

**ASSESSING IMPLEMENTATION OF ARTEMISININ BASED
COMBINATION THERAPY POLICY IN TREATMENT OF
UNCOMPLICATED MALARIA AMONG PRIVATE MEDICINES
OUTLETS IN MWANZA REGION, TANZANIA**

Stanley Mwita Mnanka

**MSc (Pharmaceutical Management) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2015**

**ASSESSING IMPLEMENTATION OF ARTEMISININ BASED
COMBINATION THERAPY POLICY IN TREATMENT OF
UNCOMPLICATED MALARIA AMONG PRIVATE MEDICINES
OUTLETS IN MWANZA REGION, TANZANIA**

By

Stanley Mwita Mnanka

**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree
of Master of Science in Pharmaceutical Management of
Muhimbili University of Health and Allied Sciences**

**Muhimbili University of Health and Allied Sciences
October, 2015**

CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; *Assessing implementation of artemisinin based combination therapy policy in treatment of uncomplicated malaria among private medicines outlets in Mwanza region, Tanzania* in (partial) fulfilment of the requirements for the degree of Master of Science in Pharmaceutical Management of Muhimbili University of Health and Allied Sciences.

Prof. Godeliver A. Kagashe

Supervisor

Date

DECLARATION AND COPYRIGHT

I, **Stanley Mwita Mnanka**, declare that this **dissertation** is my own original work and it has not been presented nor will it be presented to any other University for similar or any other degree award.

Signature

Date

This dissertation is the copyright material protected under the Berne Convention, the Copyright Act of 1999 and other international and national enactments, in that behalf, on the intellectual property. It may not be reproduced by any means, in full or in part, except in short extracts in fair dealings; for research or private study, critical scholarly review or discourse with an acknowledgement, without the written permission of the Directorate of Postgraduate Studies on behalf of both the author and the Muhimbili University of Health and Allied Sciences.

ACKNOWLEDGEMENT

This work could not have been effectively accomplished without the help and blessings from the Almighty God. I have the honor to praise him for the mercy and his blessings.

My special gratitude is expressed to my supervisor, Prof. G. Kagashe whose tireless efforts and support, patience, dedication and professional guidance during the conducting and writing of this dissertation can never go unnoticed. I thank for her contribution and constructive criticism which made this work the way it appears.

Special appreciation is also expressed to Angel Jesse (Phd Candidate), Dr. C. Moshiro and Dr. R. Mpembeni for their professional advice during proposal development and data analysis.

I also extend my gratitude to Catholic University of Health and Allied Sciences (CUHAS) for approving my study leave and funding. Special thanks to Prof. Mary Jande, Dean School of Pharmacy-CUHAS, for her maximum support.

I extend my deep gratitude to pharmacy personnel specifically pharmacy and ADDO owners, pharmacist in-charge and dispensers for devoting their time and maximum cooperation given during data collection.

I specially acknowledge the head of Department of Pharmaceutics Dr. Deborah Runyoro for accepting this work to be done and all members of staff at the Department and School of Pharmacy who directly or indirectly supported me academically and materially during the course.

I also extend my gratitude for the moral support and assistance from my colleagues in the Pharmaceutical Management Course class during difficult times academically.

DEDICATION

To my lovely family,

Dr. Angeline Izina my wonderful wife and my terrific kids, Collin Stanley and Carrin Stanley; my mother Christina Herman and my sister Stella Mwita for their understanding and patience all the time I was doing this work.

I love you so much.

ABSTRACT

Background: A combination of Artemether-lumefantrine (ALu) is recommended by Tanzania MoHSW as first line therapy for uncomplicated malaria while Sulphadoxine–pyrimethamine (SP) is recommended only for intermittent preventive treatment during pregnancy. Despite the change of the policy, SP is still being dispensed by private medicine outlets for treatment of uncomplicated malaria.

Objective: To assess implementation of artemisinin based combination therapy policy in treatment of malaria among private medicines outlets in Mwanza region, Tanzania.

Methodology: The study was a descriptive cross-sectional study, to capture quantitative data using structured questionnaires and simulated clients. Qualitative data were captured using focus group discussion. The study population was private medicine outlets i.e Pharmacies and ADDOs located in Nyamagana and Sengerema District.

Results: Knowledge level of dispensers in private medicine outlets on ACT policy for treatment of uncomplicated malaria was poor by 3.1% and good by 49.2%. Results revealed that 96.9% out of all medicines outlets participated in this study know that ALU is the first line medicine for treatment of uncomplicated malaria. During malaria patient simulation 9.7 % of outlets dispensed ALU to simulated client while 85.5% dispensed SP. Results showed that 90.6% of Pharmacies and 80% of ADDOs dispensed SP to simulated client even though SP is reserved for IPTp.

Conclusion and Recommendations: The study concluded that majority of dispensers in private medicines outlets have moderate and good knowledge on ACT policy in treatment of uncomplicated malaria. However the knowledge does not predict the actual practice, SP is still dispensed for malaria treatment rather than being reserved for IPTp where patient demand for a single dose medicine is one of driving factor for irrational dispensing and use of SP. Therefore the study recommended that MoHSW and other stakeholders to conduct training and seminars for medicine dispensers of private outlets on malaria treatment and rational dispensing of anti malarial medicines.

TABLE OF CONTENTS

CERTIFICATION	ii
DECLARATION AND COPYRIGHT	iii
ACKNOWLEDGEMENT	iv
DEDICATION	v
ABSTRACT	vi
TABLE OF CONTENTS	vii
LIST OF TABLES	x
LIST OF FIGURES	xi
LIST OF ACRONYMS	xii
DEFINITIONS OF TERMS	xiii
CHAPTER ONE	1
1.0 INTRODUCTION	1
1.1 Background	1
1.2 Statement of the Problem	7
1.3 Research Questions	8
1.4 Research Hypothesis	9
1.5 Study Objectives.....	9
1.5.1 Broad Objective	9
1.5.2 Specific Objectives	9
1.6 Rationale of the Study	10
1.7 Conceptual Framework	11
1.8 Literature Review	13
CHAPTER TWO	17
2.0 METHODS AND MATERIALS	17
2.1 Study design	17
2.2 Study sites.....	17
2.3 Study participants	17
2.4 Study period	17

2.5 Sampling technique	18
2.6 Sample size calculations.....	18
2.7.1 Inclusion Criteria	19
2.7.2 Exclusion Criteria.....	19
2.8 Instrument pre-test.....	19
2.9 Data collection.....	20
2.9.1 Data collection procedure	20
2.9.2 Data collection tools	20
2.10 Data management and analysis	21
2.11 Study Variables	22
2.11.1 Independent/explanatory variables	22
2.11.2 Dependent/outcome variables.....	22
2.12 Data Cleaning	22
2.13 Ethical Consideration	23
CHAPTER THREE.....	24
3.0 RESULTS.....	24
3.1 Response Rate	24
3.2 Results from Structured Questionnaires (Annex I)	24
3.3 Results from Simulated Client Form.....	45
3.4 Results from Focus Group Discussion (Guided).....	51
CHAPTER FOUR.....	54
4.0 DISCUSSION	54
CHAPTER FIVE.....	61
5.1 CONCLUSION AND RECOMMENDATION	61
5.2 RECOMMENDATIONS	61
5.3 Study Limitations	62
REFERENCES.....	63

ANNEXES	70
Annex 1A: Questionnaire (English Version)	70
Annex IIA: Simulated Clients form for Adult (English Version)	77
Annex IIIA: Questions Focused Group Discussion (English Version).....	79
Annex IVA: Study Participants Informed Consent Form (English Version).....	80
Annex IB: Questionnaire (Swahili version)	83
Annex IIB: Simulated Client Form (Swahili version).....	90
Annex IIIB: Questions Focus Group Discussion (Swahili version).....	92
Annex IVB: Study Participants Informed Consent (Swahili Version).....	93

LIST OF TABLES

Table 1:	Scale for measuring level of knowledge.....	21
Table 2:	Summary of social demographic characteristics of all respondents	25
Table 3:	Social demographics of respondents in ADDOs and Pharmacies.....	27
Table 4:	Response to questions assessing knowledge on treatment of malaria using ACT.....	30
Table 5:	Dispenser's level of knowledge on ACT by sex, age, profession, experience in medicine dispensing and attended training	35
Table 6:	General responses to questions which assess knowledge on IPTp.....	37
Table 7:	Dispenser's level of knowledge on IPTp by sex, age, profession, experience in medicine dispensing and attended training.....	42
Table 8:	Types of Anti malarial medicines available in medicine outlets.....	44
Table 9:	Dispenser's responses after simulated clients demand for SP.....	47
Table 10:	Dispenser's knowledge and practice on ACT policy for treatment of uncomplicated malaria in adults.....	50

LIST OF FIGURES

Figure 1:	Responses on anti malarial for first trimester pregnancy, in Pharmacies and ADDOs.....	31
Figure 2:	Responses on second line anti malarial medicine, in Pharmacies and ADDOs.....	32
Figure 3:	Knowledge levels of dispensers in all outlets on treatment of uncomplicated malaria using ACT.....	33
Figure 4:	Knowledge levels of dispensers on treatment of uncomplicated malaria using ACT, in Pharmacies and ADDOs.....	34
Figure 5:	Responses on alternative medicine for IPTp where SP is contraindicated, in Pharmacies and ADDOs.....	38
Figure 6:	Responses on effect of administering SP for treatment of uncomplicated malaria, in Pharmacies and ADDOs.....	39
Figure 7:	Knowledge levels on IPTp for dispensers in all medicine outlets.....	40
Figure 8:	Knowledge levels on IPTp for dispensers in Pharmacies and ADDOs...41	41
Figure 9:	Medicine advised by dispensers to simulated clients in all medicine outlets clients.....	45
Figure 10:	Medicines advised by dispensers to simulated clients, in Pharmacies and ADDOs.....	46
Figure 11:	Medicine dispensed to simulated clients in all medicine outlets.....	48
Figure 12:	Medicine dispensed to simulated clients, in Pharmacies and ADDOs...49	49

LIST OF ACRONYMS

AAQ	Artesunate/Amodiaquine
ACT	Artemisinin-based combination therapy
ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired Immuno deficiency syndrome
Alu	Artemether-lumefantrine
AP	Artemisinin/Piperaquine
BCC	Behavior Change Communication
CQ	Chloroquine
DPQ	Dihydroartemisinin/piperaquine
FBO	Faith Based Organization
HIV	Human Immunodeficiency virus
IPTp	Intermittent preventive treatment in pregnancy
MDS	Managing Drug Supply
MOHSW	Ministry of Health and Social Welfare
mRDT	Malarial Rapid Diagnostic Test
MSD	Medical Store Department
MSH	Management Sciences for Health
NBS	National Bureau of Statistics
NGDTM	National Guideline for Diagnosis and Treatment of Malaria
NGOs	Non Governmental Organizations
NMCP	National Malaria Control Programme
RBM	Roll Back Malaria
SP	sulphadoxine–pyrimethamine
SPP	Sulfamethoxypyrazine/pyrimethamine
TPSA	Tanzania Private Sector Assessment
WHO	World Health Organization

DEFINITIONS OF TERMS

Policy

Policy is a principle to guide decisions and achieve rational outcomes. A policy is a statement of intent and is implemented as a procedure or protocol.

Guideline

Guideline is a statement by which to determine a course of action. It aims to streamline particular processes according to a set routine or sound practice. Guidelines are documents that seek to simplify a set of processes with regard to established habit or practice.

Uncomplicated malaria

Malaria is considered uncomplicated when a patient has symptoms such as; Sensation of cold, shivering, fever, headaches, vomiting, joint ache and tiredness.

Severe malaria

Malaria is considered severe when infections are complicated by serious organ failures or abnormalities in the patient blood or metabolism. The manifestations of severe malaria includes; severe anemia, Cerebral malaria seizures, coma, acute kidney failure and hypoglycemia. Severe malaria is a medical emergency and should be treated urgently.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Malaria is a life-threatening blood disease caused by a parasite that is transmitted to humans by the *Anopheles* mosquito. Malaria is preventable and treatable disease. If malaria is diagnosed and treated early on, the duration of the infection can be considerably reduced, which in turn lowers the risk of complications and death.

Malaria is one of the leading public health concerns in Tanzania, especially for children under the age of five years and pregnant women. According to the latest Tanzania HIV/AIDS and malaria indicator survey in 2011–12, the prevalence of malaria rapid diagnostic test (mRDT) - confirmed malaria in children under five was 9% (NBS, 2013).

The impact of malaria is far reaching, including: considerable economic burden on households (Rutstein, 2004) and reduced economic growth at country level (Gallup, 2001); reduced educational attainment and intellectual development due to time lost from schooling and long-term sequelae associated with malaria (Sachs, 2002); and other consequences of sequelae, such as loss of quality of life.

On a household level, monies that might go to educating children or even investment into small enterprises goes to buying bed nets, medications and, at worst, paying funeral expenses (Jimoh, 2007). Thus combating malaria is not only salient for the protection of human health, but also for the health and welfare of future generations, whose destiny is increasingly entwined with the world community.

1.1.1 Structure of National Health & Pharmaceutical System in Tanzania

The basic goals of national medicine policies and public sector pharmaceutical supply systems are to provide access to needed medicines and supplies, promote the rational use of medicines, and ensure the quality, safety, and efficacy of medicines. Various strategies exist to achieve these goals through different combinations of public and private involvement in the pharmaceutical management cycle. National systems vary

with respect to public and private roles in financing, distribution, and dispensing of pharmaceuticals, ranging from fully public to fully private systems (MDS-3, 2012).

In Tanzania the healthcare system has two major components; the public and the private sector. The public share is 56%; the private share is 44% (which includes Faith Based Organizations (FBOs) 30% and private for profit 14 %). The health system services works at six levels and assumes pyramidal pattern; the lowest level is the community or village health services where there are village health post. Then dispensary services which cater for 6,000 to 10,000 people and supervise health post in the ward. As you go up follows the health centre services which cater for 50,000 people which is approximately the population of one division. As one move further up there is the district hospitals. Each district should have this hospital or designated Voluntary hospital where the government enters into contract terms with the FBO. Regional hospitals offer similar services like those at district hospital with additional specialist services in various fields (MOHSW, 2008). Regional hospitals are referral hospitals at the regional level. After regional level follows consultant/referral hospitals and the highest level is the National Hospital.

All public facilities receive their pharmaceutical supply shares by either using allocated financial budgets or draw supplies for use against established budget sealing. The Medical Store Department (MSD) is the main procurer and distributor of pharmaceuticals for public health facilities. Private distributors are the main source of pharmaceutical and medical products for commercial for-profit health facilities in the country. Wholesale pharmacies receive medicines from private distributors/importers. The wholesale pharmacies sell medicines to private retail pharmacies and Accredited Drug Dispensing Outlets (ADDO).

The ADDO Program began in 2003 as pilot project in Ruvuma region with the goal of improving access to essential medicines and pharmaceutical services in the rural and underserved areas of Tanzania where there are few or no registered Pharmacies. The objective is to better equip small rural drug shops (Duka la dawa baridi) to provide

quality medicines and pharmaceutical services. The Duka la dawa baridi are allowed to sell only over the counter medicines while ADDO shops the range of medicines to sell increased from Over the counter to prescription medicines. The program trains and provides oversight of the shop attendants who dispense the drugs, raises consumer awareness about accredited drug sellers, and strengthens the regulatory monitoring and inspection of outlets. The ADDO program is implemented by Pharmacy Council.

Private health facilities and pharmaceutical retail outlets play a key role in national pharmaceutical dispensing. Private retail pharmacies and ADDOs provide over 50 percent of dispensing services in Tanzania. Private pharmaceutical outlets play an important role in ensuring Tanzanians have reliable access to key prescription and over-the-counter pharmaceuticals (TPSA, 2013).

The commercial sector is able to provide a range of services that can enhance public access to essential medicines. In general, this sector would potentially respond well to new opportunities for providing supply services; however, the private commercial sector is not always sufficiently well developed or motivated to provide critical supply services to the public sector and should not be seen as a cure-all remedy for solving problems with existing systems. The commercial sector also plays a vital role in providing access to many people, especially in rural and underserved urban areas where retail drug outlets are the first stop to treat common illnesses.

1.1.2 Anti malaria treatment policy and malaria treatment guidelines

The goal of appropriate malaria diagnosis and treatment is to reduce morbidity and mortality. The National Guidelines for Diagnosis and Treatment of Malaria (NGDTM, 2006) have been guiding the National Malaria Control Programme (NMCP) to achieve this goal. The guiding principle of the national anti malarial treatment policy is to promote safe, effective, good quality, affordable and accessible anti malarial treatment (MOHSW, 2013).

The change in treatment policy occurs in three phases which are: (i) The policy review and change process: the processes and procedures leading up to the selection of the new treatment policy, including finance discussions (ii) The transition phase: the period when the decision on the new treatment policy were made but the policy has not been implemented yet (iii) The full implementation of the new policy: national rollout of the new policy. All Stakeholders such as Ministry of health, private sector, Research institutions, professional organizations and Nongovernmental organizations have to be involved in implementation of the new policy.

The key components in the implementation of the new policy can be divided into the technical components, operational components and Monitoring and evaluation. The technical components include regulatory changes, development and dissemination of essential medicines list and standard treatment guidelines, trainings and supervision of health care workers. The operational components incorporate the activities related to procurement and supply chain management, which ensure that the new medicines are available at the points of service delivery, development of phase out plan for anti malaria currently in use and pharmacovigilance (MSH, 2005).

The World Health Organization (WHO) developed policy recommendations to prevent, diagnose and treat malaria. The extent to which these policies are adopted varies between countries. With regard to malaria treatment, the WHO recommends a “combination therapy” of several anti-malarial drugs including an artemisinin derivative as first-line treatment. Since 2001, this measure has become increasingly popular and, by 2008, only Cape Verde, Dominican Republic, French Guyana and Swaziland had not adopted it (WHO, 2008).

In the year 2000 Tanzania changed its malaria treatment policy for uncomplicated malaria, whereby the former first line drug Chloroquine was replaced with Sulfadoxine-Pyrimethamine (SP). In the year 2005 Tanzania changed its malaria treatment policy for uncomplicated malaria from SP to artemisinin-based combination therapy (ACT) – specifically artemether-lumefantrine (ALU). Since the publication of the previous “2006

National Guidelines for Malaria Diagnosis and Treatment” much progress were made in the treatment of uncomplicated malaria, notably; increased access in public health facilities to confirmation of diagnosis of malaria using mRDT and evidence of benefits of Artesunate injection in the treatment of severe malaria in reducing malaria mortality compared to quinine (MOHSW, 2013). Therefore in the year 2013, Tanzania issued the current National Guidelines for Malaria Diagnosis and Treatment.

Anti malarial medicines recommended for treatment of malaria in Tanzania are ALU, which is first line medicine for the treatment of uncomplicated malaria and Dihydroartemisinin- Piperazine (DPQ) which second line medicine for the treatment of uncomplicated malaria (MOHSW, 2013).

1.1.3 Types of Antimalarials listed in National Essential Medicines list

Anti malarials are available under different formulations including tablets, suspensions, syrups and liquid injectables. Some are sold under their proprietary names, and referred to as innovator brands when they are products patented by their originators, or branded generics in the case of generic versions of innovator products marketed under a different name. Others are sold as unbranded generics without a proprietary name.

