DETERMINANTS OF NON-ADHERENCE TO PRESCRIPTIONS

FOR DISPENSING ANTIBIOTICS AMONG PHARMACY

WORKERS IN DAR ES SALAAM REGION

By

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A Dissertation in partial Fulfilment of the Requirement for
the Degree of Master of Public Health of
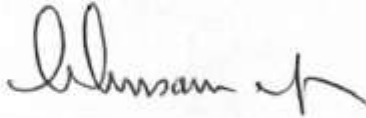Muhimbili University of Health and Allied Sciences

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November, 2009

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance a dissertation entitled *"Determinants of Non-adherence to prescriptions for dispensing antibiotics among pharmacy workers in Dar es Salaam Region"* Submitted in partial fulfilment of the requirements for the Degree of Master of Public Health of the Muhimbili University of Health and Allied Sciences.

Signature _____

Professor G.I. Msamanga MD, DPH (Dar), MSc, DSc (Harvard)

(Supervisor)

Date: _____13 . 11 . 09_____

DECLARATION AND COPYRIGHT

I, **Jason Blasius Makanzo,** declare solemnly that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature _____

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DEDICATION

The enthusiasm for knowledge has to be cultivated. It had not always been possible for me to cultivate this thirst for knowledge on my own. I owe much of this to my beloved parents who laid down the basic education foundation onto which attainment of this education level stands. It's upon this background that I dedicate this work to my mother Gaudencia Kokunura and to my late father Anselmi Blasius .

ABSTRACT

In Tanzania, health care reforms and privatization have increased the availability of drugs for lay people through private pharmacies. The private provision of drugs has been shown to be associated with irrational use of substandard drugs quality and non compliance to drug regulations. However, there is limited information regarding adherence to prescription requirements among pharmacy workers in Dar es Salaam region. The aim of the study was to determine factors influencing prescription adherence among pharmacy workers in Dar es Salaam region.

A cross sectional study was conducted in July 2009 among 165 pharmacy workers in Dar es Salaam region. Questionnaires were administered to assess pharmacy worker's knowledge about Prescription only Medicine (PoM) also to find out how they would manage a client requesting antibiotics without a prescription. A simulated client method was administered in order to measure the pharmacy worker's behaviour. Of the 165 respondents interviewed, 87.9% were females and 57% were in the age group of 20-29 years. In this study, we also had a total of 62 encounters as simulated clients among whom 72.6% were handled by female pharmacy workers.

During interview, 92.7% of pharmacy workers reported that they would request for a prescription before dispensing any antibiotics. However, in 62 simulations of a patient with diarrhea at home 87.1% (54/62) pharmacy workers did not ask for a prescription.

Although among the 54 simulations a prescription was not requested, 88.9% of the pharmacy workers agreed to dispense antibiotics. In response to the question "What is the major factor that influences a pharmacy worker to dispense antibiotics without a prescription? The major factor reported by more than a half (53%) of pharmacy workers was client demand.

The study recommends that the community should be sensitized and warned on the consequences of self administration of Prescription only Medicine (PoM) and pharmacy workers are strongly urged to perform their responsibility more competently and ethically.

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LIST OF ACRONYMS

FIP	Federation International Pharmaceuticals
GOT	Government of Tanzania
GPP	Good Pharmacy Practice
HCW	Health care Worker
MSD	Medical Stores Department
MDG	Millennium Development Goals
MOHSW	Ministry of Health and Social Welfare
NSGRP	National Strategy for Growth and Reduction of Poverty
OTC	Over the Counter
PoM	Prescription only Medicine
PHDR	Poverty and Human Development Report
SCM	Simulated Client Method
TFDA	Tanzania Food and Drug Authority
URT	United Republic of Tanzania
WHO	World Health Organization

CHAPTER ONE

1.0   BACKGROUND

In many low income countries health care reforms and privatization has increased the availability of drugs for lay people through private pharmacies (Larsson et al., 2003). The private provision of drugs has been shown to be associated with irrational use of substandard drugs quality and non compliance to drug regulations.

Although regulations commonly exist, the regulatory authorities lack resource for effective implementation and enforcement hence limiting their ability to influence private sector activities. In many low income countries, there is no national policy on use of antibiotics leading to irrational use of antibiotics. Very limited work has been done to assess compliance with regulations as well exploring how and to what extent the regulation fails. In Tanzania, a prescription and drug dispensing regulation has been in place since 1978 for part I and part II drugs. Under the act, all part I drugs should be dispensed with a prescription from a registered practitioner (Pharmaceutical and Poison act No 9. of 1978).

Several studies in developing countries have found that some pharmacies dispense prescription only drugs such as antibiotics often without any questions (Lekashingo, 2003; Hossain, 1982; Nyazema et al., 2007; Mayhew et al., 2001); hence the ability of the pharmacy staff to deal with drug requests is very important.

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Antibiotics are an important group of drugs mainly used to treat infections caused by bacteria. However, if they are improperly used they can cause drug resistance in some individuals. Due to that reason many countries including Tanzania have chosen to restrict the availability of antibiotics through prescriptions.

1.1 STATEMENT OF THE PROBLEM

Over many decades, antibiotics have been used and they are still being used to treat infectious diseases caused by some bacteria. These diseases affect a larger part of the world population particularly those from the tropical countries. The evolution of antibiotics in mid of 1930's was a great success in medical industries since antibiotics are the most suitable drugs to kill many microbes which cause diseases.

Besides, there being numerous advantages of antibiotics in fighting diseases, if they are misused in terms of over or under used they can result in very serious consequences including development of drug résistance. One of reasons that contribute to antibiotic resistance is non adherence to prescriptions. Prescriptions only medicine (PoM) include dispensing of antibiotics in pharmacies and other drug outlets. The Tanzania Food, Drugs and Cosmetics act 2003 (TFDA Act of 2003, section 74 sub sections (1) and (2) stipulates that no personnel shall sell by retail, or supply in circumstances corresponding to retail sale or administer other than to himself a drug product of PoM except in accordance with a prescription given to him by an authorized practitioner.

