned by the Rwandan pharmacy law. As, almost all community pharmacies in Rwanda are not dispensing schedule II controlled medicines, it is not a requirement for community pharmacies to possess fixed controlled substance safe as it is recommended in the DEA guidelines for controlled medicines storage. In general, the storage of controlled medicines is good among community pharmacies that are found in Rwanda referred to availability of cupboards for controlled substances in those pharmacies.

4.2.5 Storage of expired/patient returned of controlled medicines among community pharmacies

Expired and patient returned controlled medicines storage has to be effective because they may be associated with risks of abuse. That storage was assessed in this study in order to have a view on the safety of expired and patient returned controlled medicines in community pharmacies before they are incinerated. The figure 4.4 provides the details of the findings.

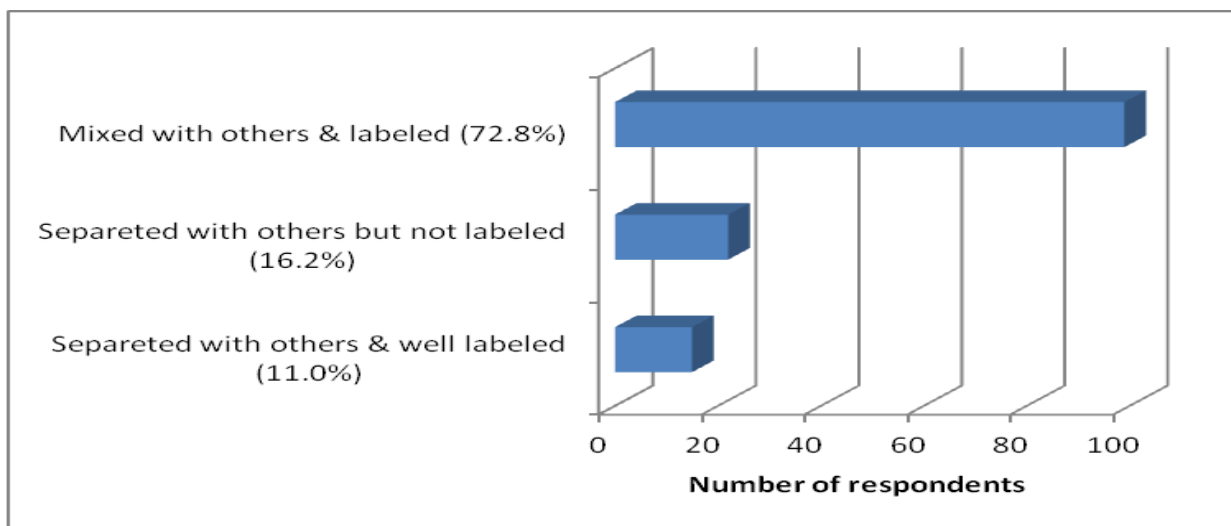


Figure 4.4 Handling of expired controlled medicines in community pharmacies

The findings showed that only 11.0 % of visited community pharmacies were storing expired or patients returned CMs in an appropriate way by separating them from other expired medicines, store them in a designated part of the CM cupboard and then label them as expired. A high percentage of community pharmacies (72.8 %) were keeping expired controlled medicines mixed with other expired medicines, and then label all of them as expired. The figure 4.4 provides details.

Expired controlled medicines have to be well and securely kept because they can also be abused. It was found that the presence of unused controlled medicines in the household is likely contributing to increasing rates of abuse those medicines among Americans, especially teenagers (Siler, 2001). Expired or patient returned Controlled substances are not allowed to be put in secure drop boxes. They are supposed to be moved to secure storage facilities operated by pharmacies (CMS, 2004). According to the findings in the current study, it was shown that community pharmacies were handling expired or patient returned controlled medicines in different ways. Most of community pharmacies (72.8%) were mixing expired controlled medicines with other medicines which are expired.

The DEA policy for controlled substances states that controlled medicines must never be disposed or thrown out in the regular garbage. This policy request community pharmacies to clearly label expired controlled drugs as expired and kept in a separate place from non-expired drugs within the securely locked cabinet until they can be disposed of properly. According to this DEA requirement, only 11.0% of visited community pharmacies were conforming to it. As conclusion, the handling of expired controlled medicines in most of community pharmacies is not appropriate and it can be a source of their diversion or abuse if appropriate measures are not taken. This require the ministry of health to plan and implement pharmacy inspections that address the handling of expired or patient returned controlled medicines.

4.3 Processing of prescriptions for controlled medicines among community pharmacies

4.3.1 Information checked by dispensers on a prescription prior to dispensing controlled medicines

Dispensers from sampled community pharmacies were requested about the information they check on a prescription of controlled medicines before they dispense it. The objective was to evaluate the processing of prescriptions for controlled medicines by dispensers before they dispense them to clients. The results of this assessment are presented in the figure below.

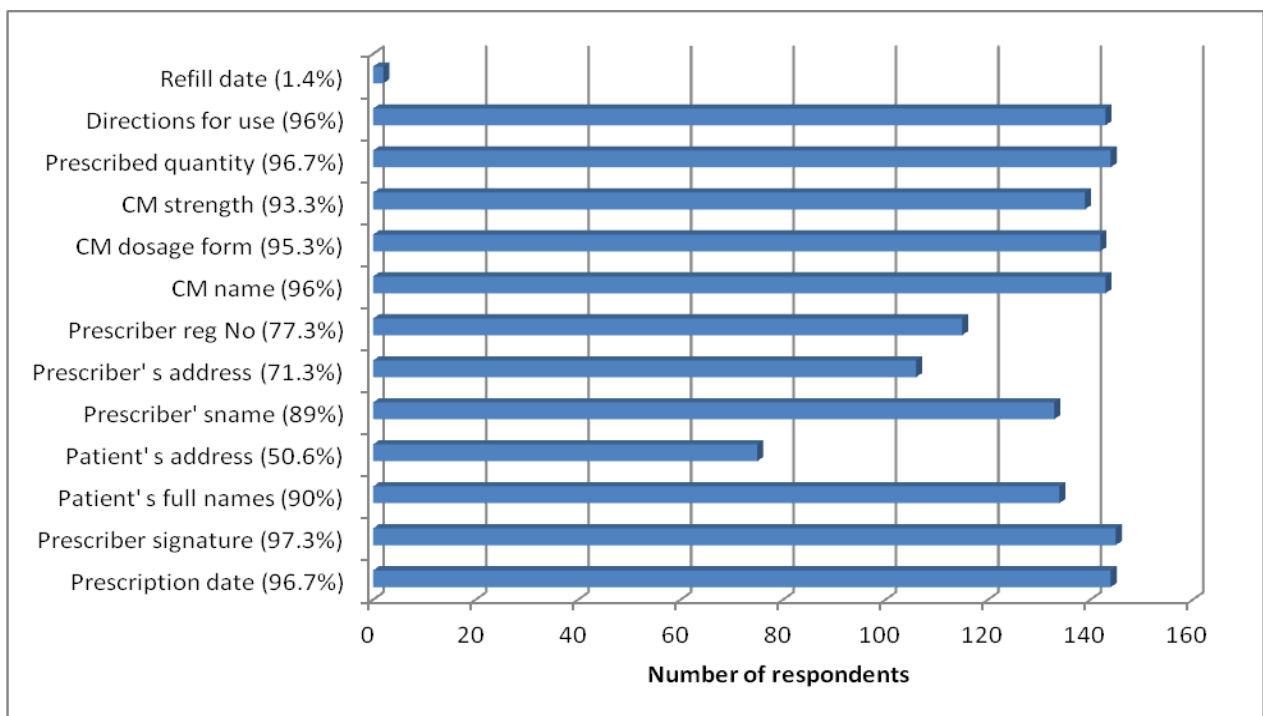


Figure 4.5 Information that is evaluated by dispensers prior to CM dispensing

It was found that almost all dispensers were checking the same things and these were general to all medicines. The refill date which is specific to controlled medicines was checked by a very small percentage of dispensers (1.4%). Many respondents (97.3%) reported that they were checking the prescriber signature and the quantity of prescribed controlled medicines (96.7%) on the prescription before dispensing controlled medicine. For more details, look at figure 4.5.

Controlled medicines have the potential to be diverted to the illicit market. Before dispensing any controlled medicine, the dispenser should check against patient record and controlled drugs register for over ordering (Tennessee, 2015). A legally accepted prescription for controlled medicines must be providing information about patient names and address, practitioner's name, address and registration number, CM name, strength and dosage form, prescribed quantity, directions for use and the number of refill if applicable. Those different traits should be evaluated by dispensers in order to judge if they will serve a given prescription of controlled medicines (BOP, 2016).

The National Center on addiction and substance abuse at Columbia University has carried out a research about how often pharmacists were performing tasks associated with dispensing controlled medicines. In this research, about one-half said that they were always checking the prescriber's registration number (51.1%) and checking patient records (52.1%) before dispensing any controlled medicine. Only 57% reported always checking for contraindications, and a mere 11.7% said they ask if the patient is taking any other controlled medicines (Fleming et al., 2013). Similar findings were gotten in the current study even though all dispensers were not evaluating exactly the same things. It was found that 97.3% of dispensers were checking the prescribers' signature and his/her council registration number.

As it was found in the previous study, the current study also highlighted that most dispensers were checking patient information (90%) and controlled medicines information like the prescribed quantity (96.7%). The current study showed that the refill date was checked by few dispensers (1.4%). According to what is discussed above, the checking done for prescriptions of controlled medicines among community pharmacies is similar to the checking done to prescriptions of other medicines while prescription for controlled medicines need special attention in order to identify some forgeries may lead to lead to the abuse of CMs.

4.4 The status of requirements for dispensing prescriptions of controlled medicines in community pharmacies

4.4.1 Professions of people allowed to dispense controlled medicines among community pharmacies

Professions of people who were allowed to dispense controlled medicines among community pharmacies were assessed during this study. Research participants were asked about their professions, and the findings are presented in the figure below.

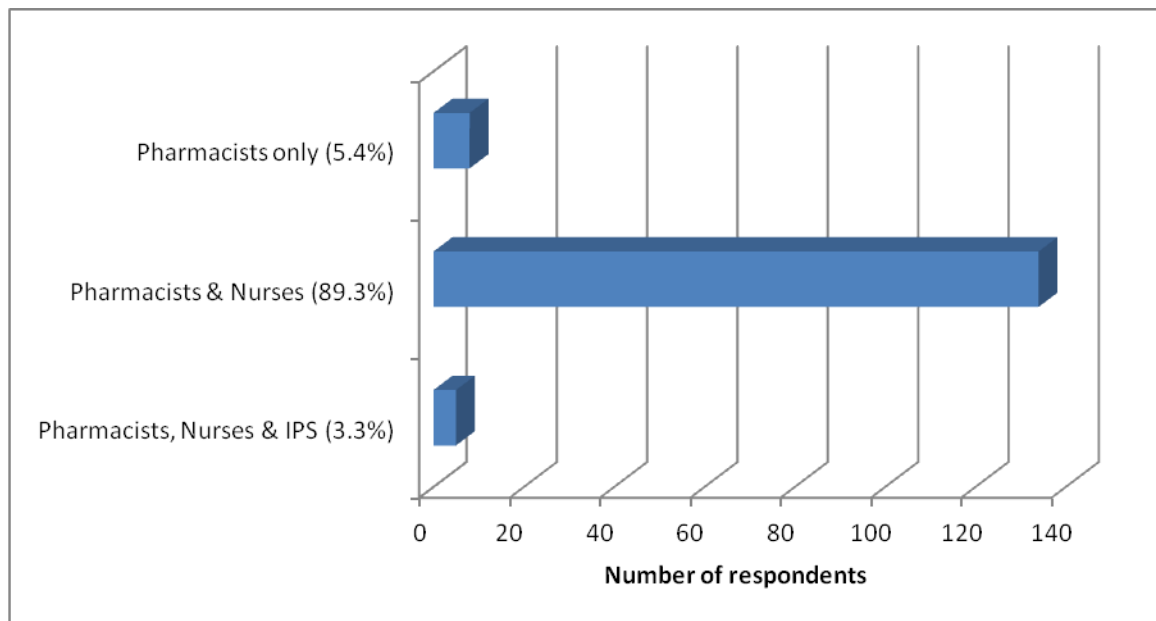


Figure 4.6 Controlled medicines dispensers among community pharmacies

It was found that most of community pharmacies (89.3%) were allowing both pharmacists and nurses to dispense controlled medicines. A small percentage of community pharmacies, 3.3% were allowing pharmacists, nurses and IPS to dispense controlled medicines as it is highlighted in figure 4.6.