Within the retail market, these products are sold by a wide range of providers whose characteristics vary substantially across settings. The current National Essential Medicines List of Tanzania as reviewed in the year 2013 has listed the following Anti malarials: (i) DPQ tablets (ii) Quinine injection (iii) Quinine tablets (iv) Artesunate injection (v) SP tablets (vi) ALU (vii) Artesunate suppositories (viii) Chloroquine tablets (CQ).

1.1.4 Intermittent preventive treatment in pregnancy (IPTp)

Intermittent preventive treatment is the administration of anti malarials in full therapeutic doses at predetermined intervals during pregnancy even if individuals have no signs of malaria. IPTp should not be considered as chemoprophylaxis; the woman is not protected from infection and still could be infected after taking IPTp.

The aim of IPTp is to prevent adverse effects on both mother and fetus, including maternal anaemia, foetal loss, premature delivery, intrauterine growth retardation, and delivery of low birth-weight infants. In an area where SP drug resistance remains high, unregulated SP dispensing to people other than pregnant women runs the risk of jeopardizing the effectiveness of the IPTp strategy. SP remains the medicine of choice for IPTp. It is particularly important that medicines used in pregnancy are known to be safe (MOHSW, 2013).

1.2 Statement of the Problem

The implementation of a policy is a continuous process and involves many activities including, but not limited to, in service training (to update the personnel in the field with new knowledge) and adoption of new practices (which comes along with changes in treatment policy). There is a greater effort in training of health service providers in the public sector on the use of ACT relative to the private sector despite the vital role they play in malaria treatment (Mugoyela, 2011).

Public sector providers have better knowledge and better practices on treatment policy and dosing regimen with policy recommended anti malarial than their counterparts in private sectors. Changes in treatment guidelines should be accompanied by subsequent implementation activities, which should involve all sector players. The assumption that providers will follow the guidelines on paper is merely a guess and therefore there is need for frequent sensitization through education, information and communication (Watsierah, 2012).

Only a few studies have examined the practices of private medicine dispensing outlets as per Malaria treatment policy and guidelines in countries that have adopted the use of ACT. Data on evaluations of knowledge and practices before or during implementation of the ACT, in the private sector in relation to the other sectors in Tanzania is scanty. Ten years after moving from SP to ALU as a first line treatment for uncomplicated malaria, SP remains the drug of choice for IPTp.

Adherence to ACT policy is important in ensuring malaria treatment efficacy, as well as to reduce the likelihood of malaria parasite resistance to ACT (Lawford, 2011). Irrational dispensing and use of ALU may lead to increasing cases of treatment failure and development of malaria parasite resistance to ALU. If the extent at which SP is used for treatment of uncomplicated malaria is significant, it may undermine its official use for IPTp through induction of resistance. In order to preserve SP efficacy for IPTp, all possible efforts should be made to avoid SP use for the treatment of clinical cases of malaria (WHO 2014). Failure of SP on IPTp would increase the adverse consequences

of malaria on maternal and fetal outcomes, such as; placental infection, clinical malaria, maternal anaemia, fetal anaemia, low birth weight and neonatal mortality (Menendez, 2010).

Therefore this study intended to examine practices of private medicines outlets in dispensing of ALU for treatment of uncomplicated malaria, to identify the extent at which SP is dispensed in treatment of uncomplicated malaria and to assess knowledge of dispensers of private medicines outlets on ACT policy in treatment of uncomplicated malaria. The study involved over the counter malaria treatment only and not prescriptions.

1.3 Research Questions

- What proportion of dispensers in private medicines outlets knows treatment of uncomplicated malaria using Artemisinin based combination therapy?
- What proportion of dispensers in private medicines outlets knows intermittent preventive treatment in pregnancy (IPTp)?
- What is proportion of dispensers in medicine outlets who dispense correct recommended first line anti malarial for treatment of uncomplicated malaria to adults?
- Which types of anti-malaria medicines are available in private medicine outlets?
- What are the perceptions and challenges faced by dispensers of private medicine outlets on implementing ACT policy for treatment of uncomplicated malaria?

1.4 Research Hypothesis

NULL HYPOTHESIS (H_0): The proportion of dispensers in private medicine outlets who dispense recommended first line anti malarial (ALU) in treatment of uncomplicated malaria is the same as those who don't dispense the recommended first line anti malaria (ALU).

ALTERNATIVE HYPOTHESIS (H_1): The proportion of dispensers in private medicine outlets who dispense recommended first line anti malarial (ALU) in treatment of uncomplicated malaria is not the same as those who don't dispense the recommended first line anti malaria (ALU).

1.5 Study Objectives

1.5.1 Broad Objective

To assess implementation of artemisinin based combination therapy policy in treatment of uncomplicated malaria among private medicines outlets in mwanza region-Tanzania.

1.5.2 Specific Objectives

- To assess knowledge of dispensers in private medicines outlets on treatment of uncomplicated malaria using combination therapy.
- To assess knowledge of dispensers in private medicines outlets on intermittent preventive treatment in pregnancy (IPTp).
- To determine the proportion of dispensers in medicine outlets who dispense recommended first line anti malarial medicine for treatment of uncomplicated malaria in adults.
- To identify types of anti malarial medicines available in private medicine outlets.
- To explore perceptions and challenges facing dispensers of private medicine outlets on implementing ACT policy for treatment of uncomplicated malaria.

1.6 Rationale of the Study

The findings from this study serve as source of information to create awareness to drug dispensers in private medicines outlets on the ACT policy in treatment of uncomplicated malaria. Dispensers were informed that SP is supposed to be used for IPTp only and not for treatment of uncomplicated malaria.

Not only that but also, the findings from this study serve as a source of information which may be used by the MOHSW in assessing the extent at which private medicine dispensing outlets abide to ACT policy in treatment of uncomplicated malaria and do intervention accordingly. Intervention by MOHSW through its agencies such as Tanzania Food and Drugs Authority (TFDA) and Pharmacy Council is significant in improving the use of ACT in treatment of uncomplicated malaria.

1.7 Conceptual Framework

The conceptual frame work below explains over the counter treatment of malaria in ADDOs and Pharmacies.

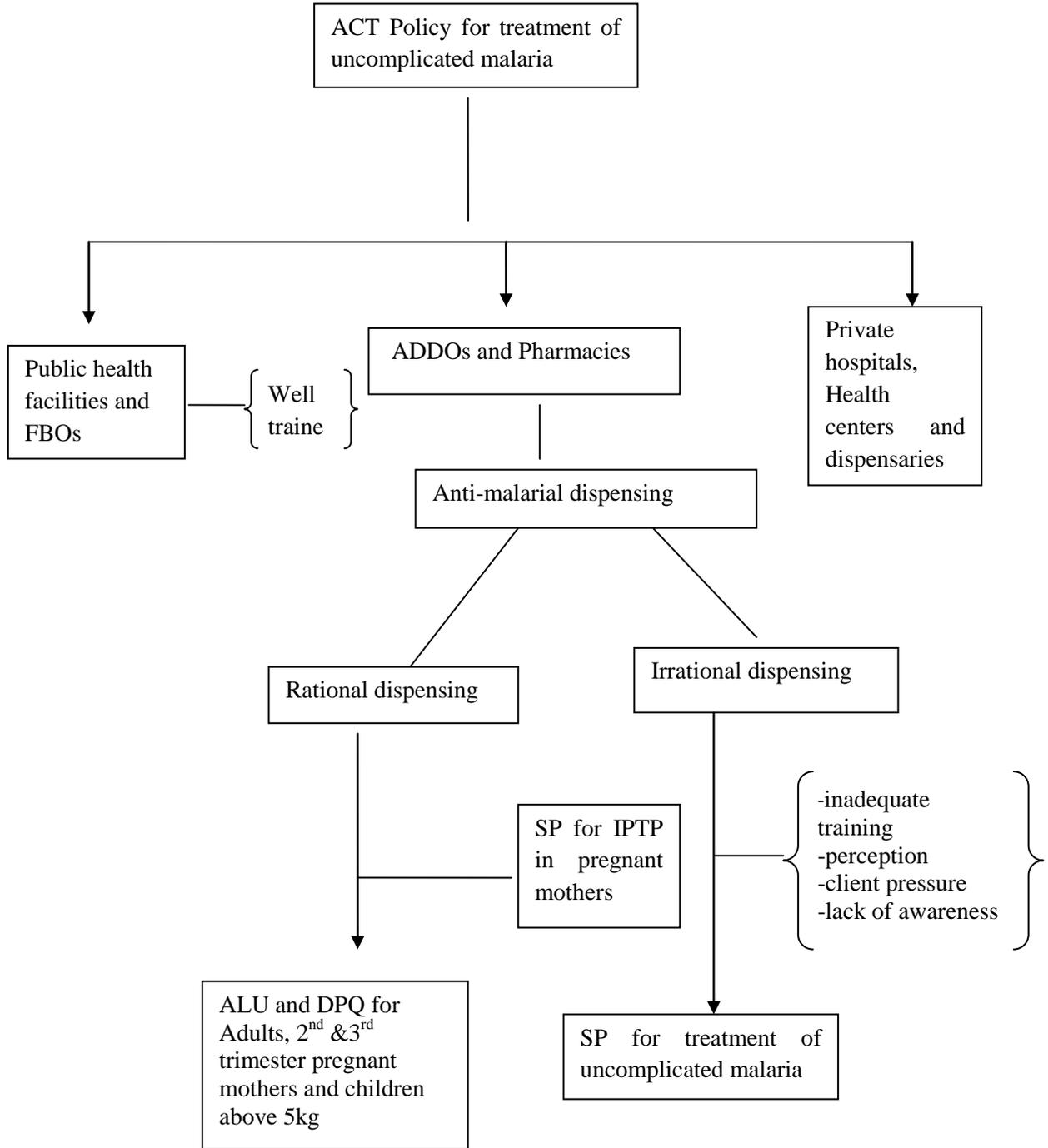
Since the year 2005, Tanzania malaria treatment policy for uncomplicated malaria changed from SP to ACT. Anti malarial medicines recommended for treatment of uncomplicated malaria in Tanzania are; ALU which is first line medicine for the treatment of uncomplicated malaria and DPQ which second line medicine for the treatment of uncomplicated malaria (MOHSW, 2013).

Both public, FBOs and private health facilities are important stakeholders in implementation of ACT policy. However public health facilities are well trained on ACT policy compared to their counterpart i.e private health facilities (Mugoyela, 2011). The study dealt with over the counter treatment of uncomplicated malaria in private medicines outlets i.e Pharmacies and ADDOs.

Dispensing of anti malarials can be rational or irrational. Rational dispensing includes dispensing of SP to pregnant mothers for IPTp or when ALU and DPQ are dispensed for treatment of uncomplicated malaria. Oral quinine is recommended anti malarial for first trimester pregnancy.

Private medicine outlets irrationally dispense SP for treatment of uncomplicated malaria instead of reserving it for IPTp. Factors which influence irrational dispensing and use of SP includes; inadequate trainings to dispensers, perceptions of dispensers with regard to ACT policy, clients pressure and demand for SP, and lack of awareness to the community about the change of the malaria treatment policy.

Thus the study assessed knowledge of dispensers on ACT policy and IPTp, explored their perception on implementation of the policy and determined the extent at which SP is dispensed for treatment of uncomplicated malaria in ADDOs and Pharmacies.



1.8 Literature Review

Malaria is one of the leading causes of death in children under five years of age and accounts for up to 40% of outpatient visits in Tanzania (NMP, 2010). Studies throughout sub-Saharan Africa have shown that the private sector is commonly utilized as an initial source of treatment for malaria or fever. In 2010, a household survey in three regions in Tanzania, found that of those who sought care for fever in the prior 14 days, 41% sought care at a pharmacy, drug shop, or general store, whereas only 19% went to a government health facility (Festo, 2011). A review of studies from some countries found that around half of caregivers initially sought medicines for the treatment of common childhood illnesses from private drug sellers (Goodman, 2007).

In many low and middle income countries, the retail sector plays an important role in the provision of malaria treatment (Hamel, 2001). For example, it was the first source of care for around 45% of households seeking malaria treatment across four communities in Enugu State, Nigeria (Onwujekwe, 2008) and in three rural districts of Tanzania nearly 40% of all anti-malarial volumes were dispensed within the retail sector (Goodman, 2007). Retail providers tend to operate closer to homes and offer a more reliable and wider range of drugs than public health providers (Ruebush, 1995).

The opportunities and risks related to retail sector medicine provision have led to the development of a number of initiatives to strengthen the provision of care in drug shops. In Tanzania, key strategies have included the ADDO program and the Affordable Medicines Facility-malaria. ADDO dispensers must attend a 35 day training course, covering key areas such as family planning, malaria treatment and other common illnesses. The Affordable Medicines Facility-malaria aimed to expand access to ACTs in the public and private sectors (Sillo, 2012).

The National Malaria Control Program identified the ADDO program as a private sector mechanism to supplement the distribution of subsidized ACTs from public facilities and increase access to the first-line anti malarial in rural and underserved areas. The ADDO

program strengthens private sector pharmaceutical services by improving regulatory and supervisory support, dispenser training, and record keeping practices

The policy and regulatory environment in Tanzania allowed the private sector to deliver subsidized ACTs. The NMCP had already identified the ADDO program as a potential mechanism to supplement public sector distribution of subsidized ACTs and increase access in rural and underserved areas (MOHSW, 2006). Few studies have examined the impact of knowledge and practices of dispensers of private facilities on the use of ACT and adherence to new treatment policy and guidelines in countries that have adopted the use of ACT. One study found that despite high level of awareness of a new malaria treatment policy, a significant percentage of clinicians (76.2%) reported continued use of SP (Tarimo, 2007). Another study done by Minzi found that there was lack of involvement of the pharmaceutical personnel working in the private pharmacies, from the preparation of new malaria treatment guidelines to their implementation, and this contributed to their poor knowledge and skill on how to correctly dispense the medicines. The study found that 49% of the visited private pharmacies were stocking and selling CQ tablets and injections. Only 30% and 7% knew the correct dose regimen of SP and ALU respectively and none of them knew the condition of taking ALU with a fatty meal for improved absorption (Minzi, 2008).

The study with the title, “Malaria treatment in the retail sector: Knowledge and practices of drug sellers in rural Tanzania” revealed that Shop keepers in drug store knew more about malaria and its treatment than their peers in general shops. In drug stores, 52% mentioned the correct child-dosage of SP compared to only 3% in general shops (Hetzl, 2008). Each year approximately 50 million women living in malaria endemic areas become pregnant and are at risk of the adverse health impact of malaria. Approximately half of them live in sub-Saharan Africa and most of them in areas of intense falciparum transmission. The increased susceptibility to malaria of pregnant women has long been recognized. Although some progress has been accomplished in recent years, resulting in

the identification of intermittent IPTp and insecticide treated nets as key strategies to control malaria in pregnancy in Africa (Menendez, 2006).

SP is used for IPTp in many sub-Saharan African countries. In Tanzania where neonatal mortality remains one of the challenging public health concerns (WHO, 2007), the national policy stipulates provision of SP to all pregnant women during each Ante Natal Clinic visits. The study done by Menendez in 2010 revealed that intermittent preventive treatment is highly cost-effective in reduction of malaria in pregnancy and consequently in reduction of neonatal mortality. Reductions in neonatal mortality by up to 61.3% have been reported following IPTp administration, (Menéndez, 2010). The study done by Ramharter in Gabon revealed that, after introduction of IPTp, the prevalence of maternal *Plasmodium falciparum* infection decreased dramatically. Whereas only a modest effect on the rate of anemia in pregnant women was observed, there was a marked benefit on the prevalence of low birth weight and premature birth for women adhering to national recommendations (Ramharter et al., 2007).

Pharmacies are generally authorized to stock both prescription-only medicines and over-the-counter (OTC) products, while ADDOs sell OTC drugs and some prescription only medicines. ACT was rarely available in private medicines outlets because of their high price relative to older, less effective alternatives. For example, in six districts of Zambia, ACT accounted for only 7% of all antimalarials sold in the retail sector and in Tanzania, SP was the most commonly retailed anti-malarial, followed by artemisinin monotherapies (Clinton Foundation, 2008). In the study conducted in Muheza by Ringsten to evaluate Saleability of antimalarials in private drug shops reveals that all surveyed drug shops illicitly sold SP and quinine, and legally amodiaquine. Local brands of SP accounted for 74% of sales volume, compared to Amodiaquine (13%), Quinine (11%) and ACT (2%), in community practice, the saleability of ACT was negligible. SP was best-selling, and use was not reserved for IPTp, as stipulated in the national anti-malarial policy (Ringsted, 2011).

The study titled, “Got ACTs? Availability, price, market share and provider knowledge of anti-malarial medicines in public and private sector outlets in six malaria endemic countries”, revealed that the proportion of public health facilities with at least one first-line quality-assured ACT in stock ranged between 43% and 85%. Most anti malarials were distributed through the private sector, but often comprised non-artemisinin therapies (O’Connell, 2011).

The study done by Kamat in Dar es Salaam to closely examines the perspectives of owners and managers of retail pharmacies and drug shops in Dar es Salaam on new malaria treatment guidelines revealed that most pharmacy owners and managers, it is ‘business as usual’ concerning the sale of conventional anti malarials, with a majority reporting that the introduction of ACT in public health facilities had not negatively affected their business. Implications of the research findings are examined in the context of proposed interventions to make pharmacy owners and managers more socially responsible and adhere to government health regulations (Kamat, 2010).

CHAPTER TWO

2.0 METHODS AND MATERIALS

2.1 Study Design

A descriptive cross sectional study design was intended to capture qualitative and quantitative data. Qualitative data were captured based on focus group discussion using guided questions. Quantitative data were captured using structured questionnaires and simulated clients.

2.2 Study Sites

The study was conducted in Mwanza region. Mwanza was conveniently selected as study site because it is one of the regions with many ADDOs and Pharmacies; also it is highly populated and has high prevalence of malaria.

The region has seven districts, namely Nyamagana, Ilemela, Sengerema, Kwimba, Misungwi, Magu and Ukerewe. Mwanza Region as the target population has 62 Pharmacies and 112 ADDOs. Their distribution is as follows; For ADDOs, 3 are located in Ukerewe, 19 in Nyamagana, 9 in Ilemela, 23 in Magu, 3 in Misungwi, 24 in Kwimba and 31 in Sengerema district. For Pharmacies, 45 are located in Nyamagana, 11 in Ilemela, 1 in Ukerewe, 2 in Magu and 2 in Sengerema.

2.3 Study Participants

The study population was medicine outlets i.e Private Pharmacies and ADDOs located in Nyamagana and Sengerema District, sampling units were medicine outlets while study units were medicine dispensers of medicine outlets.

2.4 Study Period

This study took eight months for its completion. The period includes proposal development and approval for ethical clearance from October 2014 to February 2015; data collection and analysis was done from March to April 2015; and final report writing and submission in June 2015.