However, in developing countries many studies and reports have shown that patients can get drugs from different sources without having a prescription (Lekashingo, 2003; Hossain, 1982; Nyazema et al., 2007; Mayhew et al., 2001). A study in Kibaha showed that 38% of antibiotics are dispensed without a prescription from a registered practitioner (Nsimba et al., 2007). Another study in Vietinam reported that 78% of the antibiotics were obtained without consulting a doctor (Larsson et al., 2003). Such a practice violates the TFDA Act No. 1 of 2003. Further more, the practices have negative consequences in over/under dose and the therapeutic effects can endanger a patients' life and encourage the development of drug resistance.

Therefore the aim of this study is to identify the factors contributing to the pharmacy workers non- adherence of prescriptions for antibiotics dispensing in Dar es Salaam in order to suggest measures to minimize this behaviour which lead to the consequences of antibiotics resistance.

1.2 RATIONALE FOR THE STUDY

To attain sufficient therapeutic effects, drugs must be used as recommended by experts including the manufacturers, physicians and pharmacists. Misuse of drugs especially antibiotics has been the main cause of drug resistance (Ibezim, 2005). In Tanzania, all antibiotics should be dispensed by authorised personnel and to patients with a prescription from a licensed practitioner (TFDA Act, 2003). However, there is limited information regarding non-adherence to prescription requirements among drug sellers in Dar es Salaam.

Similarly, the extent to which the regulations which prohibit selling of prescription drugs are violated is not well documented.

The findings of this study will give information on the level of adherence to regulations to prescription requirements to pharmacy workers. This will help drug authorities in devising measures to improve adherence to different drugs regulations in Dar es Salaam

1.3   RESEARCH QUESTIONS

(1)To what extent pharmaceutical workers adhere to prescriptions requirements for dispensing antibiotic drugs?

(2)What are the reasons for non-adherence to prescription requirements in dispensing antibiotics?

1.4 OPERATIONAL DEFINITION

Adherence to prescription in this study refers to the dispensation of antibiotics strictly to client/patient with prescription from authorized practitioner.

Prescription only medicine (PoM) is licensed medicine that is regulated by legislation to require a prescription before it can be obtained.

Over The Counter (OTC) .this refer to all drugs that can be obtained without prescription.

Drug resistance is the inability of drug to bring about an effect on disease causing agent that occurred previously in the presence of the same medication or is the ability of microorganism to with stand the effect of antibiotic.

Self medication is the selection and use of medicine by individuals to treat self recognized illnesses.

Antibiotics are drugs that either destroy bacterial or prevent their reproduction that is bactericidal and bacteriostatic respectively.

Pharmacy workers, these refer to the people who dispense drugs from the pharmacies. And also is used interchangeably with drug seller, dispensers, pharmacy staff and providers.

1.5 CONCEPTUAL FRAMEWORK
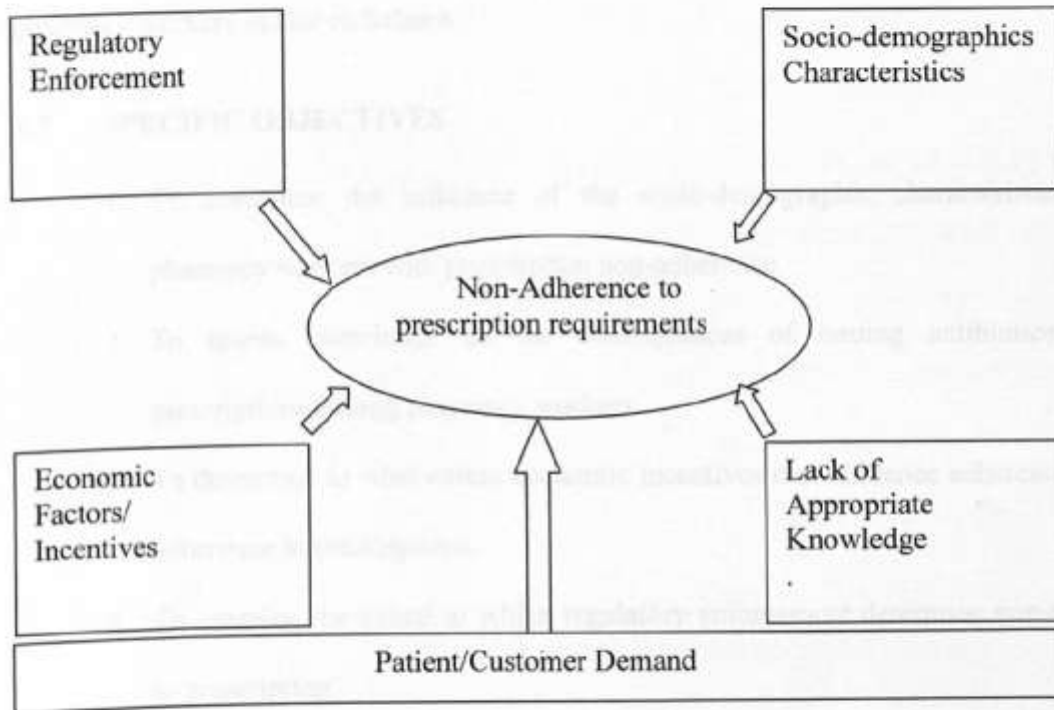
Source: Modified from Radyowijati and Haak 2003.

1.6 BROAD OBJECTIVE

To assess the determinants of non-adherence to prescriptions for dispensing antibiotics among pharmacy workers in Dar es Salaam.

1.7 SPECIFIC OBJECTIVES

1. To determine the influence of the socio-demographic characteristics of the pharmacy workers with prescription non-adherence.

2. To assess knowledge on the consequences of issuing antibiotics without prescriptions among pharmacy workers.

3. To determine to what extent economic incentives can influence adherence or non-adherence to prescriptions.

4. To examine the extent to which regulatory enforcement determine non-adherence to prescription.

CHAPTER TWO

2.0   LITERATURE REVIEW

Tanzania is committed to provide quality of health care to approximately 40 million people as one of the strategies for poverty reduction (MOH& SW National Health Policy, 2007). The National Strategy for Growth and Reduction of Poverty (NSGRP) cluster number 2 states that "The Government of Tanzania (GOT) is committed to improve the quality of life and social well being of all Tanzania' and goal number 2 of the same cluster states "To improve survival, health and well being of all children and women and especial vulnerable groups ,this commitment is in line with Millennium Development Goals (MDG's) 2000 Goal number 4 and 5 which states to reduce infant mortality and to improve maternal health, respectively (PHDR, 2007).