The American Society of Consultant Pharmacists (ASCP) supports recognizing nurses as agents of support for pharmacists to dispense controlled substances (ASCP, 2016). In a study conducted in Kibuye hospital on pharmacy operations, it was found that also nurses were allowed to dispense controlled medicines but under the supervision of the pharmacist (Dale, 2011). In a study conducted on the assessment of risks related to medicine dispensing in Colombia, it was found that even nonprofessionals can play an important part in the therapeutic chain if appropriately updated or instructed (Vacca C, 2005).

The results of the current study were not different from what was found above because, 89.3% of visited community pharmacies which were allowing both pharmacists and nurses to dispense controlled medicines. It was also found that few pharmacies were allowing interneer pharmacy students to dispense controlled medicines. In general, people who are dispensing controlled medicines among community pharmacies are able to deliver appropriate services in case they are appropriately trained. Also, pharmacists for community pharmacies need to monitor the activities of pharmacy students who are in internship because if not inappropriate dispensing of controlled medicines can happen.

4.4.2 The status of registration and working license certificates for dispensers of controlled medicines

Research participants were requested if they are registered or not at the time of data collection. The findings are highlighted in the figure below.

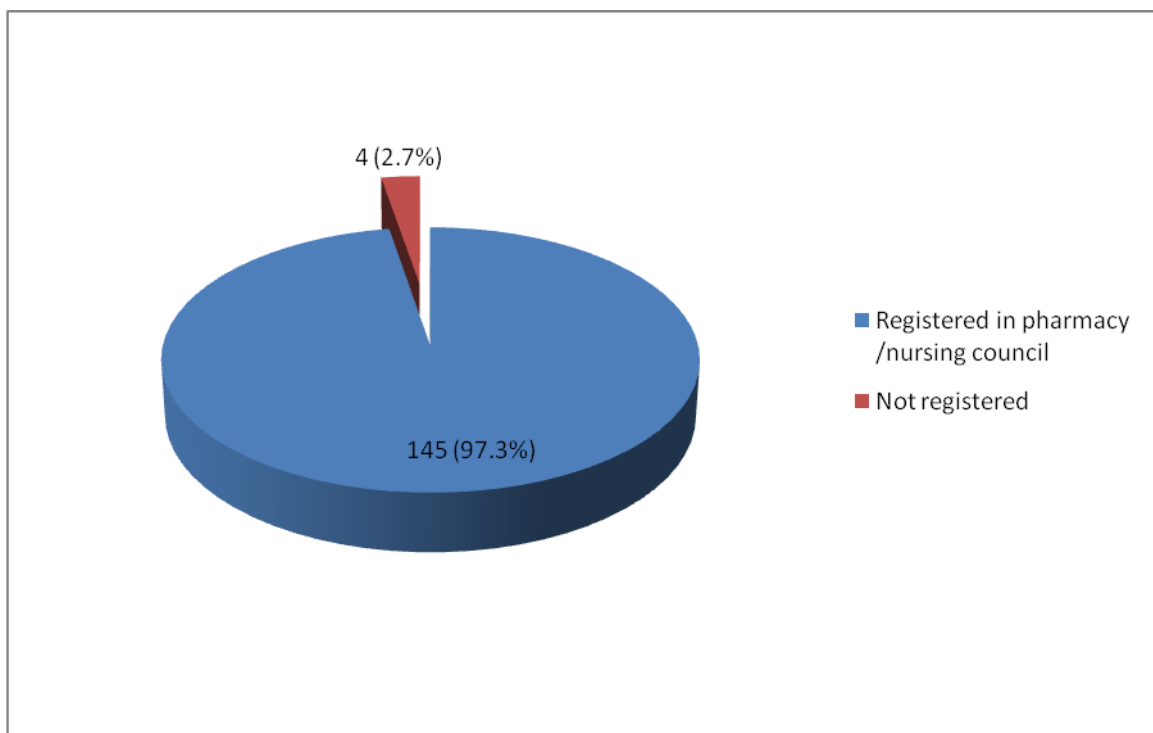


Figure 4.7 Dispensers' registration status in their council

The findings showed that a big percentage of dispensers (97.3%) were registered in pharmacy council and nursing council for pharmacists and nurses respectively (Figure 4.7).

In addition, participants were also requested if all dispensers of controlled medicines had renewed working licenses or not. The findings are presented below.

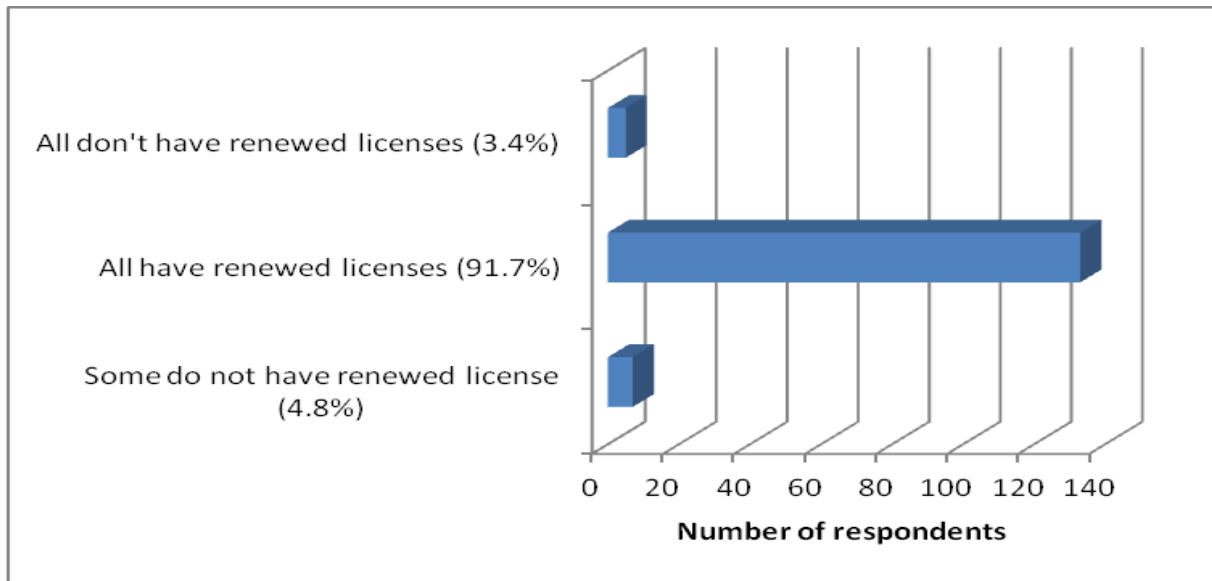


Figure 4.8 Status of working licenses for dispensers of controlled medicines

It was found that 91.7% of community pharmacies had dispensers who all had renewed working licenses. Some community pharmacies (4.8%) had CM dispensers who had renewed and others who did not renew their working licenses. Only, 3.4% of visited community pharmacies did not have any CM dispenser with a renewed working license at the time of data collection (Figure 4.8).

According to DEA and the Rwandan MOH guidelines on medicines dispensing, all people who are involved in medicines dispensing must be registered by their professional councils and their working licenses have also to be renewed each year. The findings of the current study showed that 97.3 % research participants were registered in their council, 89.3% of them had renewed working licenses while 10 % of participants had paid for the renewal of working licenses. In general, dispensers of controlled medicines among community pharmacies were fulfilling the registration and working license requirements needed for the quality dispensing of controlled medicines.

4.4.3 Prescribers whose prescriptions for controlled medicines are accepted among community pharmacies

In this study, respondents were asked about people they accept as prescribers of controlled medicines for them to dispense the prescriptions they wrote. The findings are presented in the figure below.

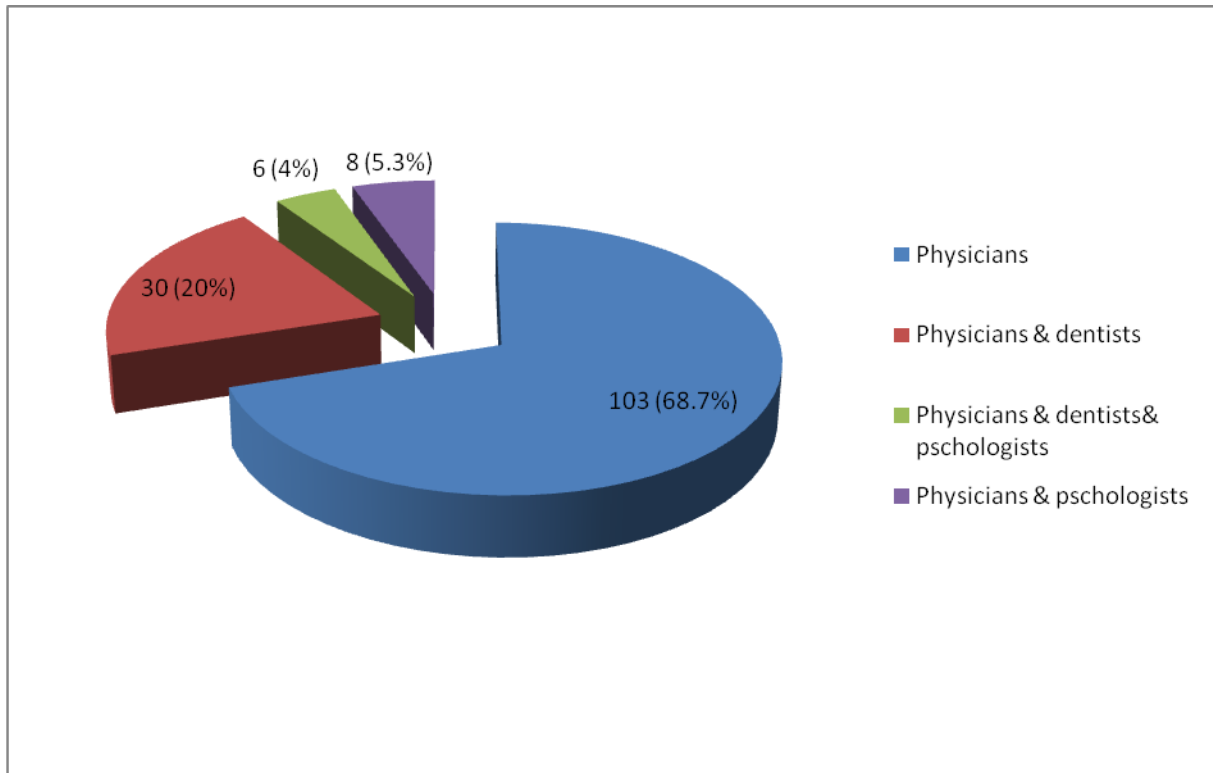


Figure 4.9 Prescribers accepted by CM dispensers among community pharmacies

The findings of this research showed that dispensers were accepting to serve prescriptions written by physicians, dentists and psychologists. It was found that a big percentage of dispensers (68.7%) were accepting to dispense controlled medicines prescribed by physicians only. A small percentage of respondents (4%) reported to be accepting controlled medicines prescriptions written by physicians, dentists and psychologists (Figure 4.9).

Different health professionals are accepted by the US Drug Enforcement Administration (DEA) as prescribers for controlled medicines. These include physicians, dentists, and mid-level practitioners (Tennessee, 2015). In the findings of the current study, it was found that prescriptions for controlled medicines written by physicians were accepted by all dispensers. Also, some dispensers reported that they were dispensing controlled medicines prescribed by psychologists and dentists as prescribers. These findings are in line with what is stated in the DEA guidelines for prescribing controlled substances. Prescriptions for controlled medicines that are dispensed among community pharmacies in Rwanda are

written by certified health professionals and this can have a positive impact on the quality of controlled medicines dispensing.

4.4.4 Status of partial dispensing of controlled medicines among community pharmacies

In order to have information on the status of the partial dispensing of prescription of controlled medicines, research participants were asked if they offer that service to their clients. They were also asked about the circumstances which induce them to give that service to their clients. The answers of respondents are summarized in the table below.

Table 4.3 Partial dispensing controlled medicines among community pharmacies

Do you do the partial dispensing of controlled medicines?		N (%)
Yes		83 (56.5%)
No		64 (43.5%)
In which case do you do the partial dispensing of CMs		
	All patients without enough cash	0%
	Known & regular patients without enough cash	83 (56.5%)

The above findings showed that 56.5 % of respondents were doing the partial dispensing of controlled medicines prescriptions. All these people said that they were offering this service to patients in order to help those come to the pharmacy while not having enough money to buy controlled medicines they need. But they said that this service is given to known and regular patients who accepts to come back to take the remaining portion of the full dose within the agreed time (Table 4.3).

