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SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

ADHERENCE TO MALARIA DIAGNOSIS GUIDELINES AMONG OVER THE COUNTER MEDICINE SELLERS (OTCMS) IN LEDZORKUKU-KROWOR MUNICIPAL – GREATER ACCRA REGION, GHANA

BY

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DECLARATION

I, **Hayford Nkansah**, hereby declare that this research work is a result of my independent work carried out at School of Public Health, College of Health Sciences, University of Ghana. References to other works have been properly acknowledged. I further state that this research work has not been submitted for award of any degree in this institution and other universities elsewhere.

…….. ……

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(STUDENT)

…….. …….

PROF. MOSES AIKINS **DATE**

ACADEMIC SUPERVISOR

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DEDICATION

I dedicate this piece to the Most High God who gave me the Enabling Grace.

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ACKNOWLEDGEMENTS

My foremost appreciation goes to my God Almighty for the Enabling Grace to finish this piece to His Glory. My very supervisor, Prof. Moses Aikins, with his constructive guidance and directions has indeed contributed massively towards the finishing of this work. I say I am indeed grateful.

To the Chief of Party of USAID/SHOPS Project, Mr. Joseph Addo Yobo and the rest of the Project team, I sincerely extend my profound gratitude to you all for assisting me in one way or the other in making this a reality. I am again grateful to Mr. Albert Wiredu Arkoh, (Deputy Registrar – Professional Development) of Pharmacy Council for his immensed support throughout this research. My research assistant, Master Alhassan Yakubu of Biostatics department, University of Ghana School of Public Health deserves much recommendation for his marvelous support during the research period. To my field workers who participated in the research work, I say a big thank you and God bless you all.

And then to my best friend and life partner, Maame Efua Akyinba Nkansah (Mrs), I say you are the best gift one can ever ask from the Creator. God bless you for being there for me.

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ABSTRACT

Background: The World Health Organisation (WHO) has reviewed malaria diagnosis guidelines, confining to only parasitologically-confirmed cases by either using microscopy or Rapid Diagnostic Test (RDT) before any treatment is considered. Regarding this evidence based rapid and far – reaching development in science of malaria treatment policy, several countries have done in-service trainings, supervision and support for health providers to improve their performance. Notwithstanding the trainings and distribution of guidelines and jobs aids, there are still low testing rates of suspected malaria cases. The main objective of the study was to determine adherence to malaria diagnosis guidelines among Over The Counter Medicine Sellers (OTCMS).

Methods: A descriptive census was employed for the study to determine adherence to Rapid Diagnostic Test (RDT) diagnosis among OTCMS providers. The indicators of adherence were displayed posters at the facility, use of the malaria RDT kits and testing of malaria. Descriptive statistics including frequencies and cross tabulations were used to describe the level of adherence among the OTCMS. Chi square test was used to determine whether there was a significant relationship between adherence and the predictor variables.

Results: The results showed that 38.1 percent of respondents were OTCMS owners and 61.9 percent being assistants. About 9.5 percent had completed JHS level, 71.4 percent completed SHS level and 19.1 percent have tertiary education. There were 8.3 percent of facilities that had malaria RDT posters displayed at their facilities. The proportion of OTCMS providers that use the malaria RDT kits was 21.8 percent. About 7.1 percent of the providers were testing for malaria. In overall, there were 2.8 percent full adherence, 25 percent partial adherence and 72 percent non-adherence to the malaria diagnosis guidelines among OTCMS.

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Conclusion: The findings from this study showed a significant number of the OTCMS providers not adhering to the malaria diagnosis guidelines as recommended by Ghana Health Service and the Ministry of Health after its adoption from WHO.

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ACRONYMS

ACT..……..	Artemisinin-based Combination Therapy
CBA……..	Community Based Agents
CDC……..	Center for Disease Control and Prevention
CHPS……	Community-based Health Planning and Services
DHAP……...	Dihydroarteminsin-Piperaquine
GHO……..	Global Health Observatory
GHS…….	Ghana Health Service
GSS……...	Ghana Statistical Service
IRB……...	Institutional Review Board
LEKMA……	Ledzorkuku Krowor Municipal Assembly
MC ……...	Mystery Client
MCS ……	Mystery Client Survey
M&E…….	Monitoring and Evaluation
MICS……	Malaria Indicator Cluster Survey
MOH…….	Ministry Of Health
MPR……..	Malaria Program Review
NMCP……...	National Malaria Control Program
OTC……..	Over The Counter
OTCMS……	Over The Counter Medicine Sellers
PfHRP2……	Plasmodium falciparum histidine-rich protein-2
PHC……..	Population and Housing Census
RDT……..	Rapid Diagnostic Test