In order to accomplish the goals and targets of NSGRP and MDG the GOT has conducted and still conducting various training programs involving health care workers so as to equip them with knowledge that will enable them to render quality health care. Pharmaceutical personnel being among the health care workers they are obliged to comply with the various regulations regarding the provision of prescriptions only medicines including antibiotics. Organisms that are normally sensitive to the action of an antibiotic may sometimes develop resistance. This, they may be a destruction of the antibiotics or by retaining their growth even in the presence of the drug. Microbial resistance to antibiotics is now widespread and this poses a serious clinical threat.

Microbial resistance can either be inherent in the organism or acquired through the environment. Factors that have led to the continued occurrence of bacterial resistance to antimicrobial agents include: over prescription of antibiotics, use of under dose, by prescribers, irrational attitudes, patient demand, inappropriate advertisements and non-adherence to the prescription requirements by some of the pharmacy workers. Microbial resistance can thus be minimized through proper training on more rational antibiotic selection during treatment and proper dispensing through adherence to prescription requirements.

Misuse of antibiotics

Inappropriate use of antibiotics has often been identified as a problem in effective health care delivery. High levels of antibiotics use, often clinically unnecessary, have led to a steady increase in drug resistance. Low-income countries are thought to have an important role in this phenomenon. Effective intervention in these practices is often difficult because of the paucity of information on determinants of antibiotic use (Radyowijati and Haak, 2003).

Antibiotics are very important drugs, but if they are over-prescribed or over used in self medication for the treatment of minor disorders they can lead to microbial resistance (Hardon et al., 2004).When antibiotics are used too often in sub- optimal dosages, some of the bacteria may become resistant to them. The result is treatment failure when a patient who is suffering from a serious disease takes some antibiotics. This is of great concern to public health policy-makers. People buy sub-optimal dosages either because they cannot afford a full dose, or because they are not aware of the need to complete their antibiotics course.

According to the Good Pharmacy Practices (GPP) guidelines developed by the Federation International Pharmaceutical (FIP) and endorsed by the World Health Organization (WHO), every pharmacist is obliged to ensure that he/she provides an appropriate quality of service to every patient including the provision of proper information and advice (GPP India, 2005). However, private practice has repeatedly been reported to be of low quality partly because of the lack of regulatory enforcement (Nyazema et al., 2007).

The sale of prescription only medicines without a prescription is an important regulatory issue. Antibiotics which are often prescription only medicines can typically be purchased from a variety of drug outlets without prescription (Bartoloni et al., 1998; Nyazema et al., 2007).

The wide spread availability of antibiotics has raised concerns about the problem of increased use and antibiotics resistance, however it makes antibiotics more available to poor people who may not be able easily to access physicians.

The roles of the pharmaceutical personnel are to dispense drugs to a client who has a prescription form from a medical practitioner also to give advice to client on how to take medication and what are the potential adverse effects to anticipate (Chamba et al,. 1999). Therefore the pharmaceutical personnel play an important role in ensuring the reduction of drug related morbidity (Young et al., 1999).

Besides the obligations of pharmaceutical personnel in ensuring good provision of health care very few do practice according to the required standard. There few case studies of pharmaceutical practices in low income countries particularly in the Anglophone countries

(Mayhew et al., 2001).In many countries people can purchase drugs over the counter (OTC) that should legally be sold only on prescription (Cheltey et al., 2007).

Lansang et al., (1990) and Lansang et al., (1991) highlighted some of the problems with antibiotics in the Philippines. In urban settings, 66% of antibiotic- purchases were issued to the clients without prescriptions while in the rural areas 57% of antibiotics were purchased without prescriptions. These findings indicate widespread sub-optimal use of antibiotics self-medications.

Obtaining antibiotics without a prescription is a common phenomenon in developing world. Studies done in Vietnam showed that 78% of the antibiotics obtained without consulting a doctor and 80% of the antibiotics were obtained from private pharmacies (Larsson et al., 2003).

Another study conducted in Brazil by Volpato et al., (2006) the authors observed that out of 107 pharmacies visited by a simulated client, the pharmacy workers offered antibiotics without asking for a prescription. The results showed also that still yet there is an inappropriate use of antibiotics for treatment infections, and this has implications on the cost of treatment and development of resistant strains.

Although evidence is limited, there are some studies that suggest that reducing antibiotics usage may reduce resistance. Studies done in Finland and Iceland showed the disappearance of antibiotics resistance when uses of antimicrobial agents were lessened (Planta, 2007).

Therefore restricting over the counter dispensation of antimicrobial agents without a prescription will eliminate a larger source of antibiotics usage in view of the fact that studies indicate that more than 50% of antibiotics dispensed in developing countries are done without prescription (Planta, 2007).A Study conducted in Bangladesh in Rajbari district showed that more than 91% of antibiotics are dispensed without a prescription (Haart & Kariuki, 1998).

A review of available literatures on non- adherence to prescriptions for antibiotics dispensing among pharmacy workers and the associated problems have a long term implication for drug resistance. This suggests that an effort should be made to understand the magnitude of the problem and identify the way to advice the law enforcement authorities. The study therefore seeks to identify factors contributing to non-adherence to prescription requirements. The following chapter presents the methodology that will be used to answer the research questions.

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CHAPTER THREE

3.0   METHODOLOGY.

3.1   Study area

The study was conducted in Dar es Salaam region. The region was chosen because it is the largest city in Tanzania with many retail pharmacies situated in both urban and peri urban areas. The pharmacy workers in Dar es Salaam appear to interact with the larger urban community and this behaviour may play a role in their dispensation of antibiotics. The region is situated on the east coast of Tanzania. It is bordered by the Indian Ocean to the East and on all other sides by the coast region. Dar es Salaam is at sea level, the climate is hot and humid throughout the year, and the temperature ranges between 26 to 35° C.

The region has two rainy seasons, short rains from November to December and long rains in March to May. The population census, 2002, it has a total population of 2,497,940 of which 1,236,864 are females (National Bureau of Statistics, 2003). Dar es Salaam has three municipalities namely Ilala, Kinondoni and Temeke. According to the TFDA, the region has 208 private owned retail pharmacies of which 104, 80 and 24 pharmacies are located in Ilala, Kinondoni and Temeke Municipals respectively.