As it is mentioned in the pharmacist checklist for dispensing controlled substances, the partial dispensing is allowed for controlled medicines. This can be done for schedule III-V controlled medicines, provided that each partial dispensing is recorded in the same manner as a refilling and the quantity dispensed in all partial dispensing should not exceed the total quantity prescribed (Tennessee, 2015). The partial filling of a prescription for a controlled substance listed in Schedule II can be accepted in case, the pharmacist is unable to supply the full quantity requested in a written or emergency oral prescription, and if he makes a notation of the quantity supplied on the face of the written prescription (DEA, 2012). The findings of the current study showed that only 22.6 % of dispensers were doing the partial dispensing of prescription for controlled. This might be resulting from a small number of written or emergency oral prescriptions in the Rwandan health system.

Respondents of the current study reported that the partial filling of controlled medicines prescriptions was a service offered by their pharmacy to regular patients who use controlled medicines in the treatment of chronic disease and who were not having enough cash at the time of picking those medicines from the pharmacy. It can be concluded that the percentage of dispensers who accept the partial dispensing of controlled medicines was small even though that service is accepted in a quality dispensing process for controlled medicines.

4.4.5 The status of controlled medicines refill among community pharmacies

Refilling prescriptions of controlled medicines is allowed in many countries. The status of refilling prescriptions for controlled medicines among community pharmacies in Rwanda was evaluated and the findings are presented below.

Table 4.4 Controlled medicine prescriptions refill status

Are you refilling controlled medicines prescriptions?		N (%)
Yes		45 (31.0%)
No		100 (70%)
Are you accepting oral refill authorization from the prescriber for refilling controlled medicines prescriptions?		N (%)
Yes		33 (22.6%)
No		113 (77.4%)
Why do you accept oral refill authorization?		
Prescriber want to reduce the patients load		2.60%
To help the patient		33 (20.0%)

It was found that 70% of community pharmacies were not refilling prescriptions for controlled medicine after they have been dispensed once. Only, 20 % and 2.6% of research participants said that, they were accepting an oral refill authorization in order to help the patient to easily get the CM and to reduce the patient load at the prescriber' s office respectively (Table4.4).

The US DEA guidelines stipulate that schedule II CMs prescriptions are not refillable and that schedule III and IV prescriptions can be refilled up to 5 times within 6 months. Those guidelines also stipulate that schedule V CMs can be refilled as authorized by the prescriber (Tennessee, 2015). The results of the current study showed a high percentage (70%) of medicines dispensers who do not refill CMs prescriptions. Many respondents said they were

not refilling controlled prescriptions because they were not used to that in their daily activities.

Different findings to those of the current study were found in a report of the supervision of community pharmacies in the United Kingdom where 58.4% community pharmacies were dispensing repeat prescriptions of controlled medicines to patients (Bradley, et al., 2013). This percentage is big compared to what was found in the current study (31.0%). As a conclusion, the level of refilling prescriptions for controlled medicines is still low while it is among the quality characteristics of the dispensing process for controlled medicines especially when treating pain for patients with cancer, HIV and arthritis. Prescribers and dispensers may be encouraged to be writing and dispensing refillable prescriptions respectively.

4.4.6 Status of labeling controlled medicines by dispensers

Labeling dispensed medicines help in reminding the patient the use directives when he/ she out of the pharmacy. The information written by dispensers on the labels they put on controlled medicines they dispense was assessed in this research. The findings which were gotten was summarized on the figure below.

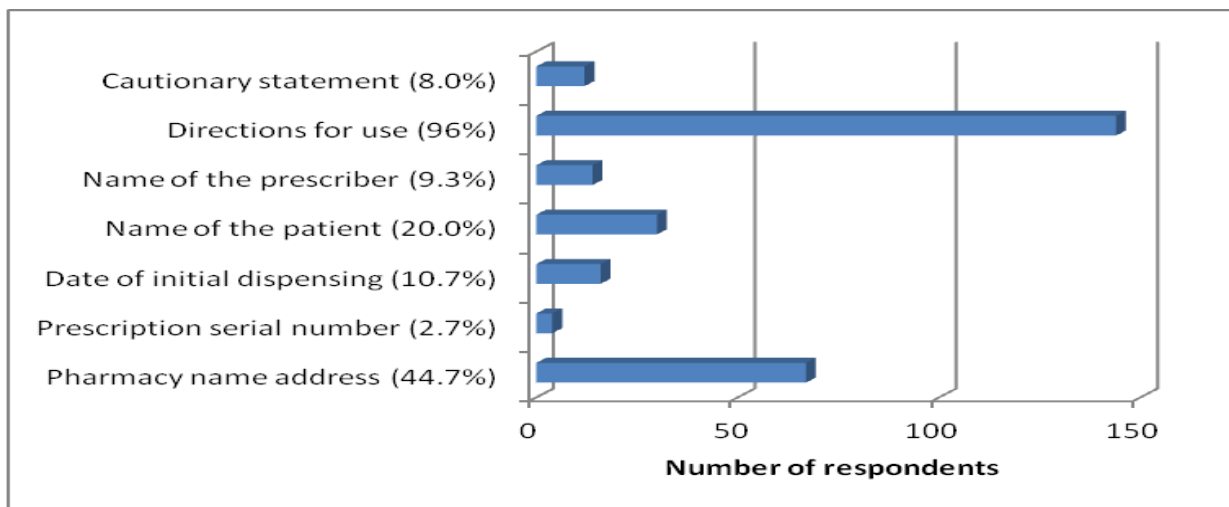


Figure 4.10 Information that is written on a label that is put on a pharmacy made CM package

The findings showed that dispensers were labeling controlled medicines in different ways. It was found that most of them (96%) were writing the directions for use of controlled medicines while few respondents (2.7%) reported to write prescription serial number on the label. The details are presented in the figure 4.10.

Medication labeling has been identified as an issue of significant importance in medication safety and one of the factors contributing to safe use of medications among users is the capability to read the medication label and proceed upon the information presented accordingly (Jennings J, 2007). The US Drug Enforcement administration (DEA) mentions

that the label to be put on packaged controlled medicines must be containing the name of the pharmacy and its address, prescription number, date of initial dispensing, the name of the patient, the name of the prescribing practitioner, directions for use and if applicable cautionary or warning statement may be provided (Tennessee, 2015).

In a study conducted in the State of Penang, Malaysia on compliance towards dispensed medication labeling standards, it was found that that majority of the dispensed medications were not labeled according to regulatory requirements. It was found that only 19.4% of the dispensed controlled medications given by community pharmacies were labeled with the name of the medication. The findings of this study showed that community pharmacists labeled dispensed medications with the words “Controlled Medicine” more often than did general practitioners (Chin, 2009).

Findings from the above study are similar to what has been found in the current research because almost all community pharmacy dispensers were not writing all information required to be put on the CM label. Most of dispensers (96%) were writing only the directions for use to packaged CM labels and 44.7 % of dispensers were providing the pharmacy name and its address on the label of controlled medicines. Even though laws for labeling dispensed controlled medicines can be found in different documentations, most community dispensers did not comply accordingly, thereby putting patients’ safety at risks of medication errors. There is a need of harmonizing information that is put on controlled medicines label among community pharmacies.

4.4.7 Status of patients counseling on controlled medicines among community pharmacies

4.4.7.1 Level of patients counseling on controlled medicines

A quality dispensing process has to include a session for counseling patients on medicines use. The percentage of dispensers who were counseling patients on controlled medicines use was determined in this study. The following table presents the findings which were gotten.

Table 4.5 Status of patients counseling on CMs use among community pharmacies

Are you counseling patients on controlled medicine use?	N (%)
Yes	147 (100%)
No answer provided	3

The findings showed that all research participants (100%) who answered the question on patient counseling reported that they were offering this service to patients after the dispensing of controlled medicines (Table 4.4).

4.4.7.2 Information that is given patients during the counseling on controlled medicines

Different information has to be given to patients while counseling them on controlled medicine use. That information was analyzed and the results are presented in the figure below.

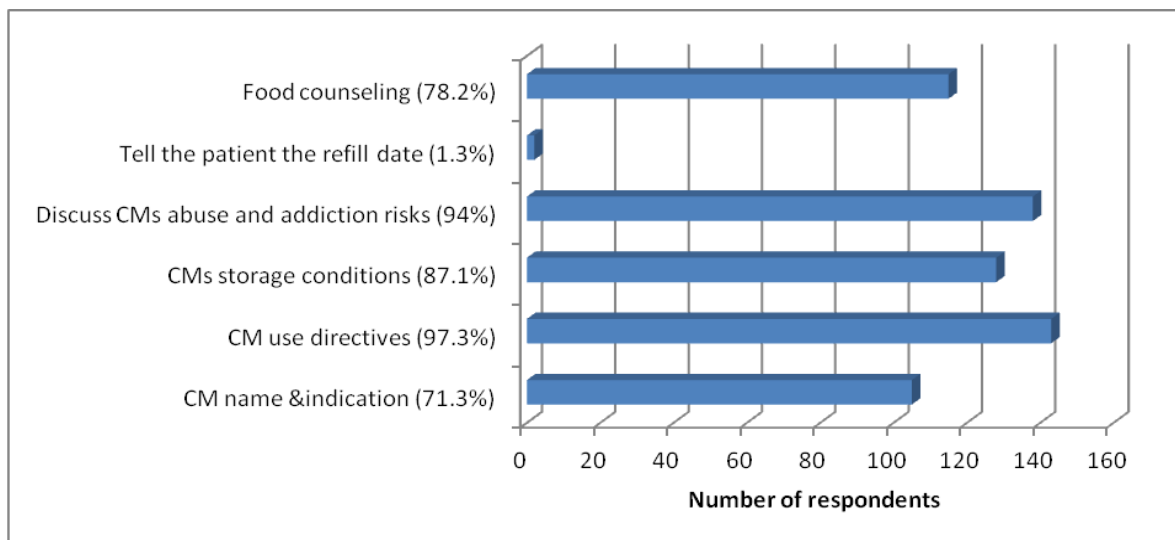


Figure 4.11 Crucial information given the patient during the counseling process

Concerning the information given to the patient during the counseling process, research findings showed that 97.3% of respondents were explaining the directions for use to the patient and 94% were explaining them on risks of abuse and addiction which can follow inappropriate use of controlled medicines. A small percentage of respondents (1.3%) reported that they tell the patient the refill time during the counseling process. The figure 4.11 provides details.

4.4.7.3 Evaluation of the knowledge retained by patients after the counseling on controlled medicines

The strategies used by dispensers to evaluate information kept by the patient after the counseling process was assessed. The findings are presented below in table 4.6.

Table 4.6 Evaluation of information retained by the patient after the counseling

Which information do you ask the patient after the counseling process?	
	N (%)
Ask if there is any other concern or question	50 (35.5%)
Ask the patient to repeat counseled key information	12 (8.5%)
Both	76 (53.9%)
Nothing is done	3 (2.1%)

Findings showed that many dispensers (53.9%) were asking the patient if there is any other question and then ask them to repeat some key information like the use directions in order to know what they kept during the counseling process. A small percentage of respondents (2.1%) reported not to do any test in order to know what the patient has kept after the counseling process (Table 4.6).

The counseling on controlled medicines should give the patient clear and complete instructions on how to take or use those drugs (Nasir T Wabe, 2011). It is stated in Arizona controlled drugs dispensing guidelines that pharmacists should educate their patients about proper use, storage and proper disposal prior to dispensing controlled substances (DrugFreeAZ, 2016). In a study conducted on the assessment of dispensing practices among private pharmacies in Dar-es-Salaam, it was found that during the dispensing process less than a quarter of dispensers gave dosage instructions of controlled medicines to the patient. On the few occasions that they gave dosage instructions these were often not consistent with national practice guidelines. Dispensers were not explaining to patients the risks that might accompany inappropriate use of medicines (Kagashe, 2011).

The results found in the current study are different from those of the above study. It was found that all dispensers were giving dosage instruction to patients during the counseling and 94% were explaining to the patient the risks of abuse and addiction which can follow inappropriate use of controlled medicines. Similar results were found in a report of the supervision of community pharmacies in the United Kingdom which showed that 85.1% of pharmacists were providing healthy living advice and 15.9% of them were giving clinical advice to patients while dispensing controlled drugs (Bradley, et al., 2013).