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SES……..	Socioeconomic Status
SOP……..	Standard Operating Procedures
USAID…….	United State Agency for International Development
WHO……	World Health Organization

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DEFINITION OF TERMS

1. **Adherence –** The degree by which the behaviour of a health provider corresponds with accepted recommendations from a health policy.
2. **Artemisinin-based combination therapy (ACT) -** A composition of artemisinin or its derivative with another class of antimalarial(s).
3. **Case, confirmed -** Detection of a parasite in malaria case (or infection) using a diagnostic test.
4. **Case, presumed -** Malaria suspected case that is not confirmed by a diagnostic test.
5. **Class C drugs -** Proprietary drugs which are to be supplied by both over the counter medicine sellers and registered pharmacists. These drugs are not sold on prescription (Narcotics control in Ghana)
6. **Diagnosis -** Process of attempting to determine a possible disease and the opinion reached by this process
7. **Drug resistance -** Parasitic strain ability to continue to live and/or reproduce regardless of the administration and absorption of a drug given in doses equal to or more than those usually approved, but within the endurance of the subject, provided exposure of the drug at the site of action is satisfactory.
8. **Endemic –** Habitual occurrence of a disease in a particular region or population.
9. **Full Adherence -** An OTCMS provider meeting all the required research objectives (displayed posters at the facility, use of the malaria RDT kits and testing of malaria)
10. **Malaria case -** A person developing malaria infection by confirmation of malaria parasites in the blood using malaria diagnostic test to detect.
11. **Mystery Client –** A trained person (usually a community member) who assumes an attitude as

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	a client by visiting a health facility without the health service provider knowing that they are conducting a research and then report (by completing a survey or through an interview) on their experience.
12. Non – Adherence -	An OTCMS provider not meeting any of the required research objectives (displayed posters at the facility, use of the malaria RDT kits and testing of malaria)
13. **Over The Counter - Medicine Seller (OTCMS)**	Small private outlets offering over-the-counter medicines or class c drugs and supplies for common illnesses, notably in rural and difficult-to-reach areas. (Wafula and Goodman et al, 2010).
14. **OTCMS Assistant**	A person who plays the role of an OTCMS in the absence of the provider or helps the OTCMS to carry out his / her health provider function
15. **Parasitaemia** –	Presence of parasites in the blood
16. **Partial Adherence -**	When an OTCMS provider does not meet all the required research objectives but some of them (displayed posters at the facility, use of the malaria RDT kits and testing of malaria)
17. **Rapid diagnostic test (RDT)**	A malaria antigen-based stick, cassette or card test with coloured line which shows that plasmodial antigens have been identified.
18. **Standard Operation Procedure**	Describe in detail the thorough procedures for carrying out tests and ensure that unvarying and reproducible results are produced
19. **Uncomplicated**	An individual having a history of fever within the preceding 2-3 days, or is

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Malaria found to have fever upon examination (axillary temperature 37.5°C or rectal temperature 38.5°C), in the absence of any other cause is considered a suspected case of malaria. In the absence of signs of severe disease, a suspected case of malaria confirmed by parasitological investigation is considered to be "uncomplicated" malaria.

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CHAPTER ONE

INTRODUCTION

1.1: Background

An approximated 212 million cases of malaria occurred globally in the year 2015 with about 429,000 estimated cases of death reported globally. WHO African Region continues to experience the impact of the worldwide burden of malaria. In 2015, 88 percent of worldwide malaria cases and 90 percent of global deaths occurred in the African Region. The wide majority of deaths (99 percent) were as a result of P. *falciparum* malaria (World Malaria Report 2016). According to Ghana Statistical data from 2011, malaria has been and continues to have severe socio-economic burden in the country. It is highly endemic and perpetual in every part of the country, with seasonal changes that are more pronounced in the north (MICS, GSS 2011).

In reference to the Global Health Observatory (GHO) data, Ghana's profile statistics conducted between 2012 and 2016 showed the number of confirmed reported malaria cases as at 2014 was 3,415,912 with 2,200 confirmed deaths. An increase of 4,319,919 with 2,137 confirmed deaths was reported in 2015 (WHO GHO data 2016). The Ghana Statistical Service (GSS) Multiple Indicator Cluster Survey (MICS) conducted in 2011 in collaboration with other donor agencies indicated that, the malaria microscopy-based prevalence was estimated at 28 percent nationally, especially with children aged 6-59 months. Large discrepancies were observed with Greater Accra having the least prevalence rate at 4 percent compared to 51 percent in the Upper West region (GSS MICS 2011). Health facility data from Ghana Health Service (GHS) indicate that, the number one cause of morbidity is malaria, which account for about 31.1 percent of all

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outpatient illnesses, admissions in all ages being 25.1 percent, and about 40.6 percent of all admission and 11.8 percent of death in children under-five years (NMCP 2016).

Effective diagnosis of uncomplicated malaria is vital as the disease with its severe form is associated with high fatality rate (WHO 2016). Rapid diagnostic tests (RDTs) are the means by which the confirmation of malaria diagnosis will be established as microscopy availability is very inadequate in most places in sub-Saharan Africa. The accuracy, reliability and outcome of treatment based on results of RDT will be a major factor in the acceptability and adherence to the new diagnosis guidelines (Bisoffi & Van den Ende, 2008; English, Reyburn, Goodman and Snow 2009).

A presumptive malaria case, without a parasitological confirmation, cannot be considered a malaria case. An early and precise malaria diagnosis is pre-eminent for both rapid and successful disease management and malaria surveillance. High-quality malaria diagnosis is very remarkable in every setting as misdiagnosis can result in consequential morbidity and mortality. WHO recommends immediate malaria diagnosis either by microscopy or malaria rapid diagnostic test (RDT) in every suspected malaria patient before treatment is considered. Diagnostic testing enhances the overall management of febrile ill patients, and may also assist the reduction of emergence and spread of drug resistance by keeping in reserve antimalarials for those who with the disease (WHO 2017). Malaria diagnostic testing boosts the quality of care for every febrile ill patient. WHO-recommended this as the initial approach in the T3: Test, Treat, Track strategy to treatment of malaria cases globally (WHO 2017). That is all malaria suspected case have to be tested, all confirmed case have to be treated with a standard-assured antimalarial drugs, and then the disease should finally be tracked through accurate and timely surveillance system. In accordance with this, Ghana adopted the T3 strategic approach in managing malaria cases in the

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country. The primary goals are to immediately confirm diagnosis and effectively treat only positive malaria cases to prevent advancement to severe disease, reduce the duration of disease and minimize the chance of developing and spreading of parasites that are drug-resistant (GHS/NMCP 2015).

The Strategic objectives for the case management as outlined in the revised National Malaria Strategic Plan 2014 – 2020 are; (1) To provide parasitological diagnosis to at least 90 percent of all suspected malaria cases; and (2) To provide immediately and effective treatment to 100 percent of all confirmed malaria cases. Precisely, Ghana aims to provide access to immediate and effective treatment so as to test 90 percent of all suspected malaria cases at all health facilities being public or private. The recommended malaria case management interventions for Ghana, adopted from WHO guidelines, are diagnosis and treatment and these include the use of (1) malaria Rapid Diagnostic Tests (RDTs) or Microscopy; and (2) ACTs in a comprehensive national treatment policy (GHS/NMCP 2015).

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1.2: Problem Statement

Malaria causes both high morbidity and mortality around the world, with 88 percent of the cases and 90 percent of global deaths occurring in the African region (World Malaria Report, 2016). It has been and continues to have severe socio-economic burden in Ghana. It is extremely endemic and perpetual in all part of the country (MICS, GSS 2011). Averagely, about 28,606 suspected Malaria cases were reported day by day in the country's health facilities (NMCP, 2016). Malaria suspected case detection and treatment in Ghana, like many other malaria endemic countries, has been largely presumptive over the years especially in medicine retail outlets (Ezeoke et al, 2012; WHO 2010).

The World Health Organisation has, since 2010, recommended that every patient suspected with malaria case should undergo malaria diagnostic testing, by either microscopy or Rapid Diagnosis Test (RDT) before treatment is administered. Despite the introduction of the test and treat malaria policy six years ago, there have been cases of over-diagnosis and overtreatment of malaria, resulting in high mortality due to failure to treat other causes of febrile illness like bacterial infections (Onchiri *et al*, 2015; Reyburn *et al*, 2004). In addition, various studies have reported cases where health care workers presumptively treat patients as having malaria without a diagnostic test, or with negative test results with anti-malarials (Olliaro, 2009; Ochola *et al*, 2006; Amexo, Tolhurst & Bates 2004; Naimoli *et al*, 2006).

The detection of suspected malaria cases using RDTs has been successfully being implemented in hospitals and clinics in Ghana for over six years. Notwithstanding, there are common perceptions with regards to the accuracy of the tests and their significant impact on patient care in places where such tests are provided. There are reported uses of anti-malarial medicines in non-malaria febrile illnesses even when RDT was conducted (Ansah *et al*, 2010; Bisoffi *et al*,

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2009; Murray *et al*, 2008). A randomized control trial conducted in some rural health facilities in Ghana indicated about 45.5 percent of patients who tested negative to malaria RDT were all the same given antimalarial (Chandler *et al*.,2010).

About half of Ghana's population report to over 11,000 OTCMS in the country when they are ill and most of these providers are at the peripheral. They constitute about 80 percent of the total number of private medicines outlets and are found in almost every town or village in Ghana (Pharmacy Council, 2012). The first point of call for a patient with uncomplicated malaria is to go to a private health facility of which the OTCMS forms majority. It is widely known that presumptive malaria treatment causes irrational use of ACTs that are costly (Seiter & Gyansa-Lutterodt, 2009).

An untimely and precise malaria diagnosis is crucial for both rapid and effective disease management and surveillance. Diagnostic testing enhances the overall management of febrile ill patients, and can also aid in the reduction of emergence and spread of drug resistance by reserving antimalarials for those with the actual disease. (WHO 2017)

The development of P. *falciparum* resistance to artemisinin is a pressing public health concern, threatening the sustainability of the ongoing worldwide effort to lessen the burden of malaria (WHO, 2017). Practice has to align with policies if the objectives set by the country are to be achieved. There have to be more studies on users' and prescribers' adherence and reasons why they do not comply, in order to find ways to correct this. This will in effect reduce resistance to antimalarial medicines.

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1.3: Justification of study

National data reported by National Malaria Control Programs (NMCPs) point out that the proportion of malaria suspected cases undergoing a parasitological test among patients presenting for care in the public sector have, since 2010, increased in most WHO regions than in the private sector. The greatest increase of a parasitological test has been in the WHO African Region, where diagnostic testing increased from 40 percent of suspected malaria cases in 2010 to 76 percent in 2015 in the public sector than in the private sector (WHO 2016).

The first point of call for majority of patients with malaria in Ghana is to seek treatment in private health facilities. Ghana being among the WHO Africa malaria-endemic countries, is tasked with the responsibility of ensuring the implementation of the recommended malaria diagnosis guidelines in efforts to control malaria and health workers, particularly OTCMS are key players in achieving this due to the fact that they serve majority of the Ghanaian population with primary health care issues.

From the public health perspective, diagnosis and treatment are intended to decrease transmission of the infection to others by lessening the infectious reservoir and preventing the emergence and spread of resistance to anti-malarial medicines. Effective malaria case-management is imperative in moving towards eliminating the disease (Net, 2011). Health providers' adherence to malaria diagnosis guidelines is, therefore, very critical for the successful implementation of any new case-management policy and prevention of drug resistance.

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Understanding the level of adherence of malaria diagnosis policy among OTCMS will guide and strengthen the implementation of malaria diagnosis guidelines being used in Ghana and globally. The findings from this study will therefore inform malaria case-management and will improve an understanding into the adherence to diagnostic guidelines in low-resourced settings.

Lastly, the level of adherence to malaria diagnosis policy among OTCMS will in the long run lead to advancement in the quality of healthcare through further research, investment in focused training, regular supervision and development of informed policies.

1.4: Conceptual Framework Model displaying Diagnosis Adherence among OTCMS

The focus of the conceptual framework, as indicated in figure 1 below, is to show the linkages between the exposure variables and the intermediate factors all influencing the outcome variable