3.2   Study design

A cross sectional study was conducted from June to mid July 2009 The objective of the study was to assess the determinants of non-adherence to prescriptions for antibiotics dispensing among pharmacy worker in Dar es Salaam.

The study also intended to investigate self reported practice and actual practice of private pharmacy workers in relation to drugs regulations in provision of antibiotics. A quantitative technique using semi-structured questionnaire having both open and closed ended questions were used together with a Simulated Client Method (SCM).

(i) Questionnaire

Interviews of the pharmacy staff at selected pharmacies were conducted using semi structured questionnaire having both open and closed ended questions regarding dispensing of prescription-only medicine including antibiotics. Interviews focused on getting the respondent to state how they would manage a client requesting antibiotics without having prescription and other related drugs management.

(ii) The Simulated Client method (SCM)

This used to measure the provider's behaviour. Research assistants with fictitious case scenarios visited a selected pharmacy and request for their assistance. In this methodology the simulated client presented specific complaints to pharmacy staff and purchase the drugs recommend.

3.3   The Study population

The study population involved workers in private retail pharmacies including Pharmacists, Pharmaceutical Technicians, Pharmaceutical Assistants, Clinical Officers (CO),Assistant

Medical Officer (AMO), Medical officer (MO), Nurses, Nursing Assistants and others who do

not have any profession but they sometimes engage themselves in drug dispensing.

Inclusion criteria

- Pharmacy staff aged 18 years and above.
- Those who grant consent.

Exclusion criteria

- Failure to grant consent.
- Pharmacy staff age below 18 year of age.

3.4   Sample size estimation

a) Number of pharmacy workers

The minimum sample size for the study was determined from the formula:

$$n= \frac{z^2 P (100-p)}{E^2}$$

Where n= the desired sample size

P = Expected proportion of the pharmacy workers adhering to prescription regulations is 38%

(Nsimba et al., 2007).

E= 8%, margin of error

z = standard deviation usually set at 1.96 which corresponds to 95% confidence

interval

$$n = \frac{1.96^2 \times 0.62 \, (1-0.62)}{0.08^2} = 148.3$$

Therefore, the required minimum sample size of respondents was 148.

By adding 10% of anticipated non respondents, the sample size was 163

Therefore a total of 163 respondents were involved in order to cater for missing and other unexpected problems during data collection.

b) Number of retail pharmacies

For studies based on health facilities, (Kielman et al., 1995) recommended a sample which should include 25-30 % of all health facilities. Thus out of 208 operating facilities in the Dar es Salaam city 60 retail pharmacies was selected to cater for the required sample size.

3.5 Sampling procedures

a) Selection of health facilities

(50) Private pharmacies were selected by simple random sampling. From the following municipalities, Ilala 40, Kinondoni, 15 and Temeke, 5 pharmacies. respectively. This calculation was based on the ratio of private pharmacies available at each municipality which is 4:3:1.

b) Selection of Pharmacy Workers

All pharmacy workers from selected retail pharmacies participated in the studying order to cater for the required sample size.

3.6   Data collection techniques

a) Recruitment and training

One day training to the research assistants was conducted on the following: Objective of the study, overview data collection process, selection criteria, recruiting, obtaining consent, interview skills, using the instrument, understanding questions, elaborating why and how it is asked, how responses are recorded, and assuring confidentiality.

b)   Data collection tool and techniques

i) Semi structured questionnaire with both open and close ended questions were used to interview the eligible and available personnel at the selected pharmacies. Questions were written in English; afterward translated in to Kiswahili language prior so as to ensure that the questions are clear and easily understood by the participants. The questionnaire has four sections-:

Knowledge, Socio- demographic characteristics, economic incentives and Regulatory enforcement.

Knowledge on prescription only medicine

This section asked questions that tried to measure the knowledge of pharmacy workers and its association on non-adherence to prescriptions

Socio- demographic characteristics

This section generated socio-demographic factors that influence poor adherence to prescriptions. The variables involved were: age (in years), sex, cadre, level of education, and working experience.

Economic incentives

This section generated economic incentives influenced by pharmaceutical companies in dispensing antibiotics. Also determined what criteria the pharmacy workers use in dispensing a new product of antibiotics. The variables involved were: Availability of new brands, and influence of pharmaceutical companies

Regulatory enforcement

This section generated information on how regulatory enforcement influences adherence to prescription regulations. Variables were: performance, Monitoring procedures and linkage with other stakeholders.

. ii)   Simulated Client Method (SCM) was used to access actual practices and behavior of the pharmacy workers regarding the provision of antibiotics. Research assistants with a fictitious case scenario of a child with acute diarrhea at home visited some of the selected pharmacies and request assistance. SCM has frequently been used to assess practice in both low and high income countries (Madden et al., 1997; Bartolini et al., 1998). A specific record sheet for simulated clients containing information regarding the drug, questions and advice were developed. The simulated client filled the sheet not more than 15 minutes after leaving a particular pharmacy in order to minimize a recall bias.

The SCM primarily is meant to describe the actual practices in the prescription request, the types of instructions and information that were provided on dispensing drugs.

Simulated Client Method as practical and consistent way to measure actual practices has become increasingly common throughout the world (Chuc, 2002).

c) Data collection procedure

The data were collected by three research assistants. Prior to the field the research assistants were trained for three days. During training were explained what the study is all about and the purpose of the study. The participants of the study were asked to give verbal consent before being interviewed. The responses were recorded on a questionnaire.

d) Pre testing

Prior commencing the study the questionnaire were pre tested in few selected pharmacies in Dar es Salaam. The aim of the pilot was to check if the questionnaire were well understood, and whether the sequence of the questions was logical.

3.7   Data management and analysis

Data were collected from June to mid July under the supervision of the principle investigator. The questionnaires were collected every day to monitor the coverage and to minimize errors in data collection. Manual data cleaning was done to check accuracy and completeness of the questionnaires. Open ended questions were coded and categorised before data entry. Data entry was done using EPI DATA. The data was analysed using the EPI INFO software

(Version 6.0). A categorical data were analysed using chi-square and Fisher's exact test and continuous data were analysed using Student t-test.

Dependent and independent variable.

Dependent variable.

- Adherence to prescriptions.

Independent variables.

- Socio- demographic characteristics.
- Economics incentives.
- Regulatory enforcement.
- Lack of knowledge.
- Client demand.