Another study conducted on patient medication counseling in Gondar, North West Ethiopia has shown that the majority of dispensers (84.12%) had interest in counseling patients on controlled medicines. In this study, 34.9% of respondents mentioned that counseling patients is all about telling patient on dose, how to use their drugs, adverse drug effect, life style modification, drug storage aspect and contraindication while 53.9% of respondents reported that the counseling is only about telling patients about dose or frequency (Dessalegn, 2015). The findings of this study can be compared to those of the current research even though the big percentages of respondents in the current study were telling the patient on dose and use of controlled medicines, their adverse effect, life style modification, storage aspect and the refill date. The counseling of patients on controlled medicines among Rwanda community pharmacies is good even though some improvements are required like on the counseling on risks that might be associated with inappropriate use of controlled medicines by patients.

4.4.8 Causes that decline dispensing controlled medicines to clients among community pharmacies

Research respondents were asked the about the causes which make them to decline the dispensing of controlled medicines to patients. The answers, which were provided, are summarized in the figure below.

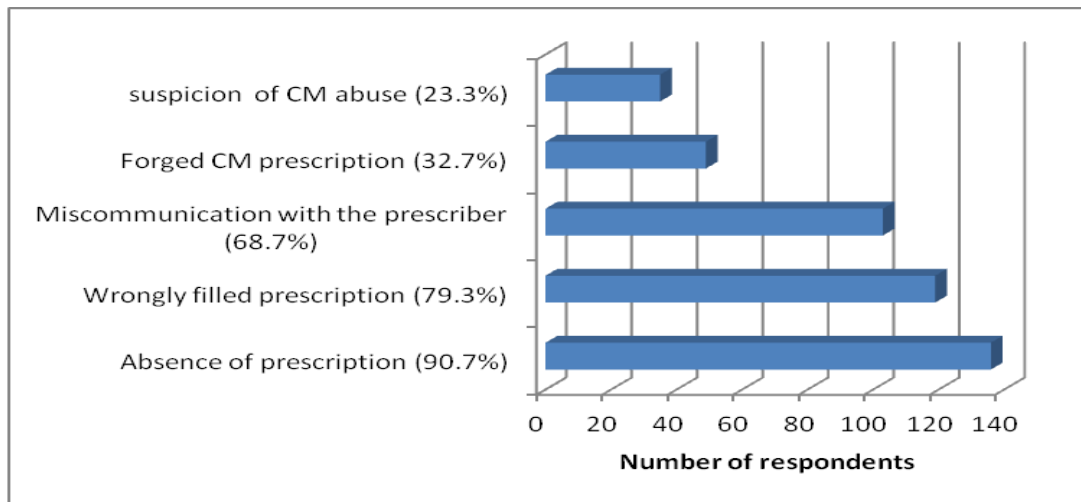


Figure 4.12 Causes for declining the dispensing of controlled medicines

Most of dispensers (90.7%) said that they do not dispense controlled medicines when a client was requesting them without a medical prescription. The other causes that were mentioned by respondents as the factors which were preventing them from dispensing controlled medicines included the suspicion of the client as an abuser of controlled medicines (23.3%), a forged prescription (32.7%), a wrongly filed controlled medicines prescription (79.3%) and the miscommunication with the prescriber in case use of prescribed controlled medicines can be associated with risks (68.7%), (Figure 4.12).

Different dispensers had varying reasons which can make them to take a decision of not dispensing a given controlled medicine. In United Arab Emirates, dispensing controlled medicines without a prescription, may lead to a prison sentence (Trial, 2016). Refusing to dispense controlled medicines may happen following different circumstances especially in prescription related problems or in case the patient is suspected to be abusing controlled medicines (DrugFreeAZ, 2016).

In that study conducted on the management of controlled medicines by pharmacists, it was shown that 14.1% of pharmacists were dispensing controlled medicines to a person whom they doubt (El-Sakka, 2012). Also, during this study, it was shown that 11.1% of pharmacists were dispensing controlled medicines to a person requesting them even though they were suspecting him/her to be abusing controlled medicines. The current study has different findings because it highlighted that many dispensers (90.7%) were refusing to issue prescriptions of controlled medicines in case the patient was requesting a controlled

medicine while not having a medical prescription or in case of suspicion of the client to abuse controlled substances.

A study conducted in Jordan on knowledge, attitude and opinion of drug misuse and abuse by pharmacy Students, 34.4 % of respondents strongly agreed that dispensing controlled drugs without a medical recipe was an important source of money for the pharmacy (Blumenthal, 2002). These results are different from those of the present study because dispensers (90.7%) showed that were convinced to not dispense any controlled medicine in case a patient does not have a legitimate prescription.

In another research conducted in New Mexico on availability of narcotics and pharmacists' attitudes toward narcotic prescriptions for cancer patients, it was found that the most common provided reasons for apprehension of controlled medicines dispensing among pharmacists were forgery (46.4 %), theft (40.4 %), high dosages (23.8 %), narcotic investigations (18.7 %), and patient addiction (9.4 %) (Holdsworth, 1992). Similar findings were gotten in the current study where some respondents (23.3%) were not dispensing controlled medicines because they were suspecting the customer to be abusing controlled medicines. Some respondents of the current study (32.7%) also reported that they do not dispense controlled medicines in case their prescription has technical issues. According to the discussions above and different guidelines dispensing for controlled medicines, the causes that were declining many respondents of the current study to dispense controlled medicines may lead to a quality dispensing of these medicines.

4.4.9 Status of recording data about dispensed controlled medicines

The status of recording data about controlled medicines and the tools which were used in community pharmacies to do that, were evaluated in this study. Below are the findings of that assessment.

Table 4.7 Status of recording controlled medicines dispensing data

Do you have recorded information about dispensed controlled medicines?		N (%)
Yes		127 (86.4%)
No		20 (13.6%)
What do you use to record CM dispensing process information?		N (%)
	Prescription registration book only	65 (43.3%)
	Computerized recording system only	37 (24.7%)
	Both the computer and registration book	26 (17.3%)
	Printed sheets	3 (2%)

The findings of this study showed that all community pharmacies which were visited did not have records about dispensed controlled medicines. It was found that only, 86.4% of them had those records. The ways used by different visited community pharmacies were different. It was found that many (43.3%) were using only prescription registration book to record dispensing information for controlled medicines and some community pharmacies (17.3%) were using both the computers and the registration book. Only a small percentage of community pharmacies (2%) were using printed papers to record CMs dispensing information (Table 4.7).

The requirements for a quality dispensing process among community pharmacies mention records to be of paramount importance as they are reviewed during audits. Recordings save as a proof of the transactions which happened between the patients and the dispenser (FMHACA, 2012). A study conducted in Palestine on the dependence on controlled substance and their management by pharmacists showed that only 33.7% of visited community pharmacies were using computers for recording data on controlled medicines dispensing (El-Sakka, 2012). The current study showed that community pharmacies do not use only computers to record dispensing information for controlled medicines. It was found that prescription registration books were used by 43.3%, computers used by 42 % and printed sheets used by 2% of all visited community pharmacies. Strategies that were used for recording information on controlled medicines dispensing among community pharmacies are adequate for a quality system even though a harmonization of those strategies is needed.

4.4.10 Information that is recorded by community pharmacies on controlled medicines dispensing

Recording data about the handling and dispensing activities is a requirement for a quality dispensing process for controlled medicines. The type of information which was recorded by community pharmacies was assessed and it is summarized in the figure below.

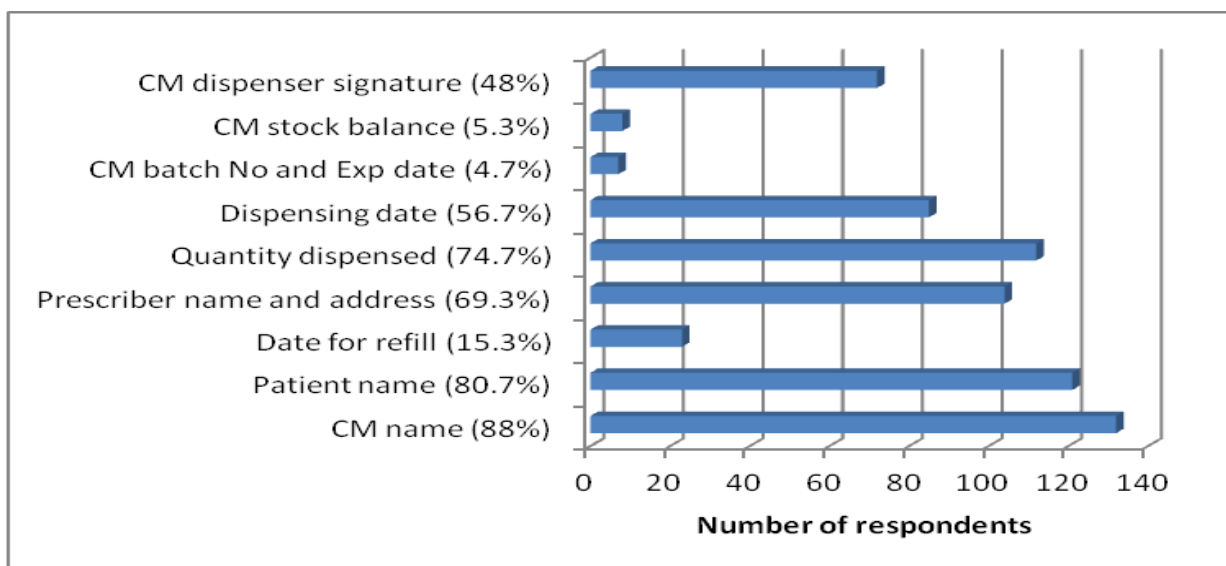


Figure 4.13 Information from the dispensed CM prescription that is recorded

Research findings showed that among visited community pharmacies, there was no harmonized way for recording information on controlled medicines dispensing. Many dispensers (88%) had records about the name of controlled medicines that they dispensed. A small percentage of respondents (4.7%) were recording the batch number and expiry date of dispensed controlled medicines (Figure 4.13).

A CM prescriptions and the dispensing process are associated with many information that should be recorded and kept by community pharmacies (Tennessee, 2015). Findings from the current study highlighted that there is no harmonization of information on controlled medicines that is recorded among community pharmacies. Most of visited pharmacies were recording only the controlled medicine name (88%) and the patient name (80.7%). These findings showed that those pharmacies are not in compliance with the DEA guidelines which require community pharmacies to record the names and address for the dispensers and prescribers, the dispensed controlled medicine name, the dispensed quantity, the dispensing and refill date, and the patient name (Tennessee, 2015). The information recorded by dispensers among different community pharmacies is not enough to ensure the quality of required records for controlled medicines. Dispensers need to be trained on controlled medicines records and MOH audits have to be carried out among different community pharmacies in order to ensure the conformance to regulations.

4.4.11 Duration for the maintenance of controlled medicines records among community pharmacies

According to different guidelines, recordings of data on controlled medicines dispensing have to be kept for the duration adequate for their use. This duration was assessed among sampled community pharmacies and the findings are presented in the figure below.

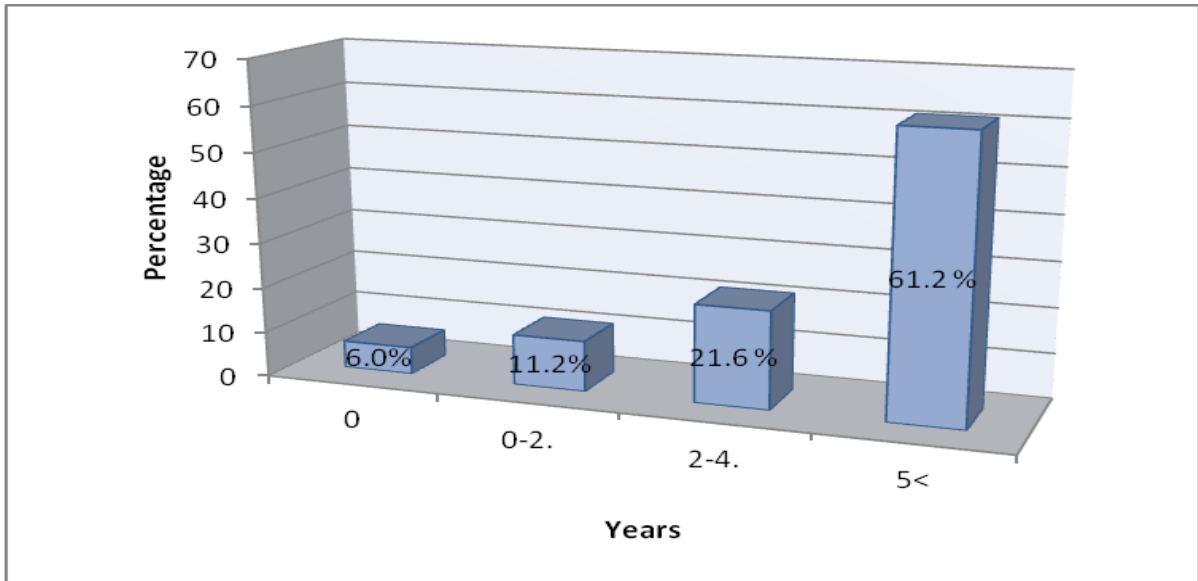


Figure 4.14 Duration for which controlled medicines records are kept

A big percentage of respondents (61.2%) had controlled medicines records which were maintained for a period above five years while a small proportion (6%) of them said that they were not keeping any record of controlled medicines (Figure 4.14).