2.5 Sampling Technique

- Nyamagana and Sengerema Districts were involved in the study because they have high number of Pharmacies and ADDOs respectively. There are 45 pharmacies and 19 ADDOs in Nyamagana district while Sengerema has 2 Pharmacies and 31 ADDOs. Therefore sampling unit constitutes of 47 Pharmacies and 50 ADDOs. That makes the total of 97 medicine outlets.
- One dispenser was involved per outlet. Random sampling was used to include dispensers in the study for those outlets with more than one dispenser.
- Purposive sampling was employed on the focus group discussion to get 10 pharmaceutical technicians with experience of not less than one year at work in private pharmacy as dispensers and 10 ADDO trained attendants with experience not less than one year at work in ADDO shop.

2.6 Sample Size Calculations for structured questionnaire

The sample size (n) was calculated using formula for calculating sample size for single proportion of the finite population (Daniel, 1999). i.e

$$n = \frac{Nz^2pq}{d^2(N-1)+z^2pq}$$

Where;

Z = level of confidence (1.96 for 95% confidence level)

p = proportion of population which dispense correct anti malarials (50%)

d = margin of error

q= (100-p)

For ADDOs

N=50, z=1.96, p=0.5, q=0.5, d=0.1

Therefore n-ADDOs =33

For Pharmacies;

N=47, z=1.96, p=0.5, q=0.5, d=0.1

Therefore n- Pharmacies =32

To get a sample of ADDOs and Pharmacies the simple random sampling was employed.

SAMPLE SIZE: For quantitative data the whole study had 65 samples which constituted 33 ADDOs and 32 Pharmacies while for qualitative data the study constituted 20 dispensers.

2.7.1 Inclusion Criteria

- The private facility which store and sale on retail basis Anti Malarial Medicines were included and Pharmaceutical personnel or any other health personnel involved with dispensing.
- Staff who consented to participate in the study was included.

2.7.2 Exclusion Criteria

- Dispensers with experience of less than two months as medicines dispensers were not included in the study.
- Wholesale only pharmacies were not included.

2.8 Instrument Pre-Test

Pre-testing of the data collection tools for their validity and appropriateness were conducted in Ilemela district which has the same type of participants as the one who are included in the study. Thereafter, pre-tested tools were revised and restructured wherever necessary to assist in data collection.

2.9 Data Collection

2.9.1 Data Collection Procedure

Data were collected by the principal researcher using data collection tools; annex I and III while data in annex II were collected by two simulated clients who were medical personnel's. Simulated clients were part of research assistants.

2.9.2 Data Collection Tools

2.9.2.1 Structured questionnaire

Structured questionnaires were used for interviewing dispensers in private medicine outlets as per annex I. The questionnaire was used to assess knowledge of dispensers on ACT policy and IPTp, as well as identifying types of anti malarial medicine

2.9.2.2 Simulated Client Form

The simulated client form (Annex II) was used by two simulated clients who acted as if they had symptoms of uncomplicated malaria and seek over the counter treatment. The form was used to record medicines advised by dispensers and medicines which were dispensed after client demand for SP.

2.9.2.3 Focus group discussion (Guided)

Guiding questions were used for the focus group discussion with dispensers in pharmacies and ADDO shops (Annex III). Questions were mainly intended to explore perceptions of dispensers on ACT policy and challenges they face on its implementation. Audio recorder was used for data collection. The focus group discussion was conducted in four sessions of five participants in each group. Participants were divided into five in each group as a result two sessions for pharmaceutical technicians working in pharmacies and two sessions for ADDO trained attendants working in ADDOs were conducted. The focus group discussion for pharmacy participants was conducted in Nyamagana district because the district has a large number of pharmacies. The focus group discussion for ADDO participants was conducted at Sengerema district because of easy accessible district.

After each session the information obtained was transcribed and translated immediately to obtain meaningful information. Transcripts were read repeatedly to identify conceptually similar fragments of text, which were then analyzed. The analysis was done manually using a content analysis approach.

2.10 Data Management and Analysis

All the collected data were counter-checked for their reliability and validity. The coded data were analyzed using Statistical Package for Social Sciences (Version 20.0) and Epi info version6 computer analysis software. A P-value of less than 0.05 was considered as statistically significance, at 95% confidence interval.

Descriptive statistics was used to measure the relative frequencies of variables. Knowledge and practice of dispensers with regard to ACT policy for malaria treatment were analyzed using cross-tabulation, Z-test and chi-square or Fisher's exact test where appropriate.

Total of 22 questions in the questionnaire were used to assess knowledge of dispensers (Annex 1). Table 1 below shows distribution of questions and knowledge scale assessment per number of questions answered correctly.

Table 1: Scale for measuring level of knowledge

	POOR	MODERATE	GOOD	Total questions
Treatment of Uncomplicated Malaria using ACT	0-5	6-10	11-15	15
IPTp	0-2	3-5	6-7	7

2.11 Study Variables

2.11.1 Independent / Explanatory Variables

- Professional of the dispenser
- Sex, age, years of dispensing experience
- Attending anti malarial training

2.11.2 Dependent / Outcome Variables

- Knowledge on treatment of uncomplicated malaria.
- Knowledge on IPTp.
- Types of anti malarial available at the time of the study.
- Anti malaria medicine dispensed to simulated clients.

2.12 Data Cleaning

This refers to data preparation, which includes editing and eliminating errors in coding and transmitting the data to the computer. The editing was done so as to detect errors and omissions at the same time correcting them where possible in order to meet the minimum quality standard of data. In the process of data cleaning the responses were studied and compared in order to assess their accuracy and consistency with other information as well as uniformity since some respondents used different terms to give the same information.

2.13 Ethical Consideration

Ethical clearance was sought from the Ethical Review Committee of MUHAS. The investigator asked for permission from in charges of medicine outlets. Finally the investigator asked for consent from dispenser at each outlet before commencing the study.

For simulated clients, the nature of this study did not allow informing the dispensers in advance and asking them for consent to participate. To protect dispensers' privacy, no names of staffs were recorded and names of outlets are not mentioned in connection with the study's results.

CHAPTER THREE

3.0 RESULTS

3.1 Response rate

All of the 65 (100%) interview questionnaires administered to 32 Pharmacies and 33 ADDOs were filled. Out of 65 medicines outlets, only 62 (95.4%) outlets participated in simulation, which involved 32 Pharmacies and 30 ADDOs. Three ADDOs did not agree to dispense anti malarial without laboratory test results.

3.2 Results from Structured Questionnaires (Annex I)

3.2.1 Socio- demographic characteristics of interviewees

Socio-demographic variables examined were sex, age groups, professional cadres and their experience at work. Socio-demographic features of interviewees are shown in table 2.

Table 2: Summary of social demographic characteristics of all respondents (n= 65)

Demographics	Frequency	Percentage
Sex		
Male	26	40
Female	39	60
Age (in years)		
15-24	5	7.7
25-34	21	32.3
35-44	19	29.2
Above 45	20	30.8
Profession		
Pharmacist	5	7.7
Pharmaceutical technician	15	23.1
Pharmaceutical Assistant	5	7.7
ADDO dispenser	32	49.2
Clinical officer	1	1.5
Nursing officer/Nurse midwife	2	3.1
Nurse Assistant	2	3.1
Others	3	4.6
Experience in medicine dispensing		
Less than 1 year	14	21.5
1 to 5 years	17	26.2
6 to 10 years	18	27.7
11 years and above	16	24.6
Attended training on malaria treatment		
Yes	5	7.7
No	60	92.3

Results show that most of the contacted respondents were female i.e 60%. Regarding to the age distribution, few respondents were at the age range of 15-24 years i.e 7.7%. Professionally, most of respondents were ADDO Dispensers i.e 49.2%. Regarding experience at work, 27.7% had experience of 6 to 10 years. Finding shows that majority (92.3%) of respondents didn't attend training on malaria treatment.

As shown in the table 3; results revealed that 66.7% of dispensers in ADDOs and 53.1% in pharmacies were females. Majority of dispensers in Pharmacies were Pharmaceutical technicians (46.9%) while in ADDOs majority were ADDO dispensers (78.8%).

Table 3: Social demographics of respondents; in ADDOs (n=33) and Pharmacies (n=32)

Demographics		Pharmacies		ADDOs	
		Frequency	Percentage	Frequency	Percentage
Sex					
	Male	15	46.9	11	33.3
	Female	17	53.1	22	66.7
Age(in years)					
	15-24	1	3.1	4	12.1
	25-34	12	37.5	9	27.3
	35-44	8	25	11	33.3
	Above 45	11	34.4	9	27.3
Profession					
	Pharmacist	5	15.6	0	0
	Pharmaceutical technician	15	46.9	0	0
	Pharmaceutical assistants	4	12.5	0	0
	ADDO dispenser	6	18.8	26	78.8
	Clinical officer	0	0	1	3
	Nursing officer/nurse midwife	1	3.1	1	3
	Nurse Assistant	0	0	3	9.1
	Others	1	3.1	2	6.1
Experience in dispensing					
	Less than 1 year	6	18.8	8	24.2
	1 to 5 years	8	25	9	27.3
	6 to 10 years	9	28.1	9	27.3
	11 years and above	9	28.1	7	21.2
Attended training					
	Yes	4	12.5	1	3
	No	28	87.5	32	97

*Others included Assistant clinical officer, Assistant medical officer and one year course medicine dispenser.

3.2.2 Knowledge on treatment of uncomplicated malaria using ACT

Table 4 is the summary of positive responses to questions which aimed at assessing level of knowledge of all dispensers in private medicines outlets of malaria treatment using ACT. Respective positive responses to questions asked include:

- SP was the recommended medicine before Tanzania adopted ACT policy for treatment of uncomplicated malaria.
- Symptoms of uncomplicated malaria includes; headache, fatigue, abdominal discomfort, muscle and joint aches, fever, chills, poor appetite, body weakness and vomiting.
- ALU is the first line medicine for treatment of uncomplicated malaria.
- ALU is not recommended in pregnancy during first trimester.
- Quinine tablet is the medicine recommended in first trimester.
- Respondents were supposed to mention one of the following side effects of ALU i.e sleep disorders, headache, dizziness, nausea, body weakness, abdominal pain, pruritus, rash, cough, and palpitation.
- The dose of ALU if vomited within 30 minutes should be repeated.
- ALU should be taken with fat meals so as to increase its absorption.
- Patients weighs; 5-14kg take 1 tablet per dose, 15-24 take 2 tablets, 25-34 take 3 tablets and above 35 kg take 4 tablets.
- For a complete course of ALU, six (6) doses should be taken.
- A dosage regimen of ALU is taken for 3 days.
- ALU dosing schedule is; the second dose to be taken 8 hours after first dose, the third dose is 16 hours after second dose then 4th, 5th and 6th dose are taken after every 12 hours OR for practical reasons the simpler dosage regimen recommended is the second dose to be taken 8 hours after first dose and subsequent doses are taken twice per day i.e morning and evening.
- Second line anti malarial is DPQ tablets.

- Respondents were supposed to mention one of the following indications for use of second line anti malarial i.e when ALU is contraindicated due to allergic reactions or when ALU has failed.

Table 4: Response to questions assessing knowledge on treatment of malaria using ACT

	Respondents with positive responses(%age)		
	Pharmacies (n=32)	ADDOS (n=33)	Total (n=65)
Mention antimalarial which was recommended for treatment of uncomplicated malaria before Tanzania as a country adopted ACT Policy	68.8	45.5	57.1
Mention three symptoms of uncomplicated malaria	97	100	98.5
Mention the first line medicine for treatment of uncomplicated malaria	100	90.9	95.4
ALU is not recommended to which group of individuals?	65.6	42.4	54.1
Which medicine is recommended for treatment for uncomplicated malaria in first trimester of pregnancy?	40.6	18.2	29.4
What are side effects of ALU?	87.5	60.6	74.1
The dose of ALU should be repeated if the medicine is vomited within how many minutes/hours?	56.3	48.5	52.4
ALU should be taken with fat meals	71.9	66.7	69.3
What is the reason for ALU to be taken with fat meals?	56.3	24.2	40.2
How many tablets of ALU a patient should take per dose considering his/her weight?	96.9	100	98.5
For the complete course of malaria treatment, how many doses of ALU a patient should take?	100	90.9	95.5
The dosage of ALU has to be taken for how many days?	100	100	100
Describe the recommended dosing schedule of ALU	96.9	93.9	95.4
Mention second line medicine for treatment of uncomplicated malaria	34.4	9.1	22
What is the indication for the use of second line medicine?	68.8	36.4	52.6

Table 4 indicates that most of respondents in all medicines outlets knew the number of days for ALU to be taken (100%), number of ALU tablets a patient should take per dose (98.5%) and symptoms of uncomplicated malaria (98.5%).

Also results shows that few respondents knew that DPQ is the second line medicine for treatment of uncomplicated malaria as it was mentioned by 34.4% of pharmacy dispensers and only 9.1% of dispensers in ADDOs.

Figure 1 below show responses from Pharmacies and ADDOs to the question about recommended medicine for treatment of uncomplicated malaria in first trimester of pregnancy.

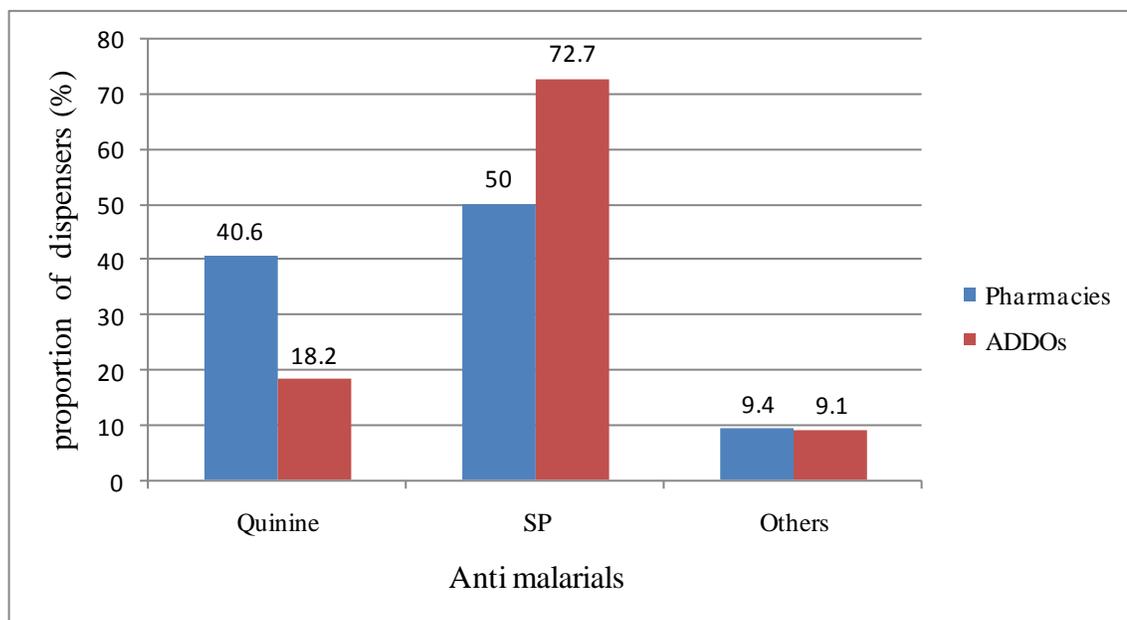


Figure 1: Dispenser's responses on anti malarial for treatment of uncomplicated malaria for first trimester pregnancy, in Pharmacies (n=32) and ADDOs (n=33)

Results show that most of dispensers in ADDOs mentioned SP i.e 72.7% and most of dispensers in Pharmacies mentioned quinine i.e 40.6%, as the medicine for treatment of uncomplicated malaria in first trimester pregnancy. Others include those who said they do not know; DPQ and sulphamethoxypyrazine / pyrimethamine (SPP).

Figure 2 below show responses from Pharmacies and ADDOs to the question about medicine recommended as second line for treatment of uncomplicated malaria.

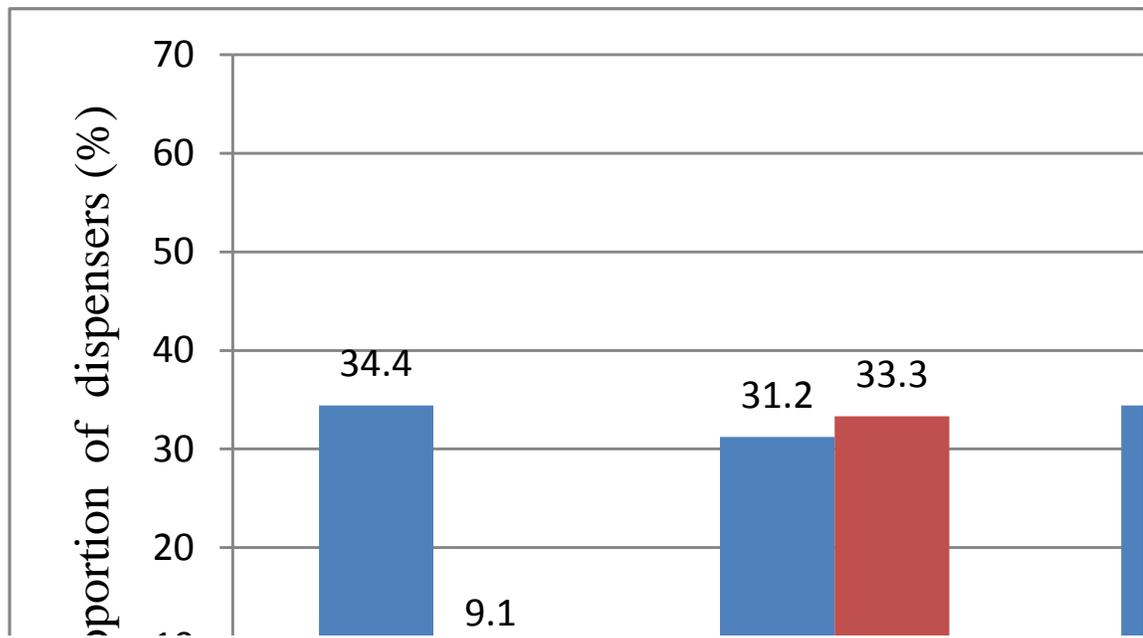


Figure 2: Dispenser's responses on second line anti malarial medicine, in Pharmacies (n=32) and ADDOs (n=33)

Results show that 33.3% of dispensers in ADDOs and 31.2% of dispensers in Pharmacies mentioned quinine tablets as second line medicine. Others include those who said they don't know; SP tablets, chloroquine tablets and SPP.

Figure 3 below show knowledge level on the use of ACT for treatment of uncomplicated malaria among all participants.