3.8   Ethical considerations

Ethical approval was obtained from the Research and Publication Directorate of the Muhimbili University of Health and Allied Sciences. Thereafter permission to conduct the study was obtained from TFDA, .All the in-charges of pharmacies in Dar es Salaam were asked to provide permission to conduct the study in their pharmacies.

The pharmacy workers were asked to provide a verbal consent after the purpose of the study has been explained. They were told that their names would not be used and the information they volunteer to the interviewer will only assist us to improve adherence to prescription for

antibiotic dispensing. Those not wished to participate were allowed to withdraw from the study.

3.9 Study limitation

In some instances pharmacy workers and the owners of the pharmacies were showing a cold cooperation when a researcher present to the them a permission letter from TFDA as they lost trust thinking that we were inspectors, with assured confidentiality and clear aim of the study we managed to interview them. In simulated client method as anticipated, recall bias was a limit. Whenever a client had doubt on a particular response, initiatives were to go to another pharmacy with emphasis being attentive to what a pharmacy workers responded and then complete the form immediately after leaving the pharmacy.

Since Antibiotics drugs are expensive, some pharmacy worker were hesitating to give all instruction whenever they realized that a simulated client was not going pay for the drug, however they turned to be cooperative when the simulated client assured the that he would definitely come back to buy the drugs.

CHAPTER FOUR

4.0   RESULTS

Socio-demographic characteristics of the study population

A total of 62 pharmacies (30%) out of 208 operating registered retail pharmacies in Dar es Salaam were covered. Fifty percent of the pharmacies (31) were located in Ilala municipality while (23) 37.1% were from Kinondoni and 12.9% (8) were from Temeke municipalities. Among the 62 pharmacies, a total of 165 respondents were interviewed. Of the 165 pharmacy workers, 87.9% (145) were females. The median age was 28 years and 57% (94) were in the age group of 20-29 years. Three quarters of the pharmacy workers were nurses and 50.9% had attained ordinary level secondary education (form four leavers). Fourty four percents of the respondents had six or more years of working experience. **(Table 1)**.

Table 1. Socio-demographic characteristics of the study population (n=165).

Characteristics	Number	%
Municipalities		
Ilala	31	50.0
Kinondoni	23	37.1
Temeke	8	12.9
Sex		
Male	20	12.1
Female	145	87.9
Age group (years)		
20-29	94	57.0
30-39	52	31.5
40-49	15	9.1
50-59	4	2.4
Cadre		
Pharmacist	14	8.5
Clinical Officer	8	4.8
Nursing Officer	13	7.9
Nurse Assistant	111	67.3
Pharmaceutical Technician.	5	3.0
Pharmaceutical Assistant.	12	7.3
Others	2	1.2
Education level		
Primary	15	9.1
Secondary	81	50.9
College	55	33.3
University	14	6.7
Working experience (years)		
< 1	7	4.2
1 – 2	18	10.9
3 – 5	68	41.2
≥ 6	72	43.6

Influence of the socio-demographic characteristics of the pharmacy workers and prescription adherence.

(Table 2) presents the influence the socio-demographic characteristics of the pharmacy workers and their adherence to prescription regulations. Overall, the findings showed that the level of education of the pharmacy workers was significantly associated with prescription non-adherence (P=0.00).

Table 2. Association of socio-demographic characteristics with prescription

Characteristics	Prescription requests						Total
	Yes		No		Sometimes		
	No	%	N	%	No	%	
Age in (years)							
20-29	70	(75.3)	1	(1.1)	22	(23.7)	93
30-39	43	(82.7)	1	(1.9)	8	(15.4)	52
40-49	15	(100.0)	0	(0.0)	0	(0.0)	15
50-59	4	(100.0)	0	(0.0)	0	(0.0)	4
Total	**132**	**(80.5)**	**2**	**(1.2)**	**30**	**(18.3)**	**164 (100%)**
Gender							
Male	19	(95.0)	0	(0.0)	1	(5.0)	20
Female	113	(78.5)	2	(1.4)	29	(20.1)	144
Total	**132**	**(80.5%)**	**2**	**(1.2)**	**30**	**(18.3)**	**164 (100%)**
Cadre							
Pharmacist	13	(92.9)	0	(0.0)	1	(7.1)	14
Clinical Officer	7	(87.5)	0	(0.0)	1	(12.5)	8
Nurse Officer	12	(92.3)	0	(0.0)	1	(7.7)	13
Nurse Assistant	85	(76.6)	1	(1.8)	24	(21.6)	111
Pharm Technician	5	(100.0)	0	(0.0)	0	(0.0)	5
Pharm assistant	9	(81.8)	0	(0.0)	2	(18.2)	11
Others	1	(50.0)	0	(0.0)	1	(50.0)	2
Total	**132**	**(80.5)**	**2**	**(1.2)**	**30**	**(18.3)**	**164 (100%)**
Education level*							
Primary	12	(80.0)	1	(6.7)	2	(13.3)	15
Secondary	71	(86.9)	1	(1.2)	10	(11.9)	81
College	36	(66.7)	0	(0.0)	18	(33.3)	54
University	13	(100.0)	0	(0.0)	0	(0.0)	14
Total	**132**	**(80.5)**	**2**	**(1.2)**	**30**	**(18.3)**	**164 (100%)**
Working experience (Years)							
< 1	6	(85.7)	0	(0.0)	1	(14.3)	7
1-2	14	(77.8)	0	(0.0)	4	(22.2)	18
3-5	52	(77.6)	0	(0.0)	15	(22.4)	67
≥ 6	60	(83.3)	2	(2.8)	10	(13.9)	72
Total	**132**	**(80.5)**	**2 (1.2)**		**30 (18.3)**		**164 (100%)**

*(P value =0.00)

Pharmacy worker's knowledge and practices on issuing antibiotics.

During interview, pharmacy workers were asked if they knew what a prescription only medicine (PoM) is and 157 (95.2%) said they were aware of it. When they were further probed, it was revealed that that only 6.4% stated part I and Part II poisons while others Instead, they mentioned different types of PoM such as antibiotics, antimalarials, antidiabetics, antidepressants and other drugs to refer to what they thought PoM meant (**Table 3**).

Table 3. Assessment of whether the pharmacy workers had a knowledge of Prescription only Medicine (PoM).