After writing controlled medicines records, they are supposed to be maintained for certain time in order to provide the history for dispensing activities which happened. Controlled medicines records keeping is a key to the traceability of a problem if a case has risen. According to the US Drug Enforcement Administration (DEA), all records of CMs must be maintained for 2 years, separately from all other records (Tennessee, 2015). These guidelines suggest that records for schedule II controlled medicines have to be further separated from schedule III-V records.

According to the results of the present study, it was found that many community pharmacies had adhered to the period for keeping controlled medicines records as it is suggested by DEA guidelines. It was found that 61.2 % of community pharmacies had kept controlled medicines records for a period beyond 5 years and 21.6% had controlled medicines records which were kept for a period between 2 and 4 years, the durations which are bigger than what is recommended. As conclusion, most of community pharmacies were keeping records of controlled medicines for a period that is adequate for a quality dispensing of controlled medicines.

4.4.12 Availability of archives for dispensed controlled medicines

4.4.12.1 Availability of archives for dispensed prescriptions of controlled medicines

The availability of archives for dispensed prescriptions of controlled medicines was assessed among sampled community pharmacies. The following figure is showing the findings which were gotten.

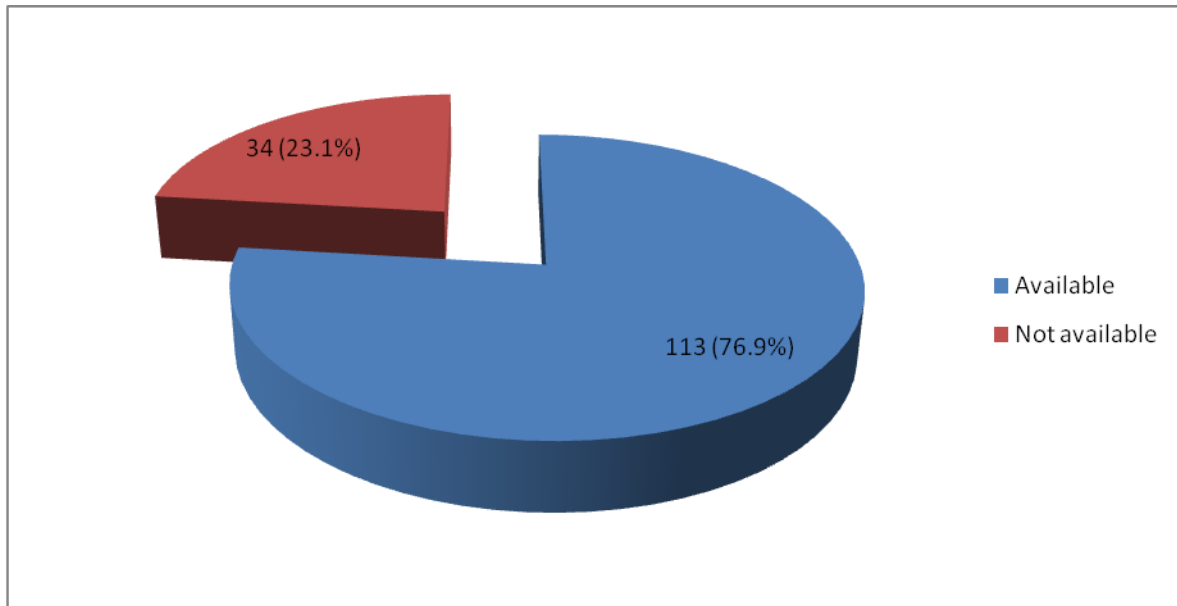


Figure 4.15 Availability of archives of dispensed CM prescriptions among community pharmacies

It was found that 76.9 % of community pharmacies had kept copies of prescriptions for controlled medicines they had dispensed to patients and 23.1 % did not have archive of prescription of those medicines (Figure 4.15).

4.4.12.2 Availability of archives of documents for inventory and disposal of controlled medicines

Not only the archives of prescriptions for controlled medicines have to be maintained by community pharmacies, but also inventory and disposal documents for those medicines should be kept for the recommended period. The following table summarizes the findings about the availability of documents about inventory and disposal of controlled medicines among community pharmacies.

Table 4.8 Availability of archives for CM inventory and disposal documents among community pharmacies

Are there documents showing that the pharmacist is routinely reviewing and checking the CM stock balance?		N (%)
Yes		109 (75.2%)
No		36 (24.8%)

Are there documentations relating to the destruction or disposal of expired CM?		N (%)
Yes		93 (63.3%)
No		52 (35.4%)
Not done		2 (1.4%)

Findings of the current study showed that only 75.2% of respondents had documents which were showing that the stock for controlled medicines was undergoing regular checks. It was also found that 63.3% of visited pharmacies had kept documents which were related to the disposal of expired controlled medicines. Only, 1.4% of respondents said that they had never experienced expired or patient returned controlled medicines in their pharmacy (Table 4.8).

For the correctness of the dispensing process and justifying that a controlled medicine was dispensed to the patient, each prescription for controlled medicines should be signed by the dispenser and filed in organized way (FMHACA, 2012). It is required that archives for controlled medicines are filed in community pharmacies because they back up recorded information (DEA, 2012). The findings of the current study showed that not all community pharmacies had kept copies of dispensed prescriptions for controlled medicines. Only 76.9% of them had copies of dispensed prescriptions for controlled medicines.

In a survey conducted in Jordan on drug and pharmacy practice law, it was seen that since 1972, inspectors from the Ministry of Health were frequently visiting community pharmacies to check any violation in general and check filed archives of controlled medicines documents (Jaber, 2015). Even though these audits are not conducted among community pharmacies in Rwanda, archives for dispensed controlled medicines prescriptions need to be kept as a requirement of a quality dispensing process for controlled medicines. The filing of dispensed prescription for controlled medicines among community pharmacies is at a good level even though there were many dispensers who needed to be trained on the filing of those prescriptions.

4.4.13 Status of reporting of information about controlled medicines by community pharmacies

Research participants were asked about the reporting of information on controlled medicines they dispense to patients in their pharmacy. The figure 4.16 presents the findings on that reporting.

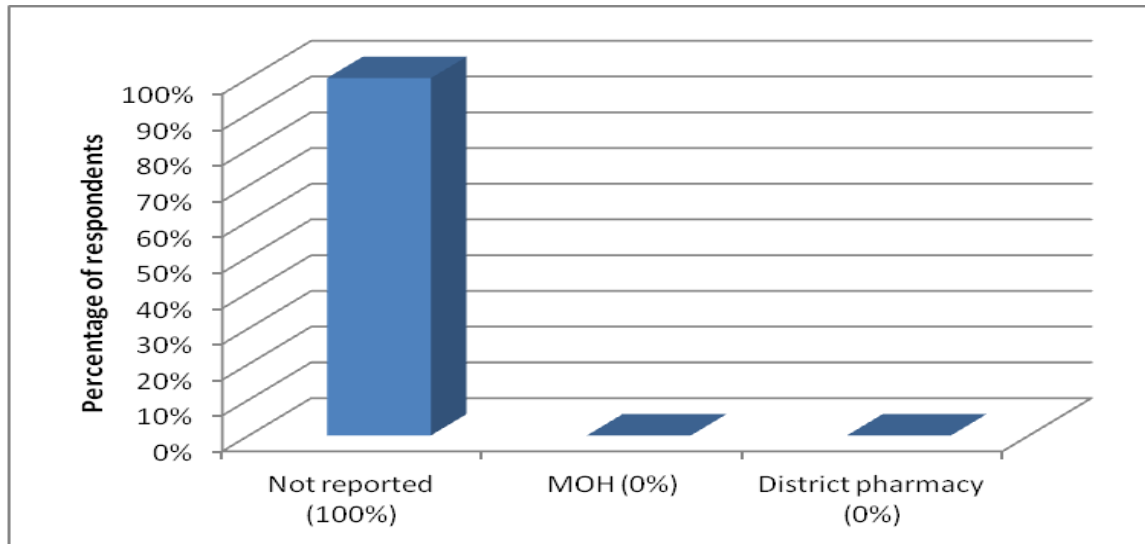


Figure 4.16 Reporting of information on controlled medicines dispensing

Findings showed that all community pharmacies (100%) were not reporting any information concerning controlled medicines to the ministry of health or to the district pharmacy. The figure 4.16 provides details.

Regulatory bodies are supposed to have data of controlled medicines handling and dispensing from community pharmacies (O'Brien, 2014). In USA, pharmacy handlers of controlled substances are required to report certain events like significant loss or any theft of controlled substances to their local DEA office (Bruce, 2016). All dispensers (100%) who participated in the current study reported that they were not reporting information on the dispensing of controlled medicines to any institution. As conclusion, the dispensing process for controlled medicines can not be of quality in case there is no reporting system for controlled medicines to the Ministry of health which is supposed to evaluate the trends in controlled medicines dispensing and take appropriate decision if need be.

4.5 Level of participation of dispensers in trainings related to controlled medicines

Trainings on controlled medicines improve the knowledge of dispensers and this is needed for the dispensing of those medicines. Research participants were requested to provide the number of training they attended on controlled medicines and the findings are provided in the table below.

Table 4.9 The number of CM related trainings attended by medicines dispensers

How many CM related trainings has the respondent done in her/his medicine dispensing career?	
	N (%)
Between 1 and 10 trainings	3 (2%)
No training done	147 (98%)

Research findings showed that almost all dispensers (98%) have not done any training related to controlled medicines throughout their career. A small percentage of respondents (2%) reported to have attended at least one training on controlled medicines in their career (Table 4.9).

4.6 Knowledge of community pharmacy dispensers on controlled medicines and their handling

Dispensers are required to have sufficient knowledge on controlled medicines in order to ensure appropriate dispensing them to patients. Research respondents were asked to define controlled medicines and the answers they provided were analyzed and presented in the figure below.

4.6.1 Knowledge of the meaning of controlled medicines

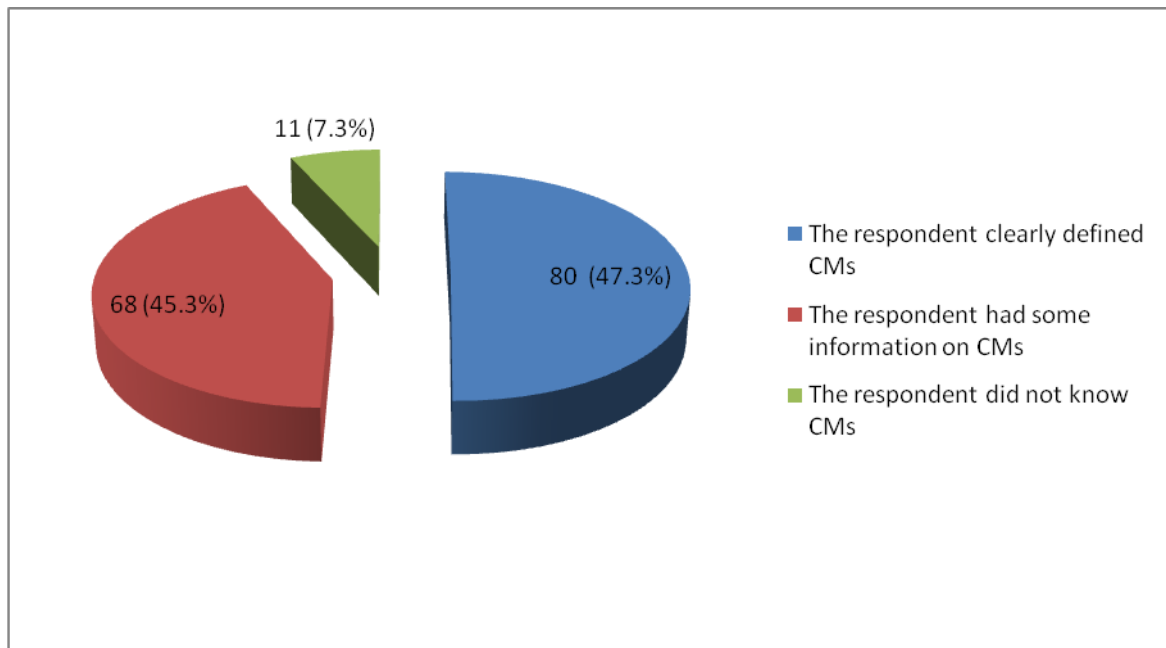


Figure 4.17 Knowledge of the meaning of CM by dispensers

Findings showed that almost all dispensers had something to say about controlled medicines but those who managed to clearly define those medicines represented 47.3% of all respondents who participated in this study. Only a small percentage of all respondents (7.3 %) were unable to explain the meaning of controlled medicines. Details are provided in figure 4.17.