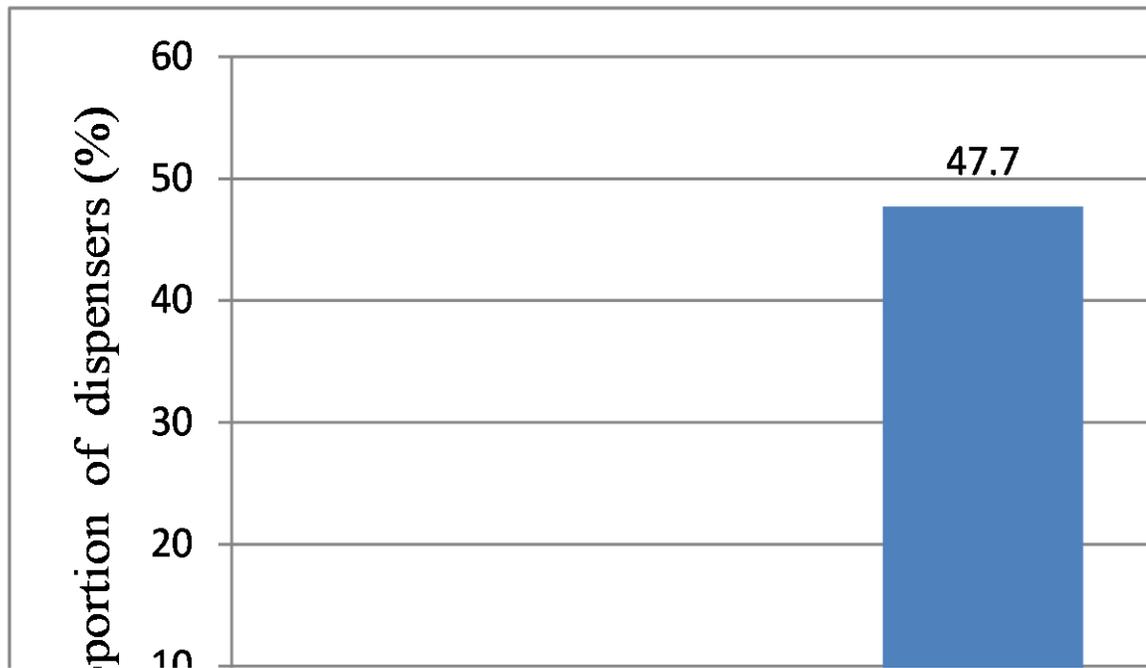


Figure 3: Knowledge level of dispensers in all medicine outlets on treatment of uncomplicated malaria using ACT (n=65)

The level of knowledge was classified as poor, moderate and good as shown in table 1. Results show that 3.1% of all respondents had poor knowledge, they were able to respond positively up to 5 questions and almost half of respondent's i.e 49.2% had good knowledge responding positively 11 to 15 questions.

Figure 4 below show the knowledge level on the use of ACT for treatment of uncomplicated malaria in Pharmacies and ADDOs.

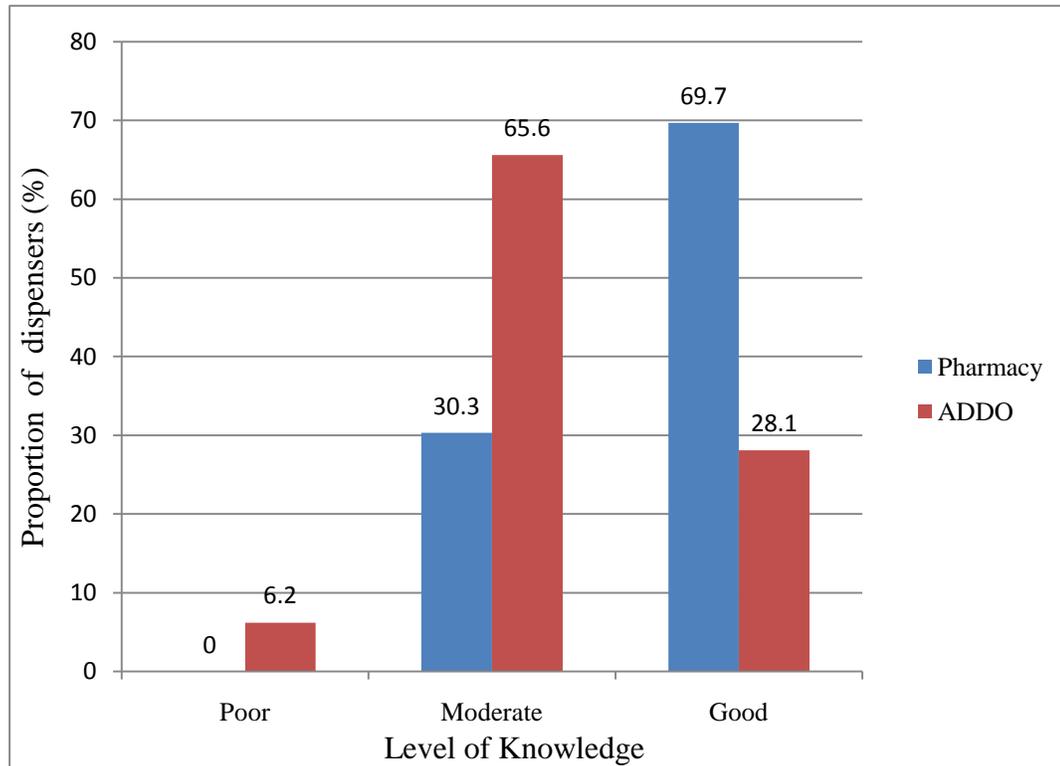


Figure 4: knowledge level of dispensers on treatment of uncomplicated malaria using ACT, in Pharmacies (n=32) and ADDOs (n=33)

As summarized in the figure above, the study shows that; most of dispensers in Pharmacies i.e 69.7% had good knowledge while most of dispensers in ADDOs had moderate knowledge i.e 65.6%.

There is relationship between type of the medicine outlet and level of knowledge on ACT, (P value=0.001).

Table 5 show level of knowledge of dispensers by social demographics i.e sex, age, profession of the dispenser, experience in dispensing and if the dispenser attended training of malaria treatment.

Table 5: Dispenser's level of knowledge on ACT by sex, age, profession, experience in medicine dispensing and attended training (n=65)

Demographics		Level of Knowledge			Total	P value
		Poor	Moderate	Good		
Sex						
	Male	0(0%)	11(42.3%)	15(57.7%)	26	0.414
	Female	2(5.1%)	31(51.3%)	17(43.6%)	39	
Age(years)						
	15-24	0(0%)	3(60%)	2(40%)	5	0.986
	25-34	1(4.8%)	9(42.9%)	11(52.3%)	21	
	35-44	1(5.2%)	9(47.4%)	9(47.4%)	19	
	45 and above	0(0%)	10(50%)	10(50%)	20	
Profession						
	Pharmacist	0(0%)	2(40%)	3(60%)	5	0.007
	Pharmaceutical technician	0(0%)	2(13.3%)	13(86.7%)	15	
	Pharmaceutical assistant	0(0%)	2(40%)	3(60%)	5	
	ADDO dispenser	1(3.1%)	20(62.5%)	11(34.4%)	32	
	Clinical officer	0(0%)	0(0%)	1(100%)	1	
	Nursing officer/nurse midwife	0(0%)	2(100%)	0(0%)	2	
	Nurse assistant	1(50%)	1(50%)	0(0%)	2	
	Others	0(0%)	2(66.7%)	1(33.3%)	3	
Experience in medicine dispensing						
	Less than 1 year	1(7.1%)	6(42.9%)	7(50%)	14	0.825
	1 to 5 years	0(0%)	10(58.8%)	7(41.2%)	17	
	6 to 10 years	1(5.6%)	7(38.9%)	10(55.6%)	18	
	11 years and above	0(0%)	8(50%)	8(50%)	16	
Attending training						
	Yes	0(0%)	0(0%)	5(100%)	5	0.066
	No	2(3.3%)	31(51.7%)	27(45%)	60	

Results show that, there is no relation between knowledge and sex of respondents (P value= 0.414). However, males were more knowledgeable compared to females as 57.7% of males had good knowledge compared 43.6% of females. Study Findings show that, there is relation between level of knowledge and professional of the dispenser (P value =0.007). Pharmaceutical technicians and clinical officer were more knowledgeable than other cadres, as 86.7% of pharmaceutical technicians had good knowledge. There was only one clinical officer who participated in the study and he had good knowledge.

3.2.3 Knowledge on IPTp.

Table 6 is the summary of positive responses to questions which aimed at assessing level of knowledge of all dispensers in private medicines outlets on IPTp.

Respective positive responses to questions asked includes (a) interval recommended for the pregnant mother to take SP for IPTp it is every clinic visit from second trimester. (b) SP is the recommended medicine for IPTp. (c) Three tablets of SP are taken per dose. (d) There is no alternative medicine for IPTp where SP is contraindicated. (e) When SP is used for treatment of malaria rather than IPTp only it may result to SP resistance for IPTp.

Table 6: General responses to questions which assess knowledge on IPTp

Questions	Respondents with positive responses (%age)		
	Pharmacie s(n=32)	ADDOs (n=33)	TOTAL (n=65)
What is the interval recommended for the pregnant mother to take SP for IPTp	6.3	6.1	6.2
What is the medicine recommended for IPTp	96.9	93.9	95.4
How many tablets of SP pregnant mother should take per dose?	68.8	69.7	69.2
SP can be given either on an empty stomach or with food	34.4	24.2	29.3
SP can be administered safely with combined ferrous sulphate 200mg+ folic acid 0.25mg (FeFo)	53.1	27.3	40.2
What is the alternative medicine for IPTp where SP is contraindicated	62.5	42.4	52.3
What will be the effect of administering SP for the use other than IPTp e.g for treatment of uncomplicated malaria	53.1	24.2	38.6

Table 6 indicates that, most of respondents' i.e 95.4% knew that SP is the medicine recommended for IPTp. Very few respondents were able to mention interval recommended for pregnant mother to take SP for IPTp, as only 6.3% of Pharmacy dispensers and 6.1% of ADDO dispensers responded correctly.

Figure 5 below show responses from Pharmacies and ADDOs to the question about alternative medicine for IPTp where SP is contraindicated.

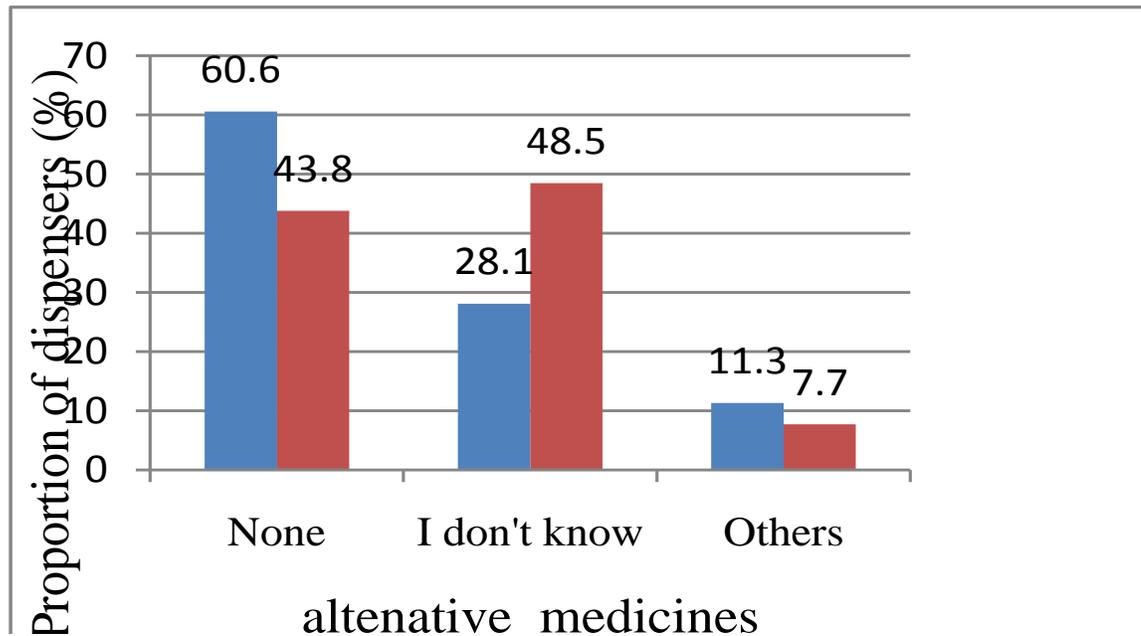


Figure 5: Dispenser's responses on alternative medicine for IPTp where SP is contraindicated, in Pharmacies (n=32) and ADDOs (n=33)

As shown in the figure above 48.5% of dispensers in ADDOs and 28.1% of dispensers in pharmacies said that, they don't know the alternative medicine for IPTp. Others include ALU, Quinine and DPQ.

Figure 6 below show responses from Pharmacies and ADDOs to the question about effect of administering SP for treatment of uncomplicated malaria.

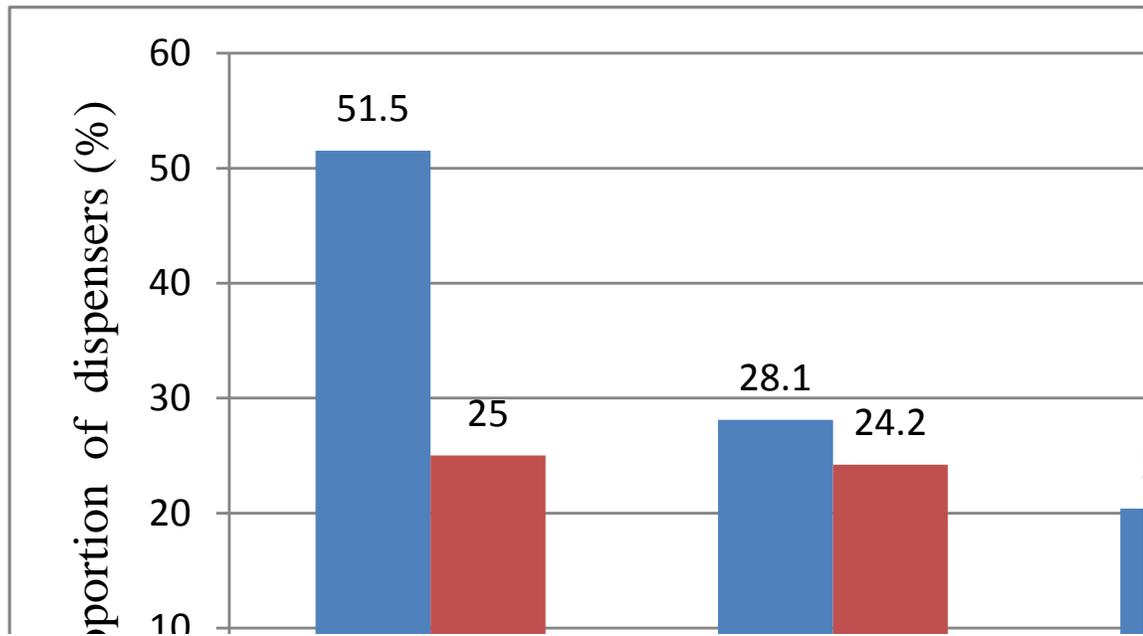


Figure 6: Dispenser's responses on the effect of administering SP for treatment of uncomplicated malaria, in Pharmacies (n=32) and ADDOs (n=33)

As shown in the figure above; 24.2% of ADDOs and 28.1% of pharmacies said that, there is no effect of using SP for treatment of malaria. 50.8% of ADDOs and 20.4% of Pharmacies gave out other responses which include; treatment failure, allergic reactions to patient; some respondents said they don't know.

Figure 7 below gives the summary of knowledge level on IPTp of all respondents.

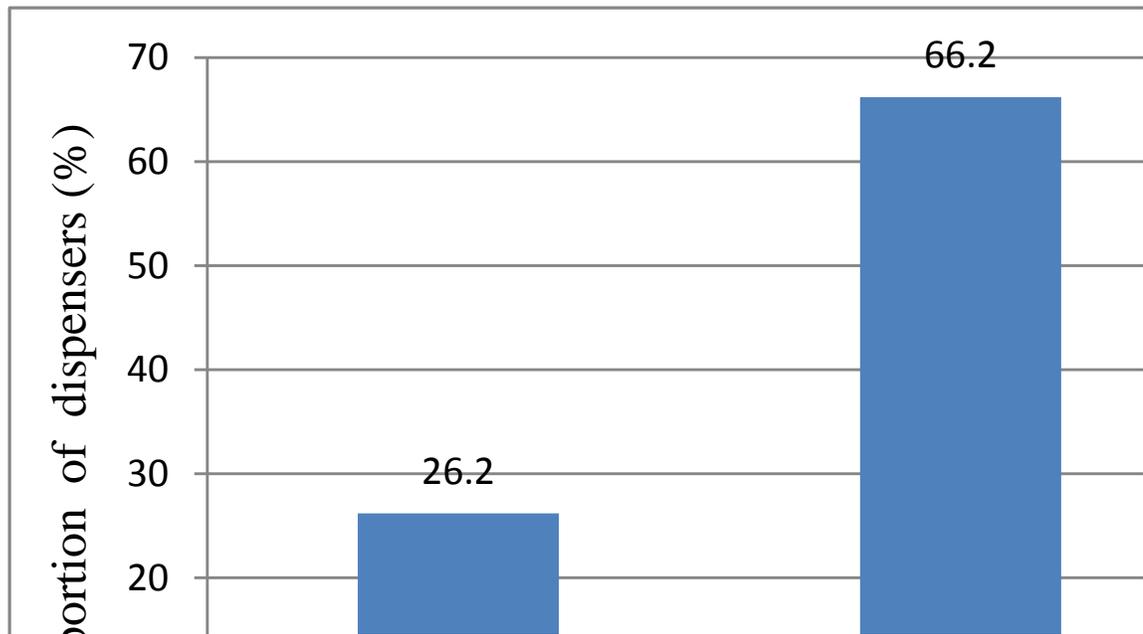


Figure 7: Dispenser's knowledge levels on IPTp, in all medicine outlets (n=65)

The level of knowledge was classified as poor, moderate and good as shown in table 1. Study findings show that, few respondents had good knowledge i.e 7.6% responding positively 6 to 7 questions.

Figure 8 below show knowledge level on IPTp for dispensers in Pharmacies and ADDOs.