Types of explanations given as the meaning of PoM	Number	%
Mentioned types of PoM	134	85.4
Mentioned only part I and Part II poisons	10	6.4
Mentioned different side effects of antibiotics	1	0.6
Did not know the answer	12	7.6
Total	157	100.0

Almost all respondents except one, 164 (99.4%) explained the meaning of antibiotics However, when asked to classify the different types of antibiotics into their classes, only one (0.6 %) respondent was able to provide a correct response.

The pharmacy workers were asked to mention what criteria they use to decide whether or not to issue antibiotics to their potential patients/clients. The majority, 152 (92.7%) said they would dispense antibiotic only with prescriptions while 13(7.3%) mentioned they sometimes dispense antibiotics without asking for a prescription

152 respondents were asked to give reasons for demanding a prescription, the commonest reason given by more than half of pharmacy workers 70.4% was that, they feared of adverse effects that might occur to patients, followed by 29.6% who said they ask for a prescription in order to obey the regulations.

The knowledge on side effects of antibiotics is vital as far as management of bacterial infections is concerned. In response to the question "could you mention some of the commonest side effect from antibiotics? 149 pharmacy workers 90.9% were able to mention some of the side effects. The commonest side effect mentioned was gastrointestinal disturbances 89(60%), followed by rashes 28(18%) and dizziness 21(14%) and others 11(7%) (**Table 4**).

Table 4: Percentage distribution of the mentioned side effects by pharmacy workers

Mentioned side effect of antibiotics	Frequency	%
Gastrointestinal disturbance	89	59.7
Rashes	28	18.8
Dizziness	21	14.1
Others	11	7.4
Total	**149**	**100**

Pharmacy workers practice assessed with Simulated Client Method (SCM)

A total of sixty two (62) Pharmacies were visited. A specific recording sheet for simulated clients containing information regarding the drugs or questions and advice given by the pharmacy workers was filled by a research assistant immediately after leaving the pharmacy. Of the 62 encounters 8 (12.9%) requested for a prescription when the research assistants asked for drugs to treat a child at home and 87.1% (54) did not ask for a prescription upon dispensing an antibiotics. A among pharmacy workers who did not ask for prescription 88.9% still yet agreed to dispense antibiotics without a prescription (**Table 5**).

Table 5. Types of information sought from interviewer during Simulated Client Method

Expected information That provider was Supposed to	Yes Number	(%)	No Number	(%)	Total
Requested prescription	8	(12.9)	54	(87.1)	62
Asked about age	58	(93.5)	4	(6.5)	62
Asked about vomiting	7	(11.3)	55	(88.7)	62
Asked about weight	2	(3.2)	60	(96.8)	62
If patient were taken to the health facility	22	(35.5)	40	(64.5)	62
Asked if drug had been taken before	17	(27.4)	45	(72.6)	62
Stool bloody or ricey	33	(53.2)	29	(46.8)	62
Agreed to dispense	50	(80.6)	12	(19.4)	62

Of 62 simulated client (54) 87.1% did not request for prescription. Among those who did not request for prescription 88.9% agreed to dispense antibiotics (**Table 6**).

Table 6: Association between prescription request and antibiotics dispensed during simulation

Prescription Request	Agreed to dispense					
	Yes		No		Total	
	N	(%)	N	(%)	N	(%)
Yes	2	(25.0)	6	(75.0)	8	(100.0)
No	48	(88.9)	6	(11.1)	54	(100.0)
Total	50		12		62	

Figure 1. Show that the commonest antibiotic that was dispensed was Cotrimoxazole followed by Metronidazole, 46.3% and 31.7%, respectively.

Figure 1: Types of antibiotics which were dispensed by pharmacy workers during SCM.
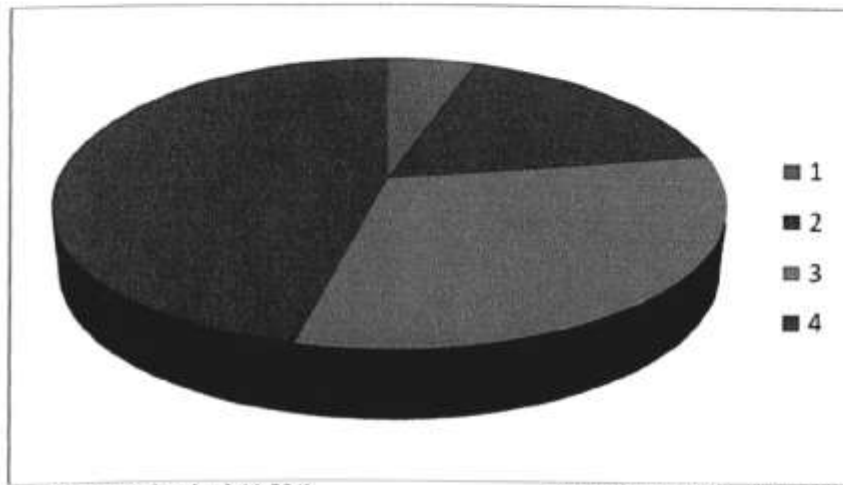
1= Chloramphenicol (4.9%)   2=Erythromycin (17.1%)

3= Metronidazole   (31.7%)   4= Cotrimoxazole (46.3%)

Role of economic incentives in influencing adherence or non-adherence to prescriptions.

When pharmacy workers were asked about the way they used to sell a drug which is not known to a patient/client, majority of them (67.1%) reported that they regularly encourage a client/patient to purchase such drugs

When asked how to handle patients with insufficient money, majority of the respondents (69.5%) reported that they typically sell the drug quantity that is equivalent to amount of money the client/ patient has tendered **(Table 7).**

Table 7. Action that pharmacy workers take when client is unable to pay for full dose of a drug

Action the pharmacy workers takes	Number	%
Send back for money to get a full dose	22	13.4
Advice for a cheaper substitute	28	17.1
Sell the drugs that are equivalent to money they have tendered	114	69.5
Total	164	100.0

The extent to which regulatory enforcement determines adherence to prescription.

We examined to what extent do regulatory enforcement determines adherence to prescriptions regulations. Pharmacy workers were asked if they knew the existence of a regulatory body in the country Of 164 respondents,(92%) mentioned they were aware of the existence of a regulatory body in the country.

However, when asked to mention the name of that regulatory body 135 (90%) pharmacy workers managed to give the correct answer and 15 (10%) could not mention it (**Table 8**).