4.6.2 The knowledge of dispensers on schedules of controlled of controlled medicines

To test the level of knowledge of dispensers on controlled medicines, they were again requested to discuss schedules of controlled medicines. The figure below shows the findings of this assessment.

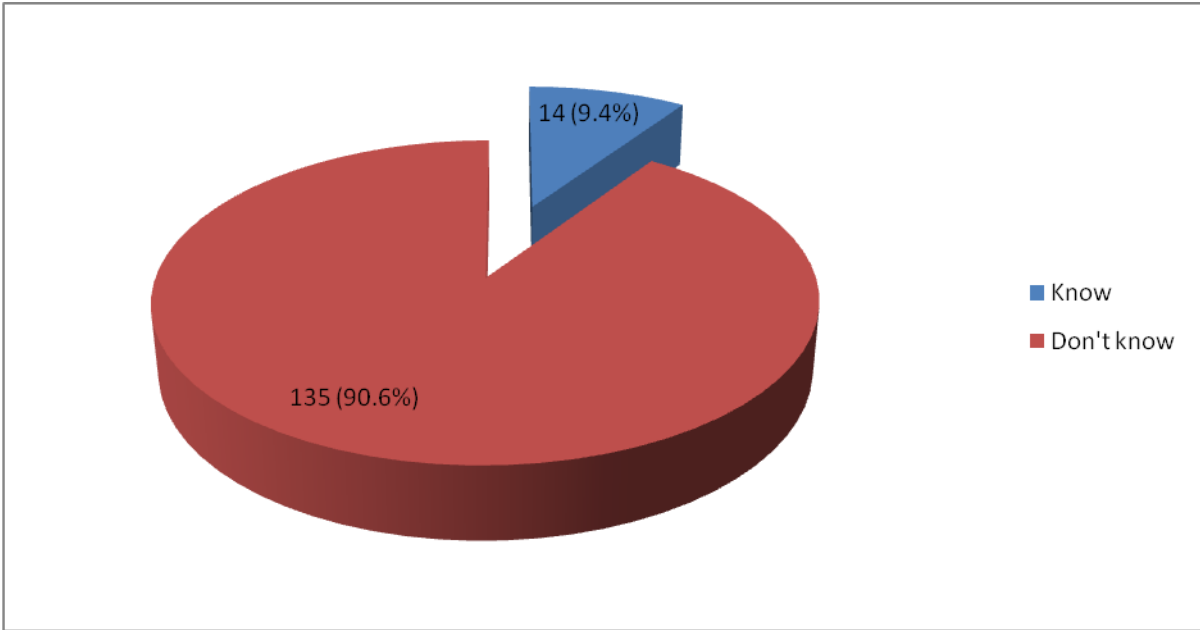


Figure 4.18 Respondents' knowledge on CMs schedules

Even though many respondents had information about controlled medicines, it was surprisingly found that many of them were not able to explain controlled medicines schedules. The findings of this research showed that only 9.4 % were able to discuss different CMs schedules clearly. Details are presented on figure 4.18.

4.6.3 Ability of respondents to differentiate abuse and addiction on controlled medicines

The knowledge of respondents on risks which can be associated with inappropriate use of controlled medicines was also assessed in this study. Respondents were requested to differentiate the abuse of controlled medicines and the addiction to them. The findings for this test are summarized in the table below.

Table 4.10 Respondents knowledge on CM associated risks

Is the respondent able to differentiate CM abuse and CM addiction?	N (%)
Clear difference provided	142 (94.7%)
The respondent confused the two words	7 (4.7%)
The respondent does not know these words	1 (0.7%)

It was found that many of them (94.7%) provided a clear difference of the two words. Some respondents (4.7%) confused the two words while only 1 person did not know the meaning of either abusing or being addicted to controlled medicines (Table 4.10).

4.6.4 Qualitative findings on the knowledge of dispensers about controlled medicines

4.6.4.1 Medicines considered by respondents as controlled medicines

The definition of controlled medicines as those medicines which can cause a danger to the public was one of the central themes as stated by research respondents. They said, they consider controlled medicines as those that might lead to public problems like addiction or abuse problems in case they are not handled well healthcare professionals or appropriately used by patients. Many of them listed Narcotics, psychotropics, some antibiotics and other medicines like misoprostol available on the Rwandan market as cytotec as the controlled medicines and they mentioned that CMs need to be accessed by the pharmacist only. The narrations below allude to define controlled medicines as those that can be associated with abuse problems.

“In our pharmacy, we consider all medicines that can be associated with abuse or misuse risks as controlled medicines. We do not put only narcotics and psychotropics in this group, but we also consider some antibiotics that can be easily abused by users or the medicine known as cytotec as controlled medicines. All these drugs are handled with care and kept in their own cupboard in our pharmacy”. Research respondent

The second cited central theme about controlled medicines definition is that they are considered as those which have a narrow therapeutic window. Many respondents said that they consider controlled medicines as those which might be associated with serious and harmful adverse drug reaction. They were considering digoxin and warfarin as controlled medicines and they were recommending dispensers to closely monitor their use because their inappropriate use can easily kill a patient. The following narration from one respondent is showing how controlled medicines are viewed by many dispensers.

“For me, I consider medicines like digoxin and other drugs acting on the heart or warfarin; which have a very narrow therapeutics index as medicines to be controlled. Me, I call them controlled medicines”. Research respondent

4.6.4.2 Discussions of dispensers on schedules and dispensing of controlled medicines

As it was shown by quantitative findings, the absence of knowledge on controlled medicines schedules was the main theme under this question. Many respondents were asking the meaning of those schedules when they were reaching this question while answering the research questionnaire. Others were saying that they had studied about controlled medicines schedules a long time ago in class. Evidence of that theme can be observed from the following narrations from different respondents.

“Sir, I do not remember these controlled medicines schedules. We had seen a little bit about them in class but I do not remember them because there is a long time”.

“Sure, it is my first time to know that controlled medicines are classified in schedules. Can you explain me what they are so that I can answer this question? It is real that we need to go back in class otherwise we will be left behind”. Research respondent

The other theme of interest from few respondents was that respondents needed trainings about controlled medicines even though some knew them and their schedules. The following discourses suggest the need of training on controlled medicines especially on the way they are put in schedules.

“For sure, me I know controlled medicines and their schedules because I have a culture of reading different research publications and international reports. But still, we need a way to help others to update their knowledge on controlled medicines like trainings that are offered through CPD programs because if not, dispensers will be like other people”. Research respondent

The other theme of importance was that respondents didn't know how many times controlled medicines prescriptions have to be refilled. Respondents also mentioned that they only refill prescriptions of non communicable diseases' medicines in case the patient is their known client as it is stated in the following narrations.

“Normally, this pharmacy does not handle many controlled medicines. We have some like tramadol and diazepam. I remember what I did last year is that there was a patient who came with a non updated prescription of diazepam and I refilled it because I knew that no problem could follow this. But sincerely speaking, I don't know how many times to refill CMs prescriptions and relate this to their schedules”. Research respondent

“Refilling CMs prescriptions? No. Here we do not do that. About prescriptions refill, we have few patient who have hypertension and who are coming in this pharmacy for taking hypertension medicines every month but they are our permanent clients”. Research respondent

Knowledge on controlled medicines and their handling is among the preliminary requirements for community pharmacy dispensers (O'Brien, 2014). The findings of the current study showed that 47. % medicine dispensers were able to define controlled medicines but a few of them (9.4%) were able to clearly explain controlled medicine schedules. Similar findings were gotten in a study conducted by Joranson and Gilson on pharmacists' knowledge of and attitudes toward controlled medicines for pain in relation to federal and state policies. These findings showed that 29% of respondents had adequate knowledge on controlled substances and their schedules. Even though that percentage is bigger than what has been found in the current study, both findings can be considered similar because the percentage of respondents who knew clearly controlled medicines 9.4% and 29% for the current and the Joranson' s studies respectively represented a small proportion of all respondents per each study.

In a study conducted in 2012 on the assessment of controlled substances their management by pharmacists (El-Sakka, 2012), it was found that most pharmacists were lacking knowledge about regulations and rules. It was found that the majority of pharmacists had never attended lectures or seminars on drug abuse even though they were convinced about the importance of those seminars. The findings from this research were similar to those of the current study as it was shown that there was a general lack of knowledge on regulations for different schedules of controlled medicines among medicine dispensers of community pharmacies in Rwanda.

The results of the current study showed that 94.7% of respondents were able to clearly differentiate the abuse of controlled medicines from addiction to them. Different findings were gotten in a study conducted in Wisconsin on pharmacists' knowledge of and attitudes toward opioid pain medications. This study showed that many respondents were unaware of the important distinctions between addiction, physical dependence, and tolerance (Joranson DE, 1998). BY comparing the findings of these two studies, it can be said that dispensers of controlled medicines in Rwanda are at a high level in knowledge about abuse of, and addiction to controlled medicines.

In a Study conducted in Jordan in 2015 on knowledge, attitude and opinion of drug misuse and abuse by pharmacy students, 92.0 % of respondents strongly agreed that all pharmacy staff must be trained on controlled medicines especially in recognizing drug abusers. This study showed that 92.6 % of respondents were trained on methods of dealing with drug abusers. It was also found that, there was a strong tendency of pharmacy undergraduate and postgraduate students at University of Jordan to receive more training about the identification and management of the problem of controlled medicines abuse. These findings are different from what has been found in the current study because a very small percentage of respondents for the current study (2%) had undergone one or more trainings on controlled in their pharmacy career.

Another study which was conducted in Connecticut and Rhode Island on how the use of a prescription monitoring program changes pharmacy practice has also provided findings that are different from those of the current study. That study showed that approximately two-thirds of respondents (66.8%) had attended continuing education on safer dispensing of controlled medicines for pain in the last previous 5 years. The number of trainings followed by dispensers of community pharmacies on controlled medicines and their level in knowledge on those medicines is very low to allow ensuring that the dispensing of controlled medicines is of quality. Dispensers need to update their knowledge in order to deliver to patients, quality dispensing services for controlled medicines.

4.7 The relationship between dispensers' experience and their knowledge on controlled medicines

The chi-square test (χ^2) was used to test the association between dispensers' knowledge on controlled medicines and their experience in dispensing medicines at 5% level of significance ($\alpha=0.05$). Concerning the association between the working experience and the ability of dispensers to define controlled medicines, a p-value of 0.097 ($p>0.05$), was found. Also, for the association between the knowledge of dispensers on controlled medicine schedules and their experience in medicines dispensing, a p-value of 0.563 ($p>0.05$) was found. Finally, a p-value of 0.878 ($p>0.05$) was found for the association between the working experience of dispensers and their capacity to differentiate the abuse and addiction to controlled medicines. As all the p-values are greater than 0.05, there is no statistically significant association between working experience of dispensers and those three variables which are the ability of dispensers to define controlled medicines, their capacity to explain controlled medicine schedules and their ability to differentiate controlled medicines abuse and addiction to controlled medicines.

Pharmacists are well positioned to help prevent and treat substance use disorders and should prepare themselves to perform these functions. Pharmacists need to be well informed about issues related to addiction and be involved fight against controlled substance abuse. (Tommasello, 2004). In the manual for medicines good dispensing practice, it was explained that experience of pharmacy staff help them to develop their knowledge and skills on medicines (FMHACA, 2012). Differently to this statement, the current study showed no association between the knowledge of dispensers on controlled medicines and their working experience. The very small number of research participants who attended trainings on controlled medicines might be the cause of absence of any association between the working experience of research participants and their knowledge on controlled medicines.

In a study conducted on medication knowledge, certainty, and risk of errors among practicing nurses, it was found that knowledge on medicines was associated with postgraduate specialization ($p = 0.01$), working in hospital ($p < 0.001$) and trainings ($p < 0.01$) (Bjoerg, 2011). This research has not shown any association between the working experience and knowledge in medications as it was found in the current study. Different findings were gotten in a study conducted in Gaza on the assessment of controlled substances, dependence on them, and their management by pharmacists. This study showed an association between the working experience for dispensers and their knowledge in controlled medicines handling. It was found that pharmacists who had fewer years of experience (3 years or less) were knowledgeable in noticing an increase in the demand for narcotic drugs in their pharmacies (81.4%) (El-Sakka, 2012).