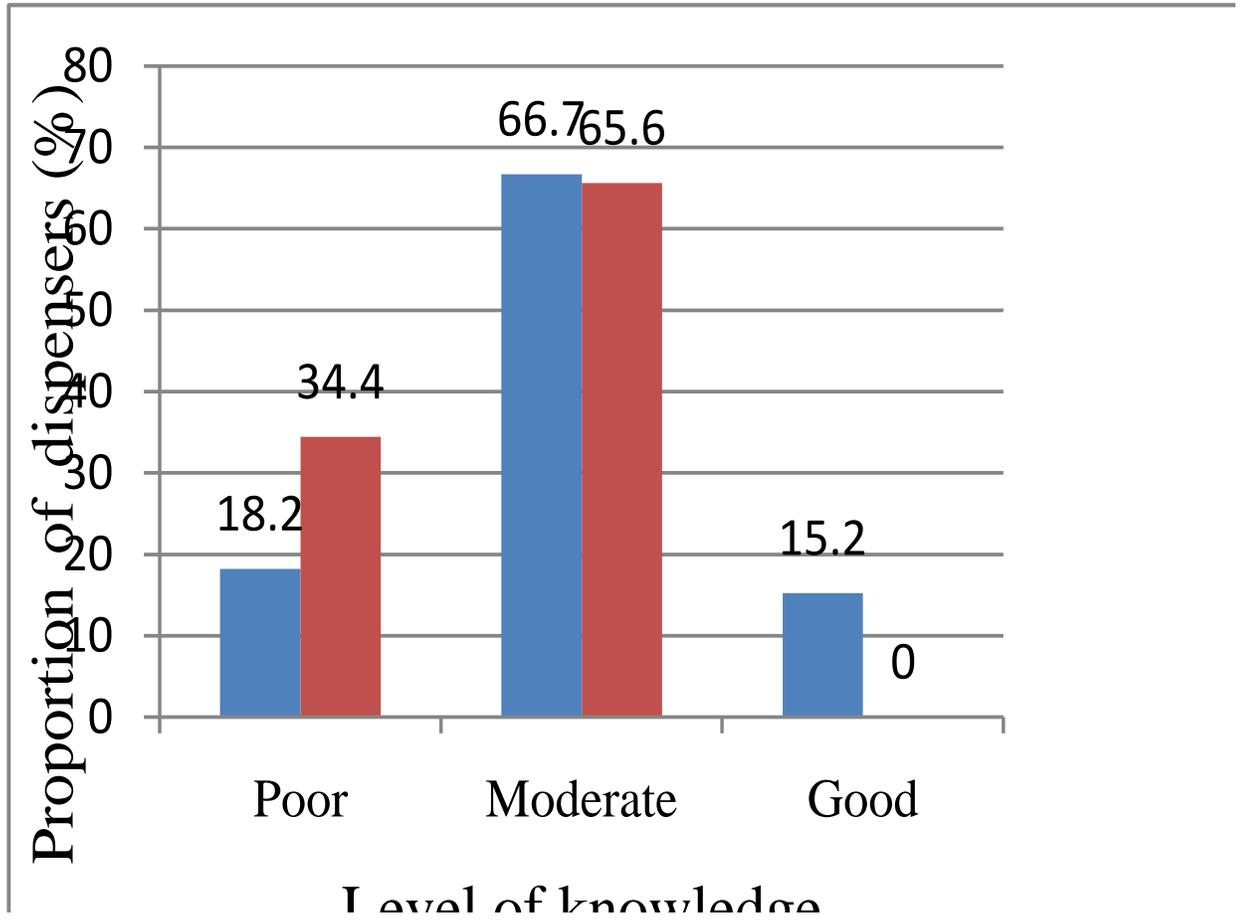


Figure 8: Dispenser’s knowledge level on IPTp, in ADDOs (n=33) and Pharmacies (n=32)

Study finding shows that, none of ADDO respondent had good knowledge while only 15.2% of respondents from pharmacies had good knowledge.

There is relationship between type of the outlet and knowledge level of participants on IPTp, (P value= 0.04).

Table 7 show level of knowledge of dispensers by social demographics i.e sex, age, profession of the dispenser, experience in dispensing and if the dispenser attended training of malaria treatment.

Table 7: Dispenser's level of knowledge on IPTp by sex, age, profession, experience in medicine dispensing and attended training (n=65)

Demographics		Level of Knowledge			Total	P value
		Poor	Moderate	Good		
Sex						
	Male	7(26.9%)	16(61.5%)	3(11.6%)	26	0.668
	Female	2(5.1%)	31(51.3%)	17(43.6%)	39	
Age(years)						
	15-24	3(60%)	2(40%)	0(0%)	5	0.391
	25-34	4(19.1%)	15(71.4%)	2(9.5%)	21	
	35-44	5(26.3%)	14(73.7%)	0(0%)	19	
	45 and above	5(25%)	12(60%)	3(15%)	20	
Profession						
	Pharmacist	1(20%)	3(60%)	1(20%)	5	0.075
	Pharmaceutical technician	2(13.3%)	9(60%)	4(26.7%)	15	
	Pharmaceutical assistant	1(20%)	4(80%)	0(0%)	5	
	ADDO dispenser	10(31.2%)	22(68.8%)	0(0%)	32	
	Clinical officer	0(0%)	1(0%)	0(0%)	1	
	Nursing officer/nurse midwife	1(50%)	1(50%)	0(0%)	2	
	Nurse assistant	2(100%)	0(0%)	0(0%)	2	
	Others	0(0%)	3(100%)	0(0%)	3	
Experience in medicine dispensing						
	Less than 1 year	5(35.7%)	8(57.1%)	1(7.2%)	14	0.598
	1 to 5 years	4(23.5%)	8(70.6%)	1(5.9%)	17	
	6 to 10 years	5(27.8%)	13(72.2%)	0(0%)	18	
	11 years and above	3(18.8%)	10(62.4%)	3(18.8%)	16	
Attended training						
	Yes	0(0%)	5(100%)	0(0%)	5	0.416
	No	17(28.3%)	38(63.4%)	5(8.3%)	60	

Study findings show that, there is no relation between level of knowledge and sex of respondents (P value= 0.668). However females were more knowledgeable than males, as 43.6% of females have good knowledge compared to 11.6% of males. Results show that, there is no relationship between level of knowledge and professional of the dispenser (P value=0.075). However Pharmacists and Pharmaceutical technicians were more knowledgeable than other cadres, as 20% of pharmacists and 26.7% of pharmaceutical technicians had good knowledge while none of other cadres had good knowledge.

3.2.4 Types of anti malarial medicines available

Table 8 indicates proportions of medicine outlets which had respective anti malarial in stock at time of the interview.

Table 8: Types of Anti malarial medicines available in medicine outlets

TYPE OF THE MEDICINE	Proportions of medicines outlets (%age)		
	Pharmacies (n=32)	ADDOS (n=33)	Total (n=65)
ALU 20mg/120mg tablets	90.6	87.9	89.2
ALU dispersible 20mg/120 mg tablets	81.3	54.5	67.9
ALU 3mg/18mg per1mil Suspension	53.1	6	29.6
Quinine 100mg/5mils Syrup	90.6	51.5	71.1
Quinine 300mg Tablets	65.6	18.2	41.9
Sulfadoxine/pyrimethamine 500mg/25mg tablets	84.4	69.7	77.1
sulfamethoxypyrazine/pyrimethamine 500mg/25mg tablets	78.1	69.7	73.9
Dihydroartemisinin/Piperaquine 40mg/320mg tablets	87.5	24.2	55.9
Artemisinin/ piperazine 80mg/400mg tablets	87.5	24.2	55.9
Artesunate/ mefloquine 200mg/250mg tablets adults	53.1	0	26.6
Artesunate/ mefloquine 50mg/125mg pediatrics dispersible tablets	37.5	0	18.8
Artesunate/amodiaquine 100mg/270mg adult tablets	59.4	6	32.7
Artesunate/amodiaquine 25mg/67.5mg infant tablets	37.5	6	21.8
Artesunate/amodiaquine 50/135mg children tablets	37.5	6	21.8
Atovaquone/proguanil 100mg/250mg tablets	9.4	0	4.7

The table 8 shows that; ALU tablets adult formulation was available in most of private medicine outlets, as it was stocked by 90.6% of Pharmacies and 87.9% of ADDOs at the time of interview. Atovaquone / proguanil tablets were the least available anti malarial, as it was available in 9.4% of Pharmacies and no ADDO shop had it in stock at the time of the interview. SP tablets were found in 84.4% of pharmacies and 69.7% of ADDOs.

3.3 Results from Simulated Client Form

3.3.1 Proportion of dispensers in medicine outlets who dispense ALU for treatment of uncomplicated malaria in adults.

After simulated clients explained their malaria symptoms, dispensers in 62 medicine outlets advised them various anti malarials to be used, figure 9 below shows anti malarial medicines which dispensers advised simulated clients who said that they have malaria and ask for the over the counter treatment.

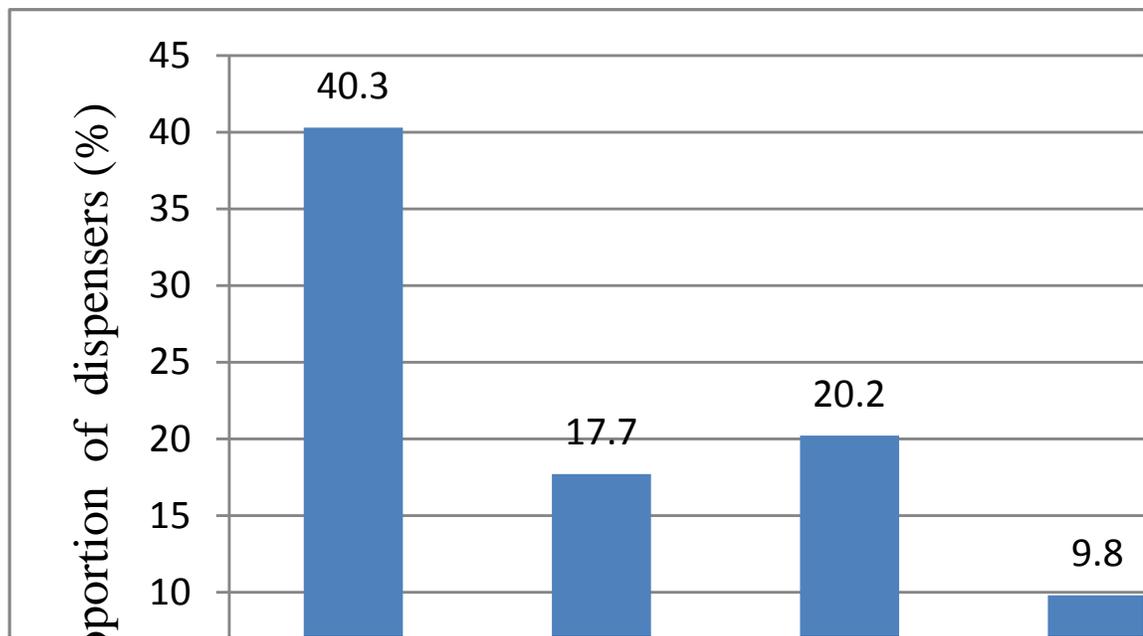


Figure 9: Medicines advised by dispensers to simulated clients in all medicine outlets (n=62)

Figure 9 shows that, most of dispensers of private medicine outlets i.e 40.3% advised the use of ALU and few of them i.e 5% only advised the use of SPP.

Figure 10 below shows percentage of medicines which dispensers in Pharmacies and ADDOs, advised simulated clients when they said that, they had symptoms of malaria and ask for the over the counter treatment.

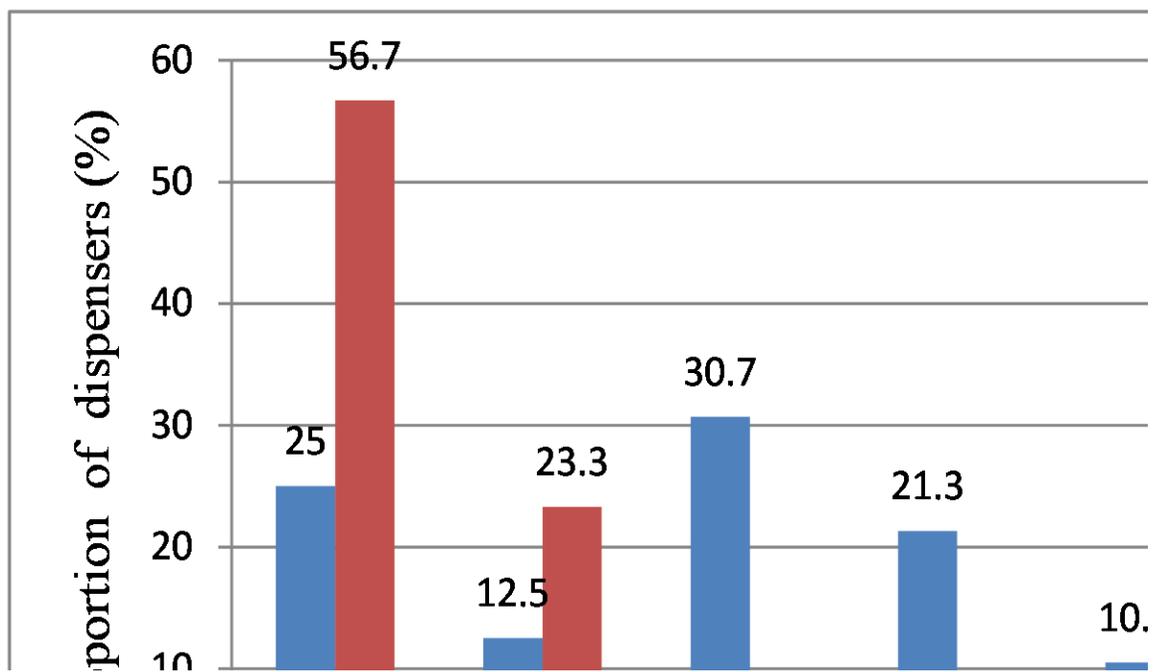


Figure 10: medicines advised by dispensers to simulated clients, in Pharmacies (n=32), ADDOs (n=30)

Results show that, there is relationship between type of the medicine outlet and the anti malarial advised by the dispenser. $\chi^2= 11.544$; P value =0.003. Most of dispensers in ADDOs i.e 56.7% advised the use of ALU while most of dispensers in Pharmacies i.e 30.7% of dispenser's advised the use of DPQ.

Out of all 62 outlets; 11 outlets advised simulated clients to use SP while other 51 outlets advised simulated clients' medicine other than SP. Thus simulated clients requested those 51 outlets to give them SP since it is single dose medicine. Some dispensers agreed while others disagreed. The table 9 below shows dispenser's responses to client request after simulated client demanded for SP.

Table 9: Dispenser's responses after simulated clients demand for SP (n=51)

Type of outlet	Dispenser's responses		TOTAL
	Agree	Disagree	
PHARMACY	25(89.3%)	3(10.7%)	28(100%)
ADDO	18(78.3%)	5(21.7%)	23(100%)
TOTAL	43(84.3%)	8(15.7%)	51(100%)

Results show that, after simulated clients demanded for SP in 51 outlets which initially advised other anti malarials, only 8 outlets (15.7%) disagreed to dispense it. There is no relation between type of medicine outlet and dispenser's response, P Value =0.442. Following dispenser's advice and simulated client's demand for SP, various anti malarials were finally dispensed.

Figure 11 below shows which anti malarial medicines were actually dispensed to simulated clients.

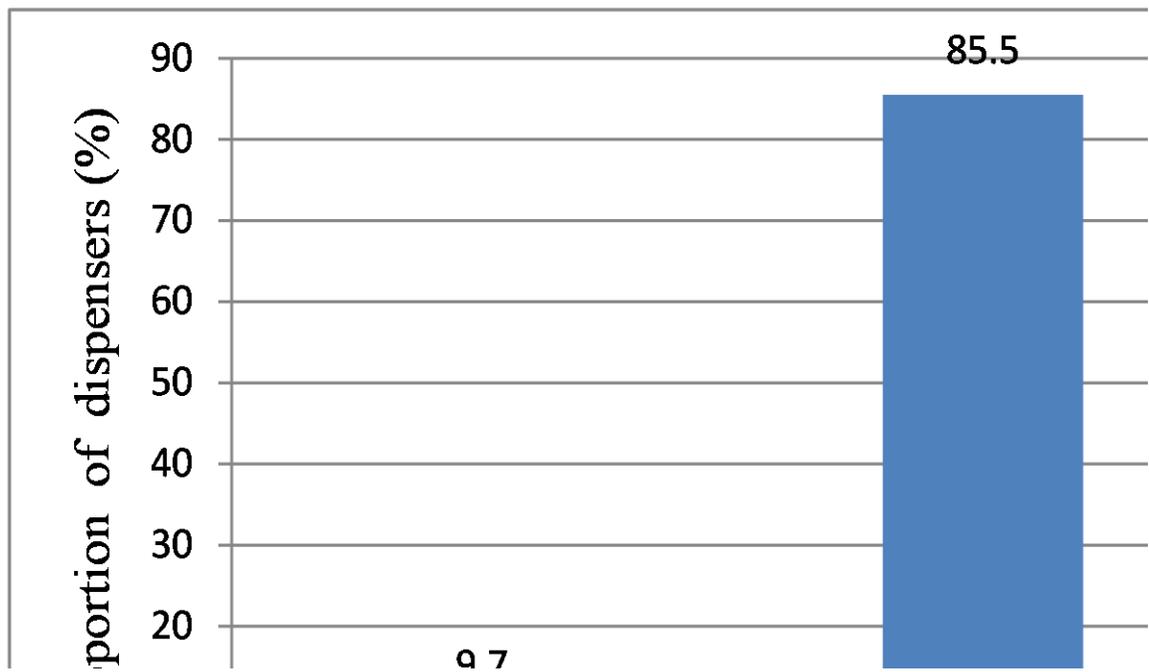


Figure 11: Medicines dispensed to simulated clients in all medicine outlets (n=62)

The Study revealed that, only 9.7 % of medicine dispenser's dispensed ALU to simulated client. Compared to Null hypothesis value i.e 50%, this proportion is significantly low than the proportion of dispensers who didn't dispense ALU, ($Z=6.346$; P value <0.0001).

Most of medicine dispenser's i.e 85.5% dispensed SP, while only 4.8% advised the use of other medicines which were DPQ, SPP and Artemisinin/ Piperazine (AP).

Figure 12 show anti malarial medicines dispensed to simulated clients in Pharmacies and ADDOs following dispenser's advice and clients demand for SP.

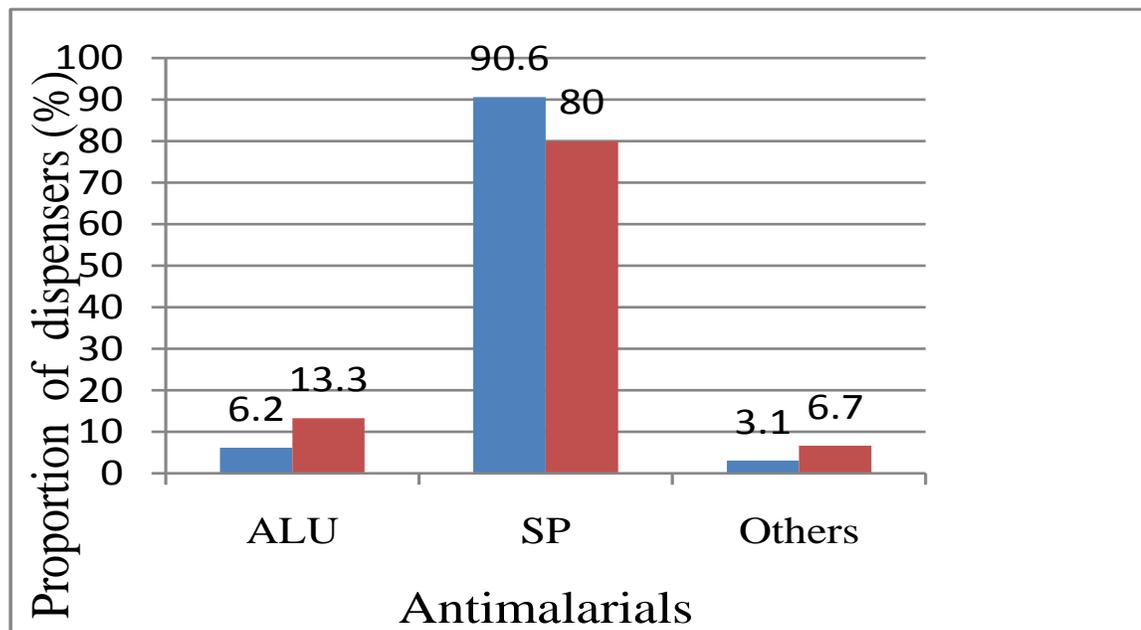


Figure 12: Medicines dispensed to simulated clients, in Pharmacies (n=32), ADDOs (30)

Results show that, most medicine dispensers from both Pharmacies and ADDOs, i.e 90.6% of Pharmacies and 80% of ADDOs dispensed SP to simulated client even though SP is reserved for IPTp. There is the no relationship between type of the medicine outlet and the medicine dispensed to simulated clients, P value= 0.466.