Table 8. Percentage distribution of pharmacy worker who named regulatory body

Mentioned Drug regulatory Authority	No	%
TFDA	135	90.0
MSD	10	6.7
MOI	2	1.3
Others*	3	2.0
Total	**150**	**100.0**

TFDA: Tanzania Food and drugs Authority; MSD: Medical Store department

MOI: Muhimbili Orthopaedic Institute; Others include pharmacist, health officer.

For those who were aware of the regulatory body, 74 (54.9%) stated that its performance is generally satisfactory while the rest alleged that it was not satisfactory (**Table 9**).

Table 9: Opinion on the general performance of Tanzania Food and Drug Authority.

Opinions	No	%
Satisfactory	74	54.9
Not satisfactory	49	36.3
I don't know	12	8.9
Total	**135**	**100.0**

For those who mentioned that the performance of the regulatory body was not satisfactory, the reasons given by majority of them 35 (72.1%) included issues such as lack of lack of human resources (**Table 10**).

Table 10. Reasons given for underperformance of Tanzania Food and Drug Authority.

Reasons for underperformance	Number	%
Lack of human resource	36	72.1
There is no equity and presence of		
Bribery	8	16.4
Don't know	5	11.5
Total	**49**	**100.0**

In order to solve problems regarding failure to observe prescription requirements, majority 68.9% of the pharmacy workers said that all stakeholders should participate in the whole process of law enforcement

When asked to give reasons for adherence or non-adherence to prescription regulations during provision of antibiotics, majority of the pharmacy workers (53.1%) reported that client demand was the main reason for failure to abide to the regulations (**Figure 2**).

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Figure 2: Percentage distribution of determinants of adherence to prescription for antibiotics dispensing

Histogram response to circumstances for antibotic[s] dispense
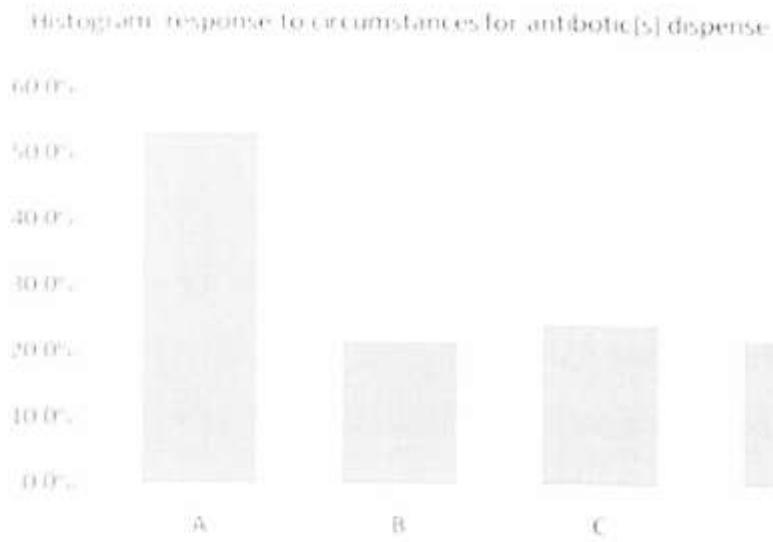
A: Client demand (53.1%)
C: Lack of knowledge (24.3%)
B: Economic incentives (21.6%)
D: Poor regulation enforcement (22.0%)

CHAPTER FIVE

5.0   DISCUSSION

The present study aimed at knowing the determinants of non-adherence to prescription requirements for antibiotics dispensing in Dar es Salaam. The study showed that there is a huge problem of inappropriate dispensing and irrational use of antibiotics, and this is in agreement with other drug utilization studies carried out in other developing countries. The present study showed that 92.7% would request a prescription before dispensing antibiotics. In practice 87.1% agreed to dispense antibiotics without prescription.

A similar study done in Bangkok, interviewees reported that 80% would request prescription before dispensing antibiotics. However in practices 83% dispensed antibiotic (Thamlikiktul, 1988). The practice of inappropriate dispensing of antibiotics and other drugs without proper indication leads to wastage of drugs, danger to health and is likely to contribute to the emergency and development of drug resistance, especially to most inexpensive drugs that can be affordable by the majority of poor rural community members in developing countries (Thamlikiktul, 1988).

Pharmacies and drug shops in developing countries provide easy access to patients/clients who need medicines as there are no long queues, shorter waiting times, cheaper drugs, wide range of drugs to choose from and any amount of drugs they want can be purchased, with or without a prescription and a full or half dose depending on their purchasing power without any restriction from pharmacy workers (Nsimba et al 2007). However, the provision of this service

by pharmacy workers has often been reported to be inappropriate (Igun, 1994). For example, antibiotics have been reported to be frequently prescribed and dispensed in common conditions such as watery diarrhea. Such drug prescriptions are irrational as antibiotics are indicated and prescribed for only patient with bloody diarrhea (WHO, 1993).

Socio- demographic characteristics with adherence to prescription requirements

Except for level of education, most of the socio-demographic characteristics were found not to be associated with adherence to prescription requirements. The study showed that as the level of education increases also the level of adherence to prescription requirements increases. Although most of the tested parameters did not show association with adherence to prescription, this is the first study which attempted to explore this aspect and further studies involving a large sample size will probably confirm the results obtained in this population.

Knowledge and practices of the pharmacy workers

As regards to knowledge of Prescription only Medicine and ability to classify antibiotics the results were not convincingly good due to the fact that only 6.4% and 0.6% respectively were able to articulate correctly. This suggests that there is need for strengthening continued education package for the pharmacy workers. Otherwise if this is not intervened, there is a likelihood that most of the pharmacy workers will continue to dispensing PoM) without asking for a prescription from an authorized practitioner. Such education as an intervention has proved to be useful in improving the knowledge of pharmacy workers in Pharmacies (Faxelid

et al., 1997). A study to improve private pharmacy practice in Vietnam, reported that there was significant improvement in the management of acute respiratory infection in children before and after intervention from 11% to 30% who were correctly managed as compared to control pharmacies which dropped from 10% to 7.0% (Chuc et al., 2002).

Similar study from nine African countries suggest that, since most people purchase their drugs from unqualified drug sellers, educating these drug sellers would probably be more beneficial for public health in many low-income countries (Viberg et al., 2007). Good knowledge is the prerequisite for good practice. However, improving knowledge may not always be the solution. A study in Sri Lanka showed that client knows what they want and pharmacy worker know the price.