In a study conducted on the Impact of educational intervention on knowledge of dispensers working at community pharmacies in Pakistan, it was highlighted that improvements in knowledge of dispensers working at community pharmacies are possible through suitable trainings (Azhar, 2013). In this study, the working experience has not been mentioned as a factor that increase the knowledge of dispensers on controlled medicines as it was found in the current study that there was no association between respondents' working experience and their knowledge on controlled medicines. As conclusion, the working experience for dispensers does not have any link with their knowledge on controlled medicines.

4.8 Limitations of the study

- a. Quantitative data were collected using a self-administered questionnaire and were therefore based on self-reports. Self-report measures are open to bias and misreporting, particularly during the time dispensers have huge workload or simply when they are not in the mood of answering research questions. This should be considered in the future studies;
- b. A cross-sectional method was used in this study. It collects the data at one point in time and does not provide time to follow up dispensers practices. Prospective study should be considered and used in the future.

CONCLUSION

Ensuring a quality dispensing of controlled medicines to patients; is a complex process that require medicine dispensers to be patient and vigilant. At the end of this study, the following conclusions are made:

- Most community pharmacies preferred not to handle controlled medicines classified in schedule II because of their increased handling requirements and their high risk of abuse while they are not needed by many clients.
- Many visited community pharmacies did not have standard operating procedules for the handling of controlled medicines although these documents are required to insure a quality dispensing of those medicines
- The storage facilities of controlled medicines among sampled community pharmacies were adequate and they can lead to improved safety of these medicines in case they are used according to regulations.
- The handling of expired or patients returned controlled medicines was inadequate in most of community pharmacies and it can be a source of their diversion or abuse if appropriate measures are not taken.
- There were not particular differences in the checking done for prescriptions of controlled medicines and the prescriptions for other medicines even though special attention is needed while checking the later prescriptions in order to ensure the rational use of controlled medicines.
- The professions of people who were dispensing controlled medicines among community pharmacies were allowing them, in case they are appropriately trained, to offer patient quality services while dispensing controlled medicines. But still, there is a need for monitoring students who are in internship to help them acquire knowledge while also keeping the quality in controlled medicines dispensing.
- Prescriptions for controlled medicines which were dispensed among community pharmacies were written by certified health professionals and this could have a positive impact on controlled medicines dispensing and their use.
- The partial dispensing and the refilling of prescriptions for controlled medicines were inadequate although these services are allowed by international guidelines for dispensing controlled medicines.
- The compliance to regulations for labeling controlled medicines was inadequate among community pharmacies. Dispensers were expecting patient counseling to be enough for helping patients to appropriately use controlled medicines.
- The causes which were declining respondents from dispensing controlled medicines are recommended by regulatory bodies as strategies to improve the safety of those medicines.

- The facilities which were used by community pharmacies for recording information on controlled medicines dispensing were adequate even though a harmonization is needed.
- Most of community pharmacies were keeping records and availing copies of dispensed prescriptions for a period that is adequate for ensuring the availability of data on dispensed controlled medicines in case they are needed.
- The reporting of information related to the dispensing of controlled medicines to the Ministry of Health and the inspection of community pharmacies on handling of those medicines were ineffective.
- The number of trainings which were attended by respondents were not allowing them to have a high level of knowledge required for dispensing controlled medicines
- The working experience for dispensers did not have any association with their Knowledge on controlled medicines.

Briefly for this study, it can be concluded that the quality of some activities recommended to dispense controlled medicines were not performed at a level that can assure a general quality of dispensing controlled medicines in all community pharmacies that are found in Rwanda.

RECOMMENDATIONS

The results of this study need to be made available to medicines dispensers and their community pharmacies, to the Ministry of health, to the Rwanda pharmacy council and to pharmacy academicians.

- The Ministry Of Health should request all community pharmacies to elaborate, avail and implement SOPs about controlled medicines handling for the purpose of improving the dispensing of those medicines.
- The Ministry Of Health is also recommended to plan and implement inspections in community pharmacies for addressing the handling of non expired, expired and patient returned controlled medicines.
- Dispensers should increase attention while evaluating prescriptions of controlled medicines in order to ensure that any patient needing these medicines receives quality services.
- Pharmacists should be monitoring activities of students doing internship in order to help them to acquire knowledge while also ensuring the quality of controlled medicines dispensing.
- Services related to the refilling and partial dispensing of prescriptions for controlled medicines should be improved by community pharmacies as these services help patients to reduced unneeded expenses.
- Community pharmacies are recommended to elaborate and implement a unique approach for labeling dispensed controlled medicines in order to ensure that patients are provided with complete information.
- Dispensers and their community pharmacies in partnership with the Ministry Of Health should design and implement a harmonized system for recording and reporting data about controlled medicine.
- Medicine dispensers should develop a culture of reading different publication and attend trainings or workshops on controlled medicines in order to upgrade their knowledge on these medicines and improve the quality of their dispensing.
- Pharmacy academicians should conduct researches on controlled medicines handling among public health facilities and private hospitals in order to have a general image on controlled medicines handling in Rwanda.
- The National Pharmacy Council should plan and facilitate trainings and workshops dedicated to improve the knowledge of dispensers on controlled medicines handling.
- Finally, it is recommended to the National Pharmacy Council to be carrying out audits among different community pharmacies in order to advise dispensers on proper handling and dispensing of controlled medicines.

REFERENCES

- Albsoul, Y.A., Wazaify, M., Yousef A & Tahaine L. (2010). *Abuse and Misuse of Prescription and Nonprescription Drugs Sold in Community Pharmacies in Jordan*. *Subst Use Misuse*; 45:1319–1329
- ASCP. (2016). *Prescribing and Dispensing Controlled Substances in LTCs*. Retrieved from American society of consultant pharmacist : <https://www.ascp.com/ControlledSubstances>
- Azhar, H. M. (2013). Impact of educational intervention on knowledge of dispensers working at community pharmacies in Pakistan. *Pharmacy practice (Granada)* , 2013 Jul-Sep; 11(3): 144–148.
- Barnes, M. C., Andrea G. Barthwell, M., Marson, J., & Florence C. Paillard, P. (2010). *National prescription drug abuse prevention strategy* . Washington, D.C.: CLAAD.
- Bjoerg, O. S., Inger, J., Gro, K. D., Lene, M.O & Per, G.F. (2011). Medication knowledge, certainty, and risk of errors in health care. *BCM health services research*, 2011 11:175.
- Blumenthal, W.J., Springer, K.W., Jones, T.S. & Sterk, C.E. (2002). Pharmacy student knowledge, attitudes, and beliefs about selling syringes to injection drug users. *Journal of the American pharmaceutical association*, S34-9.
- BOP. (2016, May 26). *Prescribing and dispensing controlled substance prescription forms*. Retrieved May 26, 2016, from Department of consumer affairs Board Of Pharmacy: http://www.pharmacy.ca.gov/licensing/prescribe_dispense.shtml
- Bradley, F., Schafheutle, E., Willis, S.C. & Noyce, R.P. (2013). *Supervision in community pharmacy final report to pharmacy research UK*. Manchester : The University of Manchester.
- Braun, V., & Clarke, V. (2006). *Using thematic analysis in psychology. Qualitative Research in Psychology*, 3 (2). pp. 77-101. ISSN 1478-0887
- Bruce R. S.(2016). *DEA In a Community Pharmacy Part 2*. Stone Ridge, Virginia , USA.
- Chin, F., & Neoh, M. A. (2009). Compliance Towards Dispensed Medication Labelling Standards: A Cross-Sectional Study in the State of Penang, Malaysia. *Current drug safety*, 199-203.
- Chui, O. K. (2012). Relationship between e-prescriptions and community pharmacy workflow. *Journal of the American Pharmacists Association*, 168-74

- Clinic, M. (2015). *Drug addiction risk factors*. Retrieved from Mayo clinic website:
<http://www.mayoclinic.org/diseases-conditions/drug-addiction/basics/risk-factors/con-20020970>
- CMS. (2004). *Review of current standards of practice for long-term care pharmacy services*. Virginia: Lewin Group.
- Creswell, J. (2009). *Research design: Qualitative, Quantitative and Mixed Methods Approaches (2nd Ed.)*. California: Sage Publications, Incorporated.
- Dale Yu, O. H. (2011). A Study on the Pharmacy Operation of the Kibuye Hospital in Rwanda. *The journal of global health care systems*, Vol1, No 3.
- DEA. (2010). *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*. Virginia: Drug Enforcement Administration.
- DEA. (2015). *Controlled drugs schedules*. Retrieved from Drug Enforcement Administration Website: <http://www.deadiversion.usdoj.gov/schedules/index.html>
- DEA. (2016). *Dispensing of Controlled Substances to Residents at Long Term Care Facilities*. Retrieved from Office of diversion control:
http://www.deadiversion.usdoj.gov/fed_regs/notices/2010/fr06294.htm
- Dessalegn Asmelashe Gelayee, M. K. (2015). Patient Medication Counseling: A Survey of Knowledge, Attitude and Practice of Pharmacy. *Journal of Scientific Research in Pharmacy*, Vol,2 Iss.3 (July-Sept).
- DrugFreeAZ. (2016). *Prescription Drug Misuse and Abuse Initiative*. Retrieved from Arizona Criminal Justice Commission : <http://azcjc.gov/ACJC.Web/Rx/default.aspx>
- El-Sakka, M. (2012). Management of Controlled Substances and Dependences by Pharmacists. *Journal of Clinical & Experimental Pharmacology*.
- EMCDDA. (2011). *The state of drugs problem in European Union*. Luxembourg: Publications Office of the European Union.
- FDA. (2015, Sept 3). *Protecting and promoting your health*. Retrieved Sept 3, 2015, from US Food and Drug Administration :
<http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm>
- FMHACA. (2012). *Manual for medicines good prescribing practice*. Addis Ababa: FMHACA.
- Holdsworth, M. &. (1992). Availability of narcotics and pharmacists' attitudes toward narcotic prescriptions for cancer patients. *The Annals of pharmacotherapy*, 1992 Mar;26(3):321-6.

- INCB. (2010). *Report of the International Narcotics Control Board*. New York : United Nations.
- INCB. (2011). *Report of the International Narcotics Control Board*. New York : United Nations.
- INCB. (2012). *Report of the International Narcotics Control Board*. New York : United Nations.
- INCSR. (2013). *Money Laundering and Financial Crimes*. BINLEA.
- Jaber, D., Bulatova, N., Suyagh, a.M. & Wazaify,M. (2015). Knowledge, Attitude and Opinion of Drug Misuse and Abuse by Pharmacy Students: A Cross-Sectional Study in Jordan. *Tropical Journal of Pharmaceutical Research*, 1501-1508.
- Jennings, J., & Foster, J. (2007). Medication safety: just a label away. *AORN J*; 86: 618-25.
- Joranson, D.E., & Gilson, A.M. (2001). Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *J Am Pharm Assoc*, 41:213–20
- Kagashe, G. M. (2011). An assessment of dispensing practices in private pharmacies in Dar-es-Salaam, Tanzania. *The international journal for pharmacy practice* , 2011 Feb;19(1):30-5.
- Kelly, P. (2016). *Australian Capital Territory*. Canberra: ACT governm
- Fleming, M.L., Barner, J.C., Brown, C.M., Shepherd, M.D., Strassels, S.A. & Novak, S. (2013). Pharmacists' training, perceived roles, and actions associated with dispensing controlled substance prescriptions. *Journal of the Amercan pharmacists association*, 2014; 54:241–250.
- Marshall, C., (1995). *Designing qualitative research (3rd Ed.)*. . California: Sage Publications, Thousands Oaks.
- McCabe, S. K. (2005). Non-medical use of prescription stimulants among US college students: prevalence and correlates from a national survey. *Addiction (Abingdon, Angland)* , 2005 Apr;100(4):573.
- Milani, B. (2011). *The world medicines situation 2011, access to controlled medicines*. Geneva: WHO.
- Miller, P. C. (2015). Miller P1, Curtis A1, Jenkinson R2, Droste N1, Bowe SJ3, Pennay A4. *Addiction (John Wiley & Sons (Journouls))*, , Nov;110(11):1803-10.