COMBINED RESULTS FROM BOTH STRUCTURED QUESTIONNAIRE AND SIMULATED CLIENT FORM

The table below shows the relationship between proportion of dispensers who know the recommended first line medicine in treatment of uncomplicated malaria, and the one which is reserved for IPTp; and what was actually dispensed to the simulated clients after they explained their symptoms and demanded for SP.

Table 10: Dispenser's knowledge and practice on ACT policy for treatment of uncomplicated malaria in adults

	KNOWLEDGE		PRACTICE	
	Dispensers who know that ALU is the recommended first line medicine for treatment of uncomplicated malaria	Dispensers who know that SP is the recommended medicine for IPTp	Dispensers who dispensed ALU to simulated clients	Dispensers who dispensed SP to simulated clients
PHARMACY	32(100%)	31(96.9%)	2(6.2%)	29(90.6%)
ADDO	30(90.9%)	31(93.9%)	4(13.3%)	24(80%)
OVERALL	62(95.4%)	62(95.4%)	6(9.7%)	53(85.5%)

Results show that; more than ninety five percent i.e 95.4% out of all dispensers who participated in this study know that, ALU is the first line medicine for treatment of uncomplicated malaria but only 9.7% dispensed it to simulated clients.

3.4 Results from Focus Group Discussion (Guided)

3.4.1 Focus group discussion with participants from selected medicines outlets

The focus group discussion was conducted in private medicines outlets in order to explore their perceptions, and challenges which they face when implementing ACT policy for treatment of uncomplicated malaria.

a) **Pharmacy dispenser's perceptions and challenges**

None of the participants had attended training or seminar on treatment of uncomplicated malaria. One of them said:

“The government have forgotten private sector, there are new changes in malaria treatment but we didn't receive any training, we depend on reading drug leaflets. So ministry should conduct trainings to private sector.” (Participant 7)

All participants mentioned ALU as the first line medicine, in general they didn't know if DPQ is second line medicine for treatment of uncomplicated malaria. SP was mentioned by all, that it is the medicine for IPTp. When asked why SP was prohibited to be used for malaria treatment, majority of respondents didn't know the reason. One of them said:

“SP is not supposed to be used for treatment of malaria because of allergic reaction to patients, but it doesn't have allergic reaction to pregnant mothers due to their antibodies.” (Participant 1)

When asked which anti malarial medicine they prefer to dispense to clients in the over the counter treatment of malaria; ALU and DPQ were mentioned. One of them commented:

“I prefer to advise my clients to use ALU, but if client don't prefer ALU cause have many tablets, I will give him/her medicine of his/her choice.” (Participant 8)

On general overview in private medicine outlets, SP is mainly dispensed for treatment of uncomplicated malaria than IPTp. When medicines dispenser's asked why they still dispense SP for the treatment of uncomplicated malaria even though it is prohibited,

they had various responses such as; lack of knowledge to dispensers, inadequate training, lack of awareness to the community that SP is reserved for IPTp only, low cost of SP compared to ALU and other available anti malarial, patient demand for single dose medicine, complicated dosing schedule of ALU and clients belief that they can only be treated by SP. One of them said:

“Reasons are poor compliance to ALU as it has a lot of tablets; ALU has high cost and is more needful e.g patients have to eat fat food before taking ALU. If the patient has only 1000tsh you can’t give him/her ALU which is more than 2000Tsh.”(Participant 9)

Private medicine outlets face the following challenges when they advise clients to use ALU for those who ask for over the counter treatment of uncomplicated malaria: (1) Some clients complains that ALU has high price, many tablets and complicated dosing schedule so they need single dose medicine. (2) There are clients who believe they can be treated with SP only, for them there is no other medicine which is better than SP. (3) Other clients says that, ALU always fails to treat them (4) Some clients believe ALU has low quality/ substandard as there are lot brands of ALU, they believe ALU with leaf symbol is the best than those which are currently available.

One of respondents said: *“there are clients who believe they can be treated with SP only, for them there is no other medicine which is better than SP. There are clients who create habit of using sp for treatment of uncomplicated malaria; it takes them only one day to be cured”*. (Respondent 2)

b) ADDO dispenser’s perceptions and challenges

None of the participants had attended training or seminar on treatment of uncomplicated malaria. All participants mentioned ALU as the first line medicine, in general they didn’t know if DPQ is second line medicine for treatment of uncomplicated malaria. SP was mentioned by all that is the medicine for IPTp. When asked why it was prohibited to be used for treatment, only one respondent knew the reason. One of them said:

“SP is reserved for pregnant mothers because it kills malaria parasite available in the placenta.” (Participant 10)

When asked which anti malarial medicine they prefer to dispense to the client for the over the counter treatment of malaria, all of them said ALU. However SP is mainly dispensed for treatment of uncomplicated malaria than IPTp. Reasons given for the SP to be still dispensed by private facilities for the treatment of uncomplicated malaria even though it is prohibited, includes; SP still treat some patients, failure of ALU, clients like to use medicine which are used to, single dose and few number of tablets, SP is cheap compared to ALU, poor adherence to ALU, patient choice, lack of awareness to the community that SP is reserved for IPTp only. One of them said:

“Clients complain are not treated by ALU but treated by SP; also many clients prefer medicine with few tablets.” (Participant 10)

Private medicine outlets face the following challenges when they advise clients to use ALU for those who ask for over the counter treatment of uncomplicated malaria: Many clients like single dose medicine so dispensers have to take much time to educate them on the use of ALU, clients demand and pressure, other clients say that ALU always fails to treat them, high price of ALU and its unstable availability, some clients fails to understand direction for using ALU. One of respondents said:

“Most of our clients do not prefer to use ALU because of its high price, they can't afford to buy one dose of ALU for Tsh2500/= - 3000/=, some clients request to buy half course or even 4 tablets only”. (Respondent 7)

CHAPTER FOUR

4.0 DISCUSSION

4.1 Dispenser's knowledge in private medicines outlets on ACT policy

The use of Artemisinin based combinations is recommended for treatment of uncomplicated malaria in all age groups, except during the first trimester of pregnancy (WHO, 2009). Dispenser's knowledge in malaria treatment is vital in implementation of ACT Policy. What was revealed from the study is that majority of dispensers in the private facilities had good knowledge (49.2%) while only 3.1% had poor knowledge on ACT policy, as shown in the Figure 3. Similar study which have been done in Burundi revealed that more than 50% of retailers were familiar with ACT, with the highest knowledge in the charitable sector (90%) and the lowest in the private sector (55%), (Diap, 2010).

As show in Table 4; More than ninety five percent i.e 95.4% of dispensers knew that ALU is the first line medicine for treatment of uncomplicated Malaria while only 22% knew that DPQ is the second line, 32% mentioned Quinine tablets as the second line. This entails that, they are not aware of changes in malaria treatment as per current guideline of 2013. Indication for the use of second line is not well known to dispensers in private medicine outlets. About thirty six percent i.e 36.4% of dispensers in ADDOs and 68.8% of dispensers in Pharmacies knew that, DPQ should be used when ALU is contraindicated due to allergic reactions or when it has failed. Lack of trainings to private sector as part of implementation of the policy is one of contributing factor for low awareness observed. From this study only 7.7% (Table 2) of respondents had ever attended training on malaria treatment.

From this study, it was revealed that only 56.3% of dispensers in Pharmacies and 24.2% dispensers in ADDOs (Table 4), knew that ALU should be taken with fat meals so as to increase its absorption. Dispensers who do not know the importance of taking ALU with fat foods may provide inadequate instructions to clients that may lead to underperformance of ALU. Taking ALU without consuming milk or fatty food has

significant impact on its bioavailability (Buck, 2010). Only 40.6% of Pharmacy dispensers and 18.2% of ADDO dispensers (Table 4) knew that Quinine is the recommended medicine for treatment of uncomplicated malaria in first trimester pregnancy. Most of the respondent's i.e 72.7% in ADDOs and 50% in Pharmacies (Figure 1) mentioned SP as the drug of choice for treatment of malaria in pregnancy, which indicate that the use of SP in IPTp only is not clear.

ALU is widely used for uncomplicated malaria during the second and third trimester of pregnancy. Because of the suspected teratogenic effects of artemether during the first trimester, quinine is used in early pregnancy unless the risks outweigh the benefits (Kamuhabwa, 2011). Study findings show that; 65.5% of Pharmacy dispensers and less than fifty percent i.e 42.4% of ADDO dispensers (Table 4), knew that ALU is not recommended to first trimester pregnancy. This entails that, it is more likely for a pregnant mothers in first trimester who seek over the counter medication for malaria treatment in ADDOs to get ALU, which will increase the chance to endanger their fetus.

Findings shows that; there is no statistical difference (p value >0.05) in level of knowledge on ACT policy for treatment of uncomplicated malaria between those who attended trainings and those who didn't. However all dispensers who attended training have good knowledge, while only 45% for those who did not had good knowledge (Table 5). This entails that, there is the need for more trainings to dispensers in private medicine outlets. All of participants in focus group discussion said that, they have never been involved in trainings and most of them didn't know about changes in malaria treatment as per current guideline

When the level of knowledge on ACT policy for treatment of uncomplicated malaria was related with professional of dispensers (Table 5), Pharmaceutical technicians were found to be more knowledgeable than other cadres, where 86.7% had good knowledge. However 45.5% of dispensers in Pharmacies were pharmaceutical technicians. Less than forty percent i.e 34.4% of ADDO dispensers had good knowledge. Training manual for ADDO dispensers have special topic which explain in detail about malaria treatment.

This contributes to knowledge level for ADDO dispensers, though most of dispensers were trained before change in malaria treatment guideline.

4.2 Knowledge of dispensers in private medicines outlets on IPTp.

SP is the current drug of choice for IPTp, it is recommended to be administered in every antenatal care visit from the second trimester of pregnancy. The study aimed at assessing the level of knowledge of dispensers in private medicine outlets on IPTp. The study finding shows that, most of dispensers in private medicine outlets had inadequate knowledge on IPTp. Very few participants i.e 6.2% (Table 6), knew the interval recommended for pregnant mothers to take SP for IPTp. Lack of trainings to dispensers working in private medicine outlets and qualifications of dispensing personnel may have contributed to their inadequate knowledge. Less than ten percent i.e 7.7% (Table 2) of interviewed participants and none of those who participated in focus group discussion attended trainings on malaria treatment. From this study, it was revealed that there is no relation between knowledge level on IPTp and profession of dispenser with p value >0.05 . However pharmaceutical technicians were more knowledgeable than all other cadres. There is relationship between level of knowledge and type of the medicine outlet, whereby; 15.2% (Figure 8) of dispensers in pharmacies were found to have good knowledge while none of ADDO dispensers had good knowledge with p value <0.05 .

IPTp has recently been shown to be highly cost effective for both prevention of maternal malaria and reduction of neonatal mortality in areas with moderate or high malaria transmission (Sicuri et al., 2010). Despite the spread of SP resistance, IPTp continues to provide significant benefit, resulting in protection against both neonatal mortality (protective efficacy 18%) and low birth weight reduction by 21% under routine program conditions (Eisele et al., 2012).

Few study participants i.e 38.6% (Table 6) knew that, the use of SP for treatment of uncomplicated malaria instead of reserving it for IPTp may lead to SP resistant, which will in turn compromise its effectiveness. In focus group discussion, most of participants when asked why SP should not be used for treatment of uncomplicated malaria, they

failed to mention that, it is because of change in treatment policy from SP to ALU due to treatment failure of SP. Most of them knew that it is because of allergic reaction of SP. This entails that; dispensers in private medicine outlets may irrationally dispense SP for malaria treatment because they do not know its impact; also there is lack of awareness for the change in treatment policy and guidelines.

4.2 Types of anti malarial medicines available in private medicine outlets.

The aim of identifying types of anti malarial medicines available in private medicine outlets at the time of data collection, was to complement the objective of determining proportion of dispensers in medicine outlets who dispense correct recommended first line anti malaria for treatment of uncomplicated malaria in adults. It was necessary to identify availability of anti malarials in order to rule out the fact that simulated clients did not receive ALU as the recommended medicine because of its unavailability and not because of malpractice. In the year 2000, Cambodia was the first country to switch to an ACT, a loose combination of artesunate and mefloquine (WHO 2002).

Up to date Tanzania have various ACT formulations which include ALU, DPQ, artemisinin/piperaquine, artesunate/ mefloquine and artesunate/amodiaquine. ALU adult tablets were available in 89.2% of all interviewed facilities while SP tablets were available in 77.1% (Table 8). DPQ tablets as the recommended second line were available in 24.2% of ADDOs (Table 8), even though it is not permitted to be available as it is not in the list of permitted medicine to be available in ADDOs. This is the challenge in areas where Pharmacies are not available and patients have indication to use second line medicine; due to either failure of ALU or being allergic to one of ALU components. During simulation to determine practice of medicine outlets, simulated clients reported price of medicines. It was revealed that SP is the cheapest medicine with price ranging from Tsh1000/= to 1500/=, ALU tablets ranged from Tsh2500/= to 3000/= while DPQ ranged from Tsh10000/= to 12000/=. In focus group discussion most of participants reported that there is unstable availability and high price of ALU which lead to irrational dispensing and use of SP for treatment of uncomplicated malaria.

4.3 Proportion of dispensers in medicine outlets who dispense ALU for treatment of uncomplicated malaria in adults.

Private medicines outlets are important source for treatment of uncomplicated malaria including dispensing of anti malarials for self medication. ALU is the recommended first line anti malarial for treatment of uncomplicated malaria. In this study, proportion of dispensers in medicine outlets who dispense ALU, SP and other anti malarials for over the counter treatment of malaria were determined. As discussed above, only 3.1% (Figure 3) of dispensers had poor knowledge on ACT policy, the rest have moderate to good knowledge but they do not practice what they know.

Study results show that 40.3% (Figure 9) of all medicine outlets advised simulated clients to use ALU, but after simulated clients requested for SP since it is a single dose medicine, 84.3% (Table 9) of those who initially did not advice on the use of SP agreed to dispense it. This entails that, without client pressure almost forty percent of private medicine outlets dispensers would dispense ALU to clients who seek over the counter treatment of malaria. More than ninety five percent i.e 95.4% out of all dispensers who participated in the interview, and all who appeared in focus group discussion know that ALU is the first line medicine for treatment of uncomplicated malaria. However, 9.7% only dispensed ALU to simulated clients, while 85.5% dispensed SP (Table10). Difference in proportion between advised medicines and dispensed medicines were due to patient demand. However the percentage of anti malarial dispensed could have been different if availability of both ALU and SP could be 100%. Availability of SP was reported to be 77.1% (Table 8) while it was dispensed by 85.5%; reason for this difference was due to out of stock at the time of interview because simulation and interview were done on different days to avoid dispensers to be suspicious. The second reason is; some dispensers thought that SP is totally prohibited and it should not be available in private market, so they feared to reveal the truth about its availability to the interviewer. In focus group discussion it was reported that, dispensers grant the request of their customers; they reported client's choice as the factor of dispensing SP instead of ALU.

There is relationship between type of the medicine outlet and anti malarial advised by dispensers. There is high chance for the patients to use ALU when she/he visit ADDO for self medication compared to when she/he go to the pharmacy. As it was revealed from this study, 56.7% of dispensers in ADDOs advised the use of ALU while 62.5% of dispensers in Pharmacies advised other anti malarials which were DPQ, AP, AAQ and SPP (Figure 10). High availability of other medicines with high price in Pharmacies than ADDOs is one of the contributing factors for the difference observed. However, there is no relationship between the type of the medicine outlet and anti malarial dispensed by dispensers with $p>0.05$. This indicates that both dispensers in Pharmacies and ADDOs are driven by patient demand which lead to irrational dispensing. From focus group discussion, dispensers from both pharmacies and ADDOs mentioned patient demand as factor for irrational dispensing. Other similar studies indicate similar results, e.g a study done in Kenya by Rusk in 2012 to determine if anti malarial drug knowledge predict anti malarial dispensing practice in drug outlets revealed that, most of the medicine retailers surveyed (65%) were able to identify ALU as the Kenyan Ministry of Health recommended first line anti malarial therapy for uncomplicated malaria. However, the proportion of medicine retailers who recommended the correct treatment was low. Only 48% would recommend ALU to adults. It was discovered that customer demand has an influence on retailer behavior. Retailer training and education were found to be correlated with anti malarial drug knowledge, which in turn is correlated with dispensing practices (Rusk et al., 2012).

4.4 Perceptions and challenges facing dispensers of private medicine outlets

The focus group discussion was conducted in private medicines outlets in order to explore their perceptions, and challenges which they face when implementing ACT policy for treatment of uncomplicated malaria. It was discovered from the study that; dispensers in private facilities know that ALU is the first line anti malarial and SP is for IPTp, but do not know the reason for the shift of policy from SP to ACT. Also they do not know the significance of dispensing SP for IPTp refill only. All participants in Focus group mentioned that, they prefer to advise their patients to use ALU. However the

actual practice differs as per results from simulated clients. Even though the aim of SP to be allowed in private market is for IPTp refill, it was evident as it was mentioned by all participants that, SP is mainly dispensed for treatment of uncomplicated malaria instead of being reserved for IPTp. This will jeopardize its effectiveness in IPTp if the situation will remain the same. Dispensers had different opinions in effectiveness of ALU, even though most of them reported that, it is effective in treating Malaria with some cases of reported treatment failure. Hence they requested the MoHSW and other stakeholders to research on its effectiveness.

It was revealed from this study that, dispensers of private medicines outlets face the following challenges in ACT policy implementation; some clients are complaining that ALU has high price, cases of reported ALU failure, many tablets and complicated dosing schedule so they need single dose medicine. Other challenges being customers believe in SP to be the best medicine than ALU, clients demand and pressure. However the study done in Tanzania by Kabanywany; from patients perspective, show that upon proper pictorial instruction and making patient believe that ALU is effective in treatment of malaria 87.1% of patients found ALU easier to take and 87.7% believed that ALU was more effective than SP (Kabanywany et al., 2010).

Participants recommended that; the government should control price of ALU, ensure its availability and quality. Also they recommended that, MoHSW and other stakeholders should create awareness to the community about use of SP for IPTp only, in order to reduce challenges mentioned. Also to involve private sector in training and seminars whenever there are changes in policy.

CHAPTER FIVE

5.1 CONCLUSION AND RECOMMENDATION

Results of this study indicates that, majority of dispensers in private medicines outlets have moderate and good knowledge on ACT policy in treatment of uncomplicated malaria. ALU is the recommended first line medicine for malaria treatment in Tanzania, but there is low awareness of changes in second line from quinine tablets to DPQ tablets. Less than half of dispensers in private medicine outlets would advise the use of ALU for treatment of uncomplicated malaria. However, SP is still dispensed for malaria treatment rather than being reserved for IPTp. Knowledge does not predict the actual practice; SP is still dispensed for malaria treatment rather than being reserved for IPTp. Patient demand for a single dose medicine is one of driving factor for irrational dispensing and use of SP, other factors being affordability of SP and lack of awareness to the community that SP should be reserved for IPTp only.

Intermittent preventive treatment of malaria during pregnancy is a key intervention in the national strategy for malaria control in Tanzania. The study revealed that; there are few dispensers of private medicine outlets having good knowledge on IPTp which contribute to irrational dispensing of SP. This may result into SP developing resistance in IPTp, and compromise the effort of the Ministry of Health and Social Welfare in reducing prevalence of malaria in pregnancy.

5.2 Recommendations

5.2.1 Education approach

MOHSW and other stakeholders should conduct trainings and seminars to medicine dispensers of private outlets on malaria treatment and rational dispensing of SP, ALU and other anti malarial medicines. The MOHSW with collaboration of other stakeholders should provide enough copies of Standard Treatment Guidelines (STGs) and educative materials such as brochures and leaflets to dispensers of private medicine outlets about rational dispensing of ALU, SP and other anti malarial medicines. Information to the community regarding proper use of SP and ALU should be

disseminated through mass media. Dispensers should impart the acquired knowledge to their patients.

(ii) Managerial Approach

Both government and donors should engage private sector in the ACT policy implementation process.

(iii) Regulatory approach

TFDA should prohibit availability of SP to private medicine outlets and instead it should be available in Private and public health facilities with Antenatal care clinics only.

5.2.2 Areas for further research

- The study focused on private medicines outlets located in Mwanza region, further research can be carried out to other regions to assess the magnitude of the problem.
- Other studies can be done to find out the reported unstable availability of ALU and extent of ALU failure rate in treatment of uncomplicated malaria.
- As part of intervention TFDA has asked pharmaceutical manufactures to write the label on SP package which will indicate that is for IPTp only. Once those labeled batches enter into the market, other study could be done to compare the practice with what has been reported in this study.

5.3 Study Limitations

The major limitation of this study is that the findings were restricted to only dispensers and private facilities of only one region. The findings would have been more meaningful if the study was carried out in more than one region so that to get the actual magnitude of ACT policy implementation in the country. In addition information about dissemination of policy and guidelines for malaria treatment was not captured from the Ministry of Health and Social Welfare. Besides this the view of the National Drug Regulatory Authority was not sought in order to be able to clarify some of the issues such as reasons for availability of SP in ADDOs and Pharmacies.

REFERENCES

1. Bloland PB, Ettling M, Meek S (2000): Combination therapy for malaria in Africa, hype or hope? *Bull World Health Org*, 78:1378-1388.
2. Buck ML (2010): Artemether-Lumefantrine for the Treatment of Malaria in Infants and Children- Pharmacokinetics. *Pediatric Pharm*, 16:10.
3. Clinton Foundation (2008): Review of the private sector anti-malarial market in Tanzania.
4. Daniel WW (1999): *Biostatistics: A Foundation for Analysis in the Health Sciences*. 7th edition. New York: John Wiley & Sons.
5. Diap G, Amuas J, Boakye I, Sevcsik A, Pecoul B (2010): Anti-malarial market and policy surveys in sub-Saharan Africa, *Malar J*,9:1.
6. Eisele TP et al. (2012): Malaria prevention in pregnancy, birth weight and neonatal mortality-meta analysis of 32 national cross-sectional database in Africa. *The Lancet infection diseases*, 12(12): 942-949.
7. Festo C, Thomson R, Bruxvoort K, Kalolella A and Nchimbi H (2011): Determinants of access to ACTs and malaria diagnosis: results from a household survey in three regions in Tanzania. American Society of Tropical Medicine and Hygiene Poster Session: Ifakara Health Institute (IHI), London School of Hygiene and Tropical Medicine (LSHTM), and Centers for Disease Control and Prevention (CDC).

8. Goodman C, Brieger W, Unwin A, Mills A, Meek S, Greer G (2007): Medicine sellers and malaria treatment in sub-Saharan Africa: what do they do and how can their practice be improved? *Am J Trop Med Hyg*, 77:203-18.
9. Gallup JL, Sachs JD (2001): The economic burden of malaria. *Am J Trop Med Hyg*, 64:85-96.
10. Hamel MJ, Odhacha A, and Roberts JM, Deming MS (2001): Malaria control in Bungoma District, Kenya: a survey of home treatment of children with fever, bednet use and attendance at antenatal clinics. *Bull World Health Organ*, 79:1014-1023.
11. Hetzel MW, Dillip A, Lengeler C, Obrist B, Msechu JJ, Makemba AM, et al (2008): Malaria treatment in the retail sector: Knowledge and practices of drug sellers in rural Tanzania. *BMC Public Health*, 8:157.
12. Jimoh, A., Sofola O., Petu, A., and Okorosobo T (2007): Quantifying the economic burden of malaria in Nigeria using the willingness to pay approach. *Cost effectiveness and Resource Allocation*, 5(1):6.
13. Kabanywanyi A, Lengeler C, Kasim P, King S et al, (2010): Adherence to and acceptability of artemether-lumefantrine as first-line anti-malarial treatment: evidence from a rural community in Tanzania. *Malar J*, 9:48.
14. Kamat VR, Nyato DJ (2010): Soft targets or partners in health? Retail pharmacies and their role in Tanzania's malaria control program. *social science & medicines*, 71(3):626-633.

15. Kamuhabwa AR, Mnyusiwalla F (2011): Rational dispensing and use of artemether-Lumefantrine during pregnancy in Dar es salaam, Tanzania. *Tanzania J of Health Res*, 13:2.
16. Lawford H, Zurovac D, O'Reilly L, Cowley A et al: Adherence to prescribed Artemisinin-Based combination therapy in Garisa and Bunyala districts- Kenya. *Malar J*, 10:281.
17. MDS-3 (2012): *Managing Access to Medicines and Health Technologies Pharmaceutical Supply Strategies*. Chapter 8.
18. Menendez (2006): *Current Molecular Medicine*. 6(2):269-273.
19. Menéndez C, Bardají A, Sigauque B, Sanz S, Aponte JJ, Mabunda S, Alonso PL (2010): Malaria prevention with IPTp during pregnancy reduces neonatal mortality. *Plos One*, 5:9438.
20. Mikkelsen-Lopez I, Tediosi F, Abdallah G, Njozi M, Amuri B, Khatib R et al (2013): Beyond antimalarial stock-outs- implications of health provider compliance on out-of-pocket expenditure during care-seeking for fever in South East Tanzania. *BMC Health Serv*, 13:444–453.
21. Minzi OM, Haule AF (2008): Poor knowledge on new malaria treatment guidelines among drug dispensers in private pharmacies in Tanzania- the need for involving the private sector in policy preparations and implementation. *East Afr J Public Health*, 5:117-121.
22. Ministry of Health and Social Welfare (2006): *National Guidelines for Malaria Diagnosis and Management Dar es Salaam*.

23. MOHSW (2008). In-depth Assessment of the Medicines Supply System in Tanzania Report.
24. Ministry of Health and Social Welfare (2013): National Guidelines for Malaria Diagnosis and Management Dar es Salaam.
25. Ministry of Health and Social Welfare Tanzania (2010): Tanzania Mainland National Health Accounts 2009/10, Dar es Salaam, Tanzania: Ministry of Health and Social Welfare Tanzania.
26. Morris A, Ward A, Moonen B, Sabot O and Cohen JM: Price Subsidies increases the use of private sector acts- Evidence from the systematic review. Health Policy Plan, 10:1093.
27. MSH (2005): Changing Malaria Treatment Policy to Artemisinin-Based Combinations, An Implementation Guide.
28. Mugoyela V, Minzi O (2011): Implementation of artemether-lumefantrine treatment policy for malaria at health facilities in Tanzania. Risk ManagHealthc Policy, 4:89–95.
29. Mubyazi GM, Gonzalez-Block MA (2005): Research influence on antimalarial drug policy change in Tanzania: case study of replacing chloroquine with sulfadoxine-pyrimethamine as the first-line drug. Malar J, 20:51.
30. NBS (2009): Chief Government Statistician, Macro International Inc: Tanzania HIV/AIDS and Malaria Indicator Survey 2007–2008. Dar es Salaam, Tanzania.

31. NBS (2013): Office of the Chief Government Statistician, CF International: Tanzania HIV/AIDS and Malaria Indicator Survey 2011–2012. Dar es Salaam, Tanzania.
32. NMCP (2006): National Guidelines for Diagnosis and Treatment of Malaria. Dar es Salaam, Tanzania: Ministry of Health and Social Welfare Tanzania.
33. National Malaria Programme (NMP) Review (2010). Dar es Salaam, Tanzania: Ministry of Health and Social Welfare (MOHSW).
34. O’Connell, Kathryn A, Hellen G, Stephen P and Julius N, (2011): Got ACTs? Availability, price, market share and provider knowledge of anti-malarial medicines in public and private sector outlets in six malaria endemic countries. . Malar J, 10:326.
35. Onwujekwe O, Uzochukwu B, Eze S, Obikeze E, Okoli C and Ochonma O (2008): Improving equity in malaria treatment: relationship of socio-economic status with health seeking as well as with perceptions of ease of using the services of different providers for the treatment of malaria in Nigeria. Malar J, 7:5.
36. Ramharter M, Schuster K, Bouyou-Akotet MK, Adegnika AA, Schmits K, Mombo-Ngoma G, et al (2007), Malaria in Pregnancy Before and After the Implementation of a National IPTp Program in Gabon. Am J Trop Med Hyg, 77(3): 418-422.
37. Ringsted FM, Massawe IS, Lemnge MM and Bygbjerg C (2011): Saleability of anti-malarials in private drug shops in Muheza, Tanzania: a baseline study in an era of assumed artemisinin combination therapy (ACT). Malar J ,10:238.

38. Ruebush TK, Kern MK, Campbell CC and Oloo AJ (1995): Self-treatment of malaria in a rural area of western Kenya. *Bull World Health Organ*, 73:229-236.
39. Rusk A, Smith N, Menya D, Obala A, Simiyu C et al (2012): Does anti-malarial drug knowledge predict anti-malarial dispensing practice in drug outlets? A survey of medicine retailers in western Kenya. *Malar J*, 11:26.
40. Rutstein SO, Johnson K (2004): The DHS Wealth Index. DHS Comparative Reports No 6.
41. Sachs J, Malaney P (2002): The economic and social burden of malaria. *Nature*, 415:680-685.
42. Sicuri E et al. (2010): Cost effectiveness of IPTp in southern Mozambique. *PLoS ONE*, 5(10): 1371.
43. Sillo H, Kimatta S (2012): Engaging Private Sector Retail Drug Outlets to Improve Access to Essential Medicines in Rural Tanzania: Experience from the Accredited Drug Dispensing Outlet (ADDO) Program. Tanzania Food and Drug Authority (TFDA), Management Sciences for Health (MSH).
44. The Global Fund to Fight AIDS Tuberculosis and Malaria (2009): Proposal Form - Round 9 Tanzania.
45. Tarimo DS, Malekela DA (2007): Health workers perceptions on chloroquine and sulfadoxine/sulfalene pyrimethamine monotherapies: implications for the change to combination therapy of artemether/lumefantrine in Tanzania. *East Afr J Public Health*, 4:43-46.

46. TPSA (2013): Tanzania Private sector Assessment.
47. Watsierah CA, Onyango RO, Ombaka JH, Abong'o BO and Ouma C (2012): Provider knowledge of treatment policy and dosing regimen with artemether-lumefantrine and quinine in malaria-endemic areas of western Kenya. *Malar J*, 11:436.
48. WHO (2007): Technical Expert Group meeting on intermittent preventive treatment in pregnancy.
49. WHO (2002). Achieving Impact: Roll Back Malaria in the Next Phase.” Report of the External Evaluation of Roll Back Malaria: Draft. Geneva, WHO.
50. WHO (2008): World Malaria Report, chapter 4, interventions to control malaria, adoption of policies and strategies for malaria control, p16-18.
51. WHO (2009): malaria case management operations manual.
52. WHO (2014): WHO Policy brief for implementation of IPTp-SP, p4.

ANNEXES

Annex IA: Questionnaire (English Version)

**ASSESSING IMPLEMENTATION OF ARTEMISININ BASED COMBINATION
THERAPY POLICY IN TREATMENT OF UNCOMPLICATED MALARIA
AMONG PRIVATE MEDICINES OUTLETS IN MWANZA REGION,
TANZANIA.**

Code NoDate:

i) General Questions

1. Type of the medicines outlet

- a) Pharmacy
- b) ADDO shop

2. District.....

3. Professional of the dispenser

- a) Pharmacist
- b) Pharmaceutical technician
- c) Pharmaceutical Assistant
- d) ADDO dispenser
- e) Clinical officer
- f) Nursing officer/Nurse midwife
- g) Nurse Assistant
- h) Others (specify).....

4. Sex

- a) Male
- b) Female

5. Age (years)

- a) 15-24
- b) 25-34
- c) 35-44
- d) 45 and above

6. What is your experience in this work of dispensing medicines?

- a) Less than 1 year
- b) 1 to 5 years
- c) 6 to 10 years
- d) 11 years and above

7. Have you ever attended training on anti malaria dispensing?

- a) Yes (go to next Question)
- b) No

8. How many times have you attended such a course within last four years?

- a) Once
- b) Twice
- c) More than twice

ii) Knowledge on treatment of uncomplicated malaria using ACT

9. Do you have knowledge about Artemisinin Based Combination Therapy (ACT) policy for treatment of malaria?

- a) Yes (go to next question)
- b) No (go to question 28)

10. Mention the recommended first line anti malarial before Tanzania as a country adopted ACT Policy?

.....

11. How did you get information about ACT Policy for treatment of malaria? Was it through?

- a) Pre-service education
- b) On job training
- c) ADDO Training
- d) Workshop and seminars
- e) Pharmaceutical bulletins and newsletter
- f) Standard treatment guidelines (STGs)
- g) News media i.e Radio, TV and Newspapers
- h) Other (Mention).....

12. Do you have any reference material e.g guideline or bulletins on treatment of uncomplicated malaria?

- a) Yes (if Yes, show me and go to next question)
- b) No

13. Name the reference material and who prepared it

- a) Name.....prepared by.....
- b) Name.....Prepared by.....

14. Mention three symptoms of uncomplicated malaria.

.....
.....

15. Mention the type of first line medicine recommended for treatment of uncomplicated malaria.

.....

16. Artemether Lumefantrine (ALU) is not recommended to which group of individuals?

.....

17. Which medicine is recommended in first trimester of pregnancy?

.....

18. Mention one side effect of Artemether Lumefantrine (ALU)?

.....
.....

19. The dose of Artemether Lumefantrine (ALU) should be repeated if the medicine is vomited within how many minutes/hours?

.....

20. ALU should be taken with fat meals

- a) Yes
- b) No
- c) I don't know

21. What is the reason for ALU to be used with fat meals?

.....

22. How many tablets of ALU a patient should take per dose considering his/her weight?

Weight (kg)	Number of tabs
5-14	
15-24	
25-34	
Above 35	

23. For the complete course of malaria treatment, how many doses of ALU a patient should take?

.....

24. The dose regimen mention above has to be taken for how many days?

.....

25. Describe the recommended dosing schedule for ALu.

.....
.....
.....

26. Mention the second line medicine recommended for treatment of uncomplicated malaria.....

27. Mention one indication for the use of second line anti malarial medicine?.....

iii) Knowledge on intermittent preventive treatment in Pregnancy

28. Do you know what is intermittent preventive treatment during pregnancy (IPTp)

- a) Yes (go to next question)
- b) No (Go to question 36)

29. What is the interval recommended for the pregnant mother to take medicine for intermittent preventive treatment during pregnancy?

.....

30. Name the medicine recommended for intermittent preventive treatment during pregnancy.....

31. How many tablets of SP pregnant mother should take per dose?

.....

32. SP can be given either on an empty stomach or with food

a) Yes

b) No

c) I don't know

33. SP can be administered safely with combined ferrous sulphate 200 mg + folic acid 0.25 mg (FeFo).

a) Yes

b) No

c) I don't know

34. What is the alternative medicine for IPTp where SP is contraindicated?

.....

35. What will be effect of administering the SP for the use other than IPTp e.g for treatment of uncomplicated malaria?

.....

iv) Types of anti malarial medicines available for treatment of uncomplicated malaria

36. Name anti malaria medicines which are now available in your stock. Please show me.

i.....

ii.....

iii.....

iv.....

v.....

vi. (others).....

Annex IIA: Simulated Clients from for Adult (English Version)

Code number.....Date.....

Name of the Simulated Client.....

Name of the facility.....Type of the facility.....

District.....

Part 1: Simulated clients Scenario

Objective of the simulation:

To determine types of anti malaria dispensed by pharmacies and ADDO dispensers to adults with uncomplicated malaria.

What are you supposed to do?

You will visit selected Pharmacies and ADDOs; act as if you have symptoms of uncomplicated malaria (i.e headache and fever) and ask for the medicine.

Steps in conducting simulation once you are at the facility;

- i) Greet the dispenser promptly.
- ii) Describe your symptoms that you feel fever and headache and those are the way you feel when you have malaria, ask the dispenser to advice appropriate medicine for your condition.
- iii) If the dispenser asks you to visit Laboratory for malaria check up, insist that you just need medicine.
- iv) If the dispenser ask you what is medicine you commonly use for malaria / which one you used last time you had malaria, answer that you don't remember neither the time nor the medicine.
- v) If the dispenser gives you SP or any medicine which is not ACT, ask if there is another medicine which is better than that, if she/ he say NO then pay for the

medicine and leave; if she/he say yes and mention them then tell her/him that, it's ok let me take the medicine you initially recommended.

vi) If the dispenser gives you ACT; tell her/him that you mainly prefer SP because it's single day dose.

vii) If she/he insists that ACT given is appropriate for your condition, pay for recommended medicine and leave.

viii) After leaving the facility find the proper place and answer the following questions. (Part 2)

ix) Submit the form and purchased medicine to the researcher.

PART 2:

i) Did the dispenser refuse to dispense medicines to you without laboratory results?

a) Yes b) No

If yes end up here

ii) What was the medicine she/he recommended after you explained your symptoms?

.....

iii) Mention medicines the dispenser recommended when you asked for availability of better medicine after you were given the medicine which is not ACT.

.....

iv) When you asked for SP since it's a single day dose did the dispenser agree and give you SP?

a) Yes b) No

If No, go to next question

v) What reasons did the dispenser give out for refusing to dispense SP?

.....

vi) Mention medicine which was finally dispensed and you paid for it.

.....

Annex IIIA: Questions Focused Group Discussion (English Version)

1. What do you understand by ACT Policy for treatment of malaria?
 - Have you involved in training or attended any seminar on treatment of uncomplicated malaria?
 - Which medicines are recommended as first choice and second choice in treatment of uncomplicated malaria?
2. What do you understand by intermittent preventive treatment during pregnancy (IPTp)?
 - What is the recommended medicine for IPTp?
 - Why shouldn't SP be used for treatment of uncomplicated malaria?
3. Perception on the use of ACT
 - Which antimalaria medicine you prefer to dispense to the client for over the counter treatment of malaria?
 - What do you think is the reason for SP to be still dispensed by private facilities for treatment of uncomplicated malaria even though it is prohibited?
4. For your experience, SP in private facilities is dispensed often for uncomplicated malaria or IPTp? What is the reason for your answer?
5. What challenges do you face when you advice your client to use ACT for those who visit your facility for over the counter treatment of uncomplicated malaria?

Annex IVA: Study Participants Informed Consent Form (English Version)**ASSESSING IMPLEMENTATION OF ARTEMISININ BASED COMBINATION THERAPY POLICY IN TREATMENT OF UNCOMPLICATED MALARIA AMONG PRIVATE MEDICINES DISPENSING OUTLETS IN MWANZA REGION -TANZANIA****NAME OF INVESTIGATOR:** STANLEY MWITA.**SPONSOR:** CATHOLIC UNIVERSITY OF HEALTH AND ALLIED SCIENCES**ADDRESS:** MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
P.O BOX 65001,
DAR-ES SALAAM.**Identification number:** _____**Introduction:**

Greetings! This consent form contains information about the research named above. In order to be sure that you are informed about being in this research, we are asking you to read or have read to you this consent form. You will also be asked to sign it or make a mark in front of the witness. You will be given a copy of this form. This consent form might contain some words that are unfamiliar to you. Please do not hesitate to ask so that explanation can be given to whatever you might not understand.

Reason for the research:

You are being asked to take part in this study which intends to assess implementation of malaria treatment policy and anti malaria dispensing practices among private medicines dispensing outlets in Mwanza region so that we can come up with future solution if any to the problem.

General information and your part in research:

The research will involve answering questions as a dispenser of medicine outlet. No experimental exercise is going to be carried out and your participation is voluntary. You will face no penalties in case you disagree not to take part in this study. The interview will be carried at your working place hence you will incur no cost.

Possible Risks:

Since the study will be done using questionnaire and non experimental, this means no harm is expected because of joining the research study.

Possible Benefits:

Your participation in the study will assist you to gain knowledge on malaria treatment policy, your participation will have input on the foreseen findings of the study that might improve dispensing practice and knowledge about malaria treatment policy among private medicine dispensing outlets.

Rights to participate or discontinue: You are free to decide if you want to be in this research after brief explanation on the aim and procedure of the research. You will be allowed to disagreed in taking part in the study or discontinue from the study at anytime as you wish. The discontinuation or refusal to participate will not affect your right at any point in time.

Confidentiality:

All the information obtained from you regarding this study will be treated with high degree of confidentiality. No information will be provided to others without your consultation.

Compensation

No payment will be provided for anyone participating in this study.

Staying in the Research

If you agree to participate in this research only the tools designed for this study will be used.

In case of problem/query contact:

If case of any problem/question/query as a study participant, please contact Mr. Stanley Mwita (Tel: 0786 671071), or Prof. Godliver Kagashe (Tel: 0713 310511), MUHAS P.O BOX 65001, Dar es Salaam.

Your rights as a Participant

This research has been reviewed and approved by the IRB of Muhimbili University of Health and Allied Sciences. An IRB is a committee that reviews research studies in order to help protect participants. If you have any questions about your rights as a research participant you may contact Prof. Mainen Moshi, Chairman of the College Research and Publications Committee, P.O Box 65001,Dar-es-salaam, Tel: 2150302-6.

Volunteer agreement

The above document describing the benefits, risks and procedures for the research titled **(IMPLEMENTATION OF MALARIA TREATMENT POLICY AMONG PRIVATE MEDICINES DISPENSING OUTLETS IN MWANZA REGION)** has been read and explained to me.

Ihave been given an opportunity to have any questions about the research answered to my satisfaction. I agree to participate as a volunteer.

Date: Signature or thumbprint of volunteer.....

Annex IB: Questionnaire (Swahili Version)

DODOSO KWA AJILI YA KUPIMA UTEKELEZAJI WA SERA YA MATUMIZI YA DAWA ZA MALARIA ZENYE MCHANGANYIKO NA DAWA JAMII YA ARTEMISININI (MSETO) KATIKA MADUKA BINAFSI YA DAWA MKOANI MWANZA-TANZANIA.

Fomu Namba..... Tarehe.....

i) Maswali ya ujumla

1) Aina ya kituo

a) Famasi

b) Duka la dawa muhimu

2. Wilaya.....

3. Taaluma ya mtoa dawa.

a) Mfamasia

b) Fundi dawa sanifu

c) Fundi dawa sanifu msaidizi

d) Mtoa dawa wa duka la dawa muhimu

e) Afisa tabibu

f) Afisa Muuguzi/Muuguzi Mkunga

g) Muuguzi Msaidizi

h) Nyingine (taja)

4. Jinsia

- a) Mme
- b) Mke

5. Umri (miaka)

- a) 15-24
- b) 25-34
- c) 35-44
- d) Zaidi ya 45

6. Uzoefu wako katika kazi ya utunzaji na kutoa dawa (miaka).

- a) Chini ya mwaka 1
- b) 1- 5
- c) 6- 10
- d) Zaidi ya miaka 11

7. Je, umewahi kuhudhuria mafunzo yoyote toka umalize chuo au mafunzo ya utoa dawa wa duka la dawa muhimu yahasuyo utoaji dawa za malaria?

- a) Ndiyo (nenda swali linalofuata)
- b) Hapana

8. Je, ni mara ngapi umehudhuria mafunzo kama hayo katika kipindi cha miaka minne iliyopita?

- a) Mara moja
- b) Mara mbili
- c) Zaidi ya mara mbili

ii) Ufahamu kuhusu sera ya matumizi ya dawa za malaria zenye mchanganyiko na dawa jamii ya Artemisinin (MSETO)?

9. Je, unafahamu kuhusu sera ya matumizi ya dawa za malaria zenye mchanganyiko na dawa jamii ya Artemisinin?

- a) Ndiyo (nenda swali linalofuata)
- c) Hapana (nenda swali la 28)

10. Taja dawa ya matibabu ya malaria iliyokuwa inapendekezwa kutumika kabla ya sera ya matumizi ya dawa za malaria zenye mchanganyiko na dawa jamii ya Artemisinin (MSETO).

.....

11. Ulipata taarifa kuhusu sera ya matumizi ya dawa za malaria zenye mchanganyiko na dawa jamii ya Artemisinin kupitia?

- a) Elimu kabla ya kuanza kazi
- b) Mafunzo sehemu ya kazi.
- c) Mafunzo ya watoa dawa wa maduka ya dawa muhimu
- d) Vipeperushi na vijarida vya madawa.
- e) Mwongozo maalum wizara wa matibabu
- f) Vyombo vya habari kama radio, luninga na magazeti
- g) Nyingine(Taja).....

12. Je una nyaraka rejea zozote kama miongozo au vipeperushi kwa ajili ya matibabu ya malaria isiyo kali?

- a) Ndiyo (nioneshe, nenda swali linalofuata)
- b) Hapana

13. Taja jina la hizo nyaraka rejea na zimetayarishwa na taasisi gani?

a) Jina.....Umetayarishwa na.....

b) Jina.....Umetayarishwa na.....

14. Taja dalili tatu za malaria isiyo kali

.....

15. Taja dawa ya ngazi ya kwanza inayotakiwa kutumika katika matibabu ya Malaria isiyo kali.

.....

16. ALU haishauriwi kutumika kwa makundi gani ya watu?

.....

17. Dawa gani inatakiwa kutumika kwa mjamzito mwenye mimba chini ya miezi mitatu?

.....

18. Taja moja kati ya maudhi ya ALU?

.....

19. Ni ndani ya dakika/masaa mangapi baada ya mgonjwa kutapika dozi ya ALU itabidi arudie kumeza tena dawa?

.....

20. ALU inatakiwa kutumika na chakula cha mafuta.

- a) Ndio
- b) Hapana
- c) Sijui

21. Taja sababu ya ALU kutakiwa kutumika na chakula cha mafuta.

.....

22. Vidonge kiasi gani vya ALU mgonjwa anatakiwa kutumia kwa kila dozi kwa kuzingatia uzito wake?

Uzito (kg)	Idadi ya vidonge
5-14	
15-24	
25-34	
Above 35	

23. Ili kumaliza kozi kamili, mteja anatakiwa kumeza dozi ngapi za ALU?

.....

24. Je dozi hizo za ALU zinatakiwa kutumika kwa muda wa siku ngapi?

.....

25. Elezea utaratibu wa masaa wa kumeza dozi za ALU.

.....

26. Taja dawa ya ngazi ya pili inayotakiwa kutumika katika matibabu ya Malaria isiyo kali.

.....

27. Kigezo gani ya kuzingatia kabla hujampa mteja dawa ya ngazi ya pili ?

.....

iii) ufahamu kuhusu Kinga ya malaria kwa vipindi kwa mama mjamzito?

28. Je unafahamu kuhusu Kinga ya malaria kwa vipindi kwa mama mjamzito?

- a) Ndiyo (nenda swali linalofuata)
- b) Hapana (nenda swali la 36)

29. Je mama mjamzito anatakiwa kutumia dawa ya Kinga ya malaria kwa vipindi kwa mama mjamzito kila baada ya muda gani?

.....

30. Taja dawa inayotakiwa kutumika kwa ajili ya Kinga ya malaria kwa vipindi kwa mama mjamzito.

.....

31. Mama mjamzito anatakiwa kutumia vidonge vingapi kwa dozi moja ya SP?

.....

32. SP inaweza kutumika na wakati wowote; kwa tumbo tupu au lenye chakula.

- a) Ndio
- b) Hapana
- c) Sijui

33. SP inaweza kutumika pamoja na kwa usalama na dawa ya mchanganyiko wa ferrous sulphate 200 mg + folic acid 0.25 mg (FeFo).

- a) Ndio
- b) Hapana
- c) Sijui

34. Ni dawa gani mbadala kwa mjamzito ambaye hatakiwi kutumia SP?

.....

35. Yapi ni madhara ya kutumia SP kwa matumizi tofauti na Kinga ya malaria kwa vipindi kwa mama mjamzito, mfano kwa matibabu ya malaria isiyo kali?

.....

iv) Aina za dawa zilizopo

36. Taja dawa za kutibu malaria zilizopo sasa hapa dukani. Tafadhari naomba unioneshe

i.....

ii.....

iii.....

iv.....

v. (Nyingine).....

Annex IIB: Simulated Client Form (Swahili Version)

Namba ya fomu.....Tarehe.....

Jina la anayeigiza ugonjwa.....

Jina la duka.....Aina ya duka.....

Wilaya.....

SEHEMU YA KWANZA: JINSI YA KUIGIZA

- a) Msalimie muuzaji
- b) Muambie kuwa wajisikia dalili za malaria, homa na kichwa kuuma, unaomba dawa ya malaria
- c) Akikuuliza kama umepima muambie hapana ila unataka dawa kwa kuwa hizo ndio dalili zako za malaria
- d) Akikuuliza kuwa unatumia dawa gani ukiumwa malaria muambie hukumbuki dawa ya mwisho kutumia
- e) Akikupa SP au dawa yeyote ambayo sio ALU, Muulize kama kuna dawa nzuri zaidi, akikuonesha muambie sawa lakini ngoja nichukue hio hio uliyonipa
- f) Akikupa ALU muambie unapanda dawa ya kumeza mara moja tu kama SP
- g) Akikataa kukupa SP, lipia dawa aliyokupa na ondoka dukani
- h) Ukitoka dukani jaza sehemu ya pili ya fomu hii

SEHEMU YA PILI

a) Je muuzaji alikataa kukupa dawa mpaka umuoneshe majibu ya maabara?
Ndiyo/hapana

Kama ndio ishia hapa

- b) Alikushauri dawa gani baada ya kumueleza dalili zako za malaria?.....

- c) Kama alikushauri dawa ambayo sio ALU, je ulipo muuliza kama kuna dawa bora zaidi alikutajia dawa gani?.....
- d) Uliyomuambia unapenda dawa ya kumeza siku moja kama SP alikubali ali alikataa.....
- e) Kama alikataa alitoa sababu gani?.....
- f) Taja dawa uliyonunua na bei ya kununulia
.....

Annex IIIB: Questions Focus Group Discussion (Swahili Version)

1. Unafahamu nini kuhusu sera ya matumizi ya dawa za malaria zenye mchanganyiko na dawa jamii ya Artemisinin?
 - Je umewahi kuhudhuria mafunzo au warsha yeyote kuhusu matibabu ya malaria isiyo kali?
 - Ni dawa zipi zinashauriwa kutumika kama ngazi ya kwanza na ngazi ya pili kwa matibabu y malaria isiyo kali?

2. Je unafahamu kuhusu Kinga ya malaria kwa vipindi kwa mama mjamzito?
 - Ni dawa gani inashauriwa kutumika katika Kinga ya malaria kwa vipindi kwa mama mjamzito?
 - Je ni kwa nini SP haitakiwi matibabu ya malaria isiyo kali?

3. Mtizamo kuhusu dawa zenye mchanganyiko wa Artemisinin (ACT)
 - Dawa gani ya kutibu malaria hupendelea kumpatia mgonjwa wa malaria anayefika dukani bila cheti cha daktari?
 - Unafikiri ni kwa nini bado SP inatumika kwa matibabu ya malaria isiyo kali japokuwa imezuiwa?

4. Kwa uzoefu wako; SP hutolewa zaidi katika maduka ya dawa kwa matibabu ya malaria isiyo kali au Kinga ya malaria kwa vipindi kwa mama mjamzito? Nini sababu ya jibu lako?

5. Ni changamoto gani hukumbana nazo unapomshauri mgonjwa atumie dawa zenye mchanganyiko wa Artemisinin (mseto) anapokuja dukani bila cheti cha daktari?

Annex IVB: Study Participants Informed Consent (Swahili Version)

FOMU YA KUKUBALI KUJIUNGA KWA HIARI KATIKA KWA AJILI YA KUPIMA UTEKELEZAJI WA SERA YA MATUMIZI YA DAWA ZA MALARIA ZENYE MCHANGANYIKO NA DAWA JAMII YA ARTEMISININI KATIKA MADUKA BINAFSI YA DAWA MKOANI MWANZA-TANZANIA.

JINA LA MTAFIGI: STANLEY MWITA.

MFADHILI: CHUO KIKUU CHA KIKATOLIKI CHA AFYA - BUGANDO.

ANWANI: CHUO KIKUU CHA AFYA NA SAYANSI ZA TIBA MUHIMBILI,

S.L.P 65001,

DAR-ES SALAAM.

Namba ya Utambuzi: _____

Utangulizi:

Salamu!

Fomu hii inajumuisha taarifa juu ya utafiti tajwa hapo juu. Ili kuthibitisha kukubali kwako kushiriki katika utafiti utasoma au kusomewa fomu hii ya kukubali na kisha utaisaini. Au utasaini kutumia kidole gumba mbele ya shahidi. Baadaye utapewa nakala ya fomu hii. Endapo hutaelewa usisite kuuliza kabla ya kusaini.

Sababu za kufanya utafiti:

Utafiti huu una kusudi la kuangalia kupima utekelezaji wa sera ya matibabu ya malaria katika maduka binafsi ya dawa mkoani mwanza namna ya kutatua changamoto zinazokabili utekelezaji wa sera husika.

Taarifa za jumla na nafasi ya ushiriki kwako:

Utafiti huu ni wa hiari na utahusisha kujibu maswali kulingana na nafasi yako kama mtoa dawa katika duka la dawa. Hautapata adhabu yeyote kwa kukataa kushiriki utafiti huu. Hatutegemei utaingia gharama zozote kwa ushiriki wako kwani shughuli zote za utafiti zitafanyika katika sehemu yako ya kazi.

Athari tarajiwa:

Kwa kuwa utafiti huu utahusisha kujibu maswali yaliyopo kwenye dodoso, hivyo hatutegemei madhara wala hatari zozote kwa ushiriki wako kwenye utafiti huu.

Faida tarajiwa:

Kukubali kujiunga katika utafiti huu kutakusaidia kuongeza ufahamu kuhusu sera ya matibabu ya malaria, pia matokeo ya utafiti huu unategemewa kuongeza ufahamu na utendaji wa watoa dawa wa maduka binafsi ya dawa katika utekelezaji wa sera ya matibabu ya malaria.

Haki ya kushiriki au kutokushiriki:

Ushiriki wako katika utafiti huu ni wa hiari baada ya kupata maelezo kuhusu lengo na mlolongo wa utafiti. Unaweza kuamua kutoshiriki au kujitoa kwenye utafiti muda wowote ule na kwa sababu yoyote ile. Maamuzi yako ya kuamua kujitoa/ kutokushiriki yataheshimiwa na hayataathiri mahusiano baina yako na mtafiti.

Usiri:

Taarifa zote utakazotoa wakati wa utafiti zitatunzwa kwa siri na kutumika kwa lengo la utafiti tu na si vinginevyo.

Fidia:

Ushiriki wako katika utafiti huu ni wa hiari na hivyo hakutakuwa na malipo yoyote kwa ajili ya kushiriki kwako.

Kubaki katika utafiti:

Kama utakubali kushiriki katika utafiti huu, ni dodoso lililoainishwa pekee ndilo litakalotumika katika utafiti huu.

Kama una hoja/ tatizo lolote juu ya utafiti husika tafadhali wasiliana na;

Mr. Stanley Mwita(simu namba; 0786 671071), au Prof. Godliver Kagashe (simu namba; 0713 310511), Chuo Kikuu cha Afya na Sayansi za Tiba Muhimbili, S.L.P 65013, Dar es salaam, Simu Na: 02221507

Haki zako kama mshiriki:

Utafiti huu umepitiwa na kuidhinishwa na jopo la Kamati ya Utafiti na Machapisho ya Chuo Kikuu cha Afya na Sayansi ya Tiba cha Muhimbili. Kama utakuwa na swali au maswali kuhusu haki zako kama mshiriki katika utafiti huu wasiliana na:

Profesa Mainen Moshi, Mwenyekiti wa Kamati ya Utafiti na Uchapishaji, Chuo Kikuu cha Afya na Sayansi ya Tiba, S.L.P 65001, Dar es salaam. Simu Na : 2150302-6.

Makubaliano ya hiari

Maelezo ya hapo juu, yanayoelezea faida, hasara na taratibu za utafiti wenye kichwa kisemacho **“AJILI YA KUPIMA UTEKELEZAJI WA SERA YA MATIBABU YA MALARIA KATIKA MADUKA BINAFSI YA DAWA MKOANI MWANZA..”** nimezisoma au kusomewa na kuzielewa.

Mimi..... (andika jina lako) naridhia kushiriki katika utafiti na majibu yote niliyoyatoa kwa ufahamu wangu ni ya kweli.

Tarehe:Sahihi au alama ya dole gumba.....