Pharmacy worker practices assessed by Simulated Client Method

We observed that there is big different between the stated behavior during interview and those collected through simulated client method (SCM). In the present study interview results showed that (92.7%) of the pharmacy workers will request for a prescription before dispensing a PoM. While during actual practices, 87% simulated client of pharmacy workers did not request for prescription. Such unprofessional conduct have also been reported in other developing countries (Madden et al., 1997; Larsson et al., 2003; Volpato et al., 2006). A study in Hanoi showed that 74% of private pharmacies would not dispense antibiotics without prescription and yet, 84% still dispensed prescription only antibiotics (Chalker et al., 2000).

In this study we observed that of 54 (87.1%) simulations where prescription was not requested, still yet 88.9% of pharmacy workers agreed to dispense some antibiotics. This underlines the importance to assess not only knowledge but also practices. This shows also that if one was using a questionnaire by it self the results would have grossly underestimated the incidence of irrational antibiotic dispensing by pharmacy workers in Dar es Salaam. However, a cross sectional study in Zimbabwe shows that, there is a low sale of antibiotics without prescription which is in sharp contrast to other studies from low income countries (Nyazema et al., 2007)

The influence of economic incentive in adherence to prescription requirements

Economic incentives play an important role in dispensing drugs, including antibiotics. Quantities of antibiotics dispensed in Bolivian pharmacies varied according to client's ability to pay (Bartoloni et al., 1998). In India, pharmacies changed antibiotic prescriptions to suit the financial means of customers (Dua et al., 1994).

The findings of the present study indicated that more than 67% of pharmacy workers said they would dispense the drugs by convincing a client to purchase if the product is not common and overall they were ready to dispense even a half dose to the patient/client. Due to increase a number of pharmacies, competition also increases a profit margin decreases, pharmacy worker may feel compelled to focus more on profit than on their professional role (Parades et al., 1996)

Such malpractices have been reported in other studies where commercial pressure and profit needs may have more impact on actual practices compared to regulations and clinical indications (Brugha & Zwi 1998; Paredes et al., 1996).

Customer demand is often mentioned as the main cause of inappropriate antibiotic dispensing. However, it is not clear to what extent it is usually counter attendants or customers making the actual purchasing decisions (Radyowijati and Haak 2003). To support this the present stud showed that customer client demand contributed up to 53.1% as determinant of adherence prescription.

The extent to which regulatory enforcement determines adherence to prescription

Regulation is one important factor influencing pharmacy practice (Goel et al., 1996; Brugha & Zwi 1996). Even with existing regulations, effective enforcement mechanism are often absent in low and middle income countries (Kumanarayake et al., 2000; Stenson et al., 2001).

Study showed more than 72% of the respondents alleged the regulatory authority in Tanzania is not performing well probably because they lack human resource. This is common in most of developing countries; a study in Lao showed that the regulatory system was not able to deal with existence of dangerous, fake or substandard drugs (Stenson et al., 1997)

When selling drugs to customers, dispensers often ignore national legislation. Drugs are routinely dispensed without prescriptions. Dispensers in India stated that they simply ignored legislation on dispensing antibiotics, as they knew that enforcement was impossible (Dua et

al., 1994). In Kenya, chemists were reported as selling antibiotics under the name 'Septrin®', although another antibiotic was actually provided (Indalo, 1997).

With the current situation whereby pharmacies and drug shops are privately owned and profit oriented, strong regulation bodies are urgently needed to protect the public from misconducts of pharmacy workers. Therefore is needed to enforce greater regulation of the use of antibiotics and other PoM. However, this must be accompanied by strategies to educate all stakeholders on the appropriate use of antibiotics.

The misuse of antibiotics by health care professionals, unskilled practitioners and patients can be alleviated by, limiting antibiotics choice, developing prescription guidelines and emphasizing continuing medical and public education.

Pharmacy was the unit of analysis however; data were analyzed based on the encounters. It might be argued that by using encounters as the unit of analysis the power was inflated as the number of encounters was roughly three times as many as the number of pharmacies. Another drawback observed during the study that not all pharmacy workers who participate during simulation not always were the same pharmacy workers that were interviewed.

It also be questioned that the study focused on only part of pharmacy workers which are not enough to generate substantial and sustainable improvement. In order to achieve a sustainable changes towards more rational use of antibiotics other measure may be needed including intervention on the demand side (community) and prescribe. This can be achieved by

informing and empower community in relation to rational use of drugs as the ultimate decision makers in the use of medicine (Hongoro & Kumanarayake 2000).

CHAPTER SIX

6.0 CONCLUSION AND RECOMENDATIONS

6.1 Conclusion

1. Most of the drug outlet did not employ appropriately qualified since majority of the service providers were nurses.

2. Although there was little significant association between socio-demographic characteristics and adherence to prescription, the findings showed that education level could be a major determinant in observing appropriate dispensing of prescription only medicine.

3. Majority of workers provided antibiotics without prescription despite their response during interviews which showed that they always demanded for the prescription before dispensing the drugs.

4. The knowledge of pharmacy workers on prescription only medicine and antibiotics in generally was not convincingly good.

5. Client demand was observed to be a major factor influencing pharmacy workers to dispense antibiotics without prescriptions.

6.2   RECOMMENDATIONS

Since private pharmacies do not just provide Over the Counter (OTC) and prescription -based drugs but also deals with case management including childhood diarrhea. The findings from this study revealed that the majority of pharmacy workers do not adhere to prescription requirements. This is because they are either not aware of existing regulations or because they are practicing unethically with clear intention of profit making.

Findings underline the need to initiate interventions aiming to improve private pharmacy practice in Dar es Salaam. The study recommends:-

1. There is a need to provide comprehensive health education package to all pharmacy workers regarding use of antibiotics as Prescription only Medicine.

2. There is a need to develop a Nation Policy on antibiotics and improve human resource capacity of TFDA so that it can provide a frequent supportive supervision of all drugs outlets by professionals.

3. Further studies are needed to examine how interventions can be developed in order to facilitate private pharmacies to adhere to the existing regulation.

4. Assessment methods addressing knowledge as well as practice are recommended for monitoring and evaluation of interventions so as to ensure good pharmacy practice (GPP) in Tanzania.

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