- MOH. (2015, 23-June-2015). *list of retail pharmacies*. Retrieved from Republic of Rwanda ministry of health: <http://www.moh.gov.rw/index.php?id=2>
- Nasir, T., & Wabe, N. R. (2011). Knowledge, attitude and practice of patient medication counseling among drug dispensers in North West Ethiopia. *Journal of applied pharmaceutical sciences*.
- Noble, M., Tregear, S.J., Treadwell, J.R. & Schoelles, K. (2008). Long-term opioid therapy for chronic noncancer pain: a systematic review and meta-analysis of efficacy and safety. *Journal of Pain and symptom management*, 2008 Feb;35(2):214-28.
- O'Brien, M. (2014). *To dispense or not to dispense...is that prescription in question?* California.
- PSA. (2010). *Professional practice standards version 4*. Deakin : Pharmaceutical society of australia .
- PSA. (2010). *Professional Practice Standards*. Deakin West: Pharmaceutical Society of Australia.
- Retailing, S. (2016, May 20). *Smart Retailing Rx Insights for Better Pharmacy Health*. Retrieved May 20, 2016, from The Pharmacist's Role in Preventing Prescription Drug Abuse: <http://smartretailingrx.com/regulatory-public-affairs/pharmacists-role-preventing-prescription-drug-abuse/>
- RHC. (2016, April 14). *Narcotic Abuse Overview Risk factors*. Retrieved April 14, 2015, from Remedy's Health.com Communities: <http://www.healthcommunities.com/narcotic-abuse/overview-of-narcotic-abuse.shtml>
- Rosen, L. W. (2015). *International Drug Control Policy: Background and U.S. Responses*. New York: CRS.
- RPS. (2007). *Safer Management of Controlled Drugs*. London: Crown copyright .
- SAPC. (2010). *Good pharmacy practice in south Africa Four edition*. Pretoria: South Africa Pharmacy Council.
- Siler, S., Duda, S., Brown, R., Gbemudu, J., Weier, S. & Glaudemans, J. (2001). *Safe Disposal of Unused Controlled Substances*. King Pharmaceuticals, Inc.
- Tennessee, U. O. (2015, May 1). *Pharmacist checklist for dispensing controlled substances*. Retrieved from University of Tennessee: <http://www.utasip.com/files/articlefiles/pdf/Checklist3.pdf>

- Tommasello, A. C. (2004). Substance abuse and pharmacy practice: what the community pharmacist needs to know about drug abuse and dependence. *Harm reduction journal*, 2004; 1: 3.
- Trial, F. (2016, Feb 23). *List Of Controlled Pharmaceutical Substances In UAE*. Retrieved Feb 23, 2016, from Defending the Human Right to a Fair Trial: <https://www.fairtrials.org/press/list-of-controlled-pharmaceutical-substances-in-uae/>
- UN. (1961). Single convention on narcotic drugs . *United Nations conference* (pp. 1-3). Vienna: UN.
- UN. (1971). Convention on psychotropic substances. *United Nations Conference* (pp. 2-5). Vienna: UN.
- UNODC. (2012). *World Drug Report* . New york: UN.
- UNODC. (2013). *Patterns and Trends of Amphetamine-Type Stimulants and Other Drugs:Challenges for Asia and the Pacific*. VIENNA: UN.
- UNODC. (2014). *World drug report*. Vienna: UN.
- Vacca, C.O.J. (2005). Assessment of risks related to medicine dispensing by nonprofessionals in Colombia: clinical case simulations. *The annals of pharmacotherapy* , 527-32.
- WHO. (2011). *Safety of Medicines in Sub-Saharan Africa*. Geneva: World Health Organization.
- WHO. (2015). *Essential Medicines and Health Products Information Portal*. Retrieved from Guide to Good Prescribing - A Practical Manual: <http://apps.who.int/medicinedocs/en/d/Jwhozip23e/5.4.html>

APPENDICES

Appendix 1: Research questionnaire

Title of Research Project: QUALITY OF CONTROLLED MEDICINES DISPENSING PROCESS AMONG RWANDA COMMUNITY PHARMACIES

We are conducting a study important for professionals working in pharmacies and the public in general. The aim is to collect data related to the quality of controlled medicines dispensing in private pharmacies. Your answers are very important to us. We also argue you to note that all answers will be kept confidential and presented anonymously and scientifically. Thank you for your participation in this study!

Part 1: Demographic data

- 1.1 Research respondent code.....
- 1.2 Age.....
- 1.3 Sex.....
- 1.4 Profession.....
- 1.5 Pharmacy code.....
- 1.6 Pharmacy localization (district)
- 1.7 Experience of the respondent (years).....

Part 2: To assess the general requirements for controlled medicines dispensing among community pharmacies in Rwanda

Questions	Yes	No	Comment
Q2.1 Are you handling controlled medicine in your pharmacy?			
Q 2.2 Which class of controlled medicines do you handle in your pharmacy?	Schedule II CMs		
	Schedule III-IV CMs		
Q 2.3 Does your pharmacy have SOPs for controlled medicines dispensing and handling?			
Q2.4 is the pharmacy having a secured cupboard for CM?			

Q2.5 does the CM cupboard have sufficient capacity to permit the orderly storage of all schedule II & III CM?			
Q2.6 Is the CM cupboard reserved only for the storage of medicines not other items?			
Q2.7 are expired/ patient returned CMs stored in a designated part of the CMs cupboard and appropriately labeled?	Mixed with others & labeled		
	Separated with others but not labeled		
	Separated with others and well labeled		
	Specify other ways you use		

Part 3: To assess CMs prescriptions processing requirements among community pharmacies

Questions		Yes	No	Comment
Q3.1 what do you evaluate on a controlled medicines prescription prior to their dispensing?	Prescription date			
	Prescriber signature			
	Patient' s full names			
	Patient' s address			
	Prescriber' s name			
	Prescriber' s address			
	Prescriber' s registration number			
	Controlled medicine name			
	Controlled medicine strength			
	Medicine dosage form			
	Prescribed quantity			
	Directions for use			
	If others, specify			

Part 4: To evaluate CMs prescriptions dispensing requirements among community pharmacies

Questions		Yes	No	Comment
Q4.1 who are dispensing medicines in your pharmacy?	Pharmacist			
	Nurses			
	Pharmacy account			
	Cleaners			
	Specify any other person if applicable			
Q4.2 Are all dispensers for controlled medicines registered by their professional councils?				
Q4.3 Are the working licenses for all controlled medicines dispensers renewed?	Some do not have renewed licenses			
	All have renewed licenses			
	All do not have renewed licenses			
Q4.4 Who do you accept as a prescriber of controlled medicines in your pharmacy?	Physicians			
	Dentists			
	Psychologist			
	Specify if any other			
Q4.5 which are patient information do you require prior to the dispensing of a controlled medicine?	Patient medication history			
	Patient's full names			
	Patient's address			
	Patient ID No			
	ADRs information			
	Patient's therapy information			
	Appropriately filled information			

	Specify others if applicable			
Q4.6 Are you refilling controlled medicines prescriptions?				
Q4.7 Are you accepting oral refill authorization from the prescriber for refilling controlled medicines prescriptions?				
Q4.8 Do you do the partial dispensing controlled medicines?				
Q4.9 What do you write on a label to be put on the package of CMs?	Cautionary statement			
	Directions for use			
	Name of the prescriber			
	Name of the patient			
	Date of initial dispensing			
	Prescription serial number			
	Pharmacy address			
	Specify other information			
Q4.10 Are you counseling patients on controlled medicine use?				
Q4.11 Which crucial information do you tell patients during the counseling about CMs use?	Medications and food counseling			
	Educate techniques for self-monitoring			
	Tell the patient the refill date			
	Discuss ADRs &			

	possible CM associated risks			
	Explain CM storage conditions			
	Tell the patient CM use directives			
	CMs name & indication provision			
	Specify others if applicable			
Q4.12 which information do you ask the patient after the counseling process?	Ask if there is any additional concerns or questions			
	Ask the patient to repeat key information to check if instructions were understood			
	Do both			
Q4.13 In which case do you refuse to dispense a controlled medicine to the patient?	Suspicion of CM abuse			
	Forged CM prescription			
	Miscommunication with the prescriber			
	Wrongly filled prescription			
	Absence of prescription			
	Specify others if			

	applicable			
	Suspicion of CM abuse			
Q4.14 Do you have recorded information about dispensed controlled medicines?				
Q4.15 what do you use to record CM dispensing process information?	Prescription registration book			
	Computerized recording system			
	Both the computer and registration book			
	Printed sheets			
	Specify another way if applicable (comment box)			
Q4.16 which information from the dispensed prescription do you record?	CM dispenser signature			
	CM stock balance			
	Dispensing date			
	Quantity dispensed			
	Prescriber name & address			
	Date for refill			
	Patient name			
	CM name			
Specify others if applicable				

Q4.17 for how long do you maintain controlled medicines records?			
Q4.18 Are there documents showing that the pharmacist is routinely reviewing and checking the CM stock balance?			
Q4.19 Are there documentations relating to the destruction or disposal of expired CM?			
Q4.20 Do you have archives of dispensed controlled medicines prescriptions?			
Q4.21 where do you report controlled medicines dispensing information?	MOH		
	District pharmacy		
	Specify others if applicable		

Part 5: To evaluate the knowledge of community pharmacy dispensers on controlled medicines and their handling

Questions	Yes	No	Comment
Q5.1 does the respondent know the definition of controlled medicines?			
Q5.2 does the respondent know CMs schedules?			
Q5.3 does the respondent know CMs schedules?			
Q5.4 how many CM related trainings have you attended in your career?			

Appendix 2: Interview guide

Title of Research Project: QUALITY OF CONTROLLED MEDICINES DISPENSING PROCESS AMONG RWANDA COMMUNITY PHARMACIES

We are conducting a study important for professionals working in pharmacies and the public in general. The aim is to collect data related to the quality of controlled medicines dispensing in private pharmacies. Your answers are very important to us. We also argue you to note that all answers will be kept confidential and presented anonymously and scientifically. Thank you for your participation in this study!

1. Which group of medicines do you consider as controlled medicines in your pharmacy?
2. What do you know about controlled medicines schedules and their dispensing?

Appendix 3: Consent form

Title of Research Project: QUALITY OF DISPENSING OF CONTROLLED MEDICINES AMONG COMMUNITY PHARMACIES IN RWANDA

The study has been described to me in language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name.....

Participant's signature.....

Date.....

Witness' name.....

Witness' signature.....

Date.....

Should you have any questions regarding this study or wish to report any problems you have experienced related to the study, please contact the study coordinator: Study Coordinator's Name: Dr Emile BIENVENU.

University of Rwanda

Department of pharmacy

Msc pharmaceutical sciences and quality control

Tel: +250783020584

Email: desirerugamba@gmail.com

Appendix 4: Letter for data collection request



COLLEGE OF MEDICINE AND HEALTH SCIENCES

School of Medicine and Pharmacy

Huye, 09th December 2015

To: Responsible Pharmacist
PHARMACY


Dear Pharmacist,

Re: Recommendation for Data collection

Within the frame of collaboration between your Pharmacy 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, **Desire RUGAMBA**, to collect data in your pharmacy. According to Masters of Pharmaceutical Sciences Quality Assurance and Quality Control program, he has to perform a research project in final year. His project is entitled "Quality of controlled medicines dispensing in Rwanda. Case of private pharmacies" supervised by Dr. Emile BIENVENU. Attached is a list of pharmacies from which data will be collected.

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

Yours faithfully,


Prof. Pierre Claver **KAYUMBA**
Deputy Dean
School of Medicine and Pharmacy
pc.kayumba@ur.ac.rw
Tel: +250788309768



Appendix 5: Number of pharmacies that each district/province contributed to the sample

Province	District	Total number of pharmacies	Number of pharmacies considered per district	Number & percentage of pharmacies considered per district
Eastern	Nyagatare	2	1	10 (6.7%)
	Gatsibo	1	1	
	Kayonza	3	2	
	Ngoma	3	2	
	Kirehe	2	1	
	Rwamagana	3	2	
	Bugesera	1	1	
Kigali city	Kicukiro	35	22	97 (64.7%)
	Gasabo	67	41	
	Nyarugenge	55	34	
Southern	Kamonyi	1	1	21 (14%)
	Muhanga	7	4	
	Ruhango	7	4	
	Nyanza	3	2	
	Huye	12	7	
	Gisagara	0	0	
	Nyaruguru	2	1	
	Nyamagabe	3	2	
Northern	Rulindo	0	0	10 (6.7%)
	Gakenke	1	1	
	Gicumbi	3	2	
	Musaze	11	7	
Western	Rubavu	13	8	13 (8.7%)
	Nyabihu	0	0	
	Ngororero	0	0	
	Rutsiro	0	0	
	Karongi	3	2	
	Nyamasheke	2	1	
	Rusizi	4	2	
Total	30	245	150	150 (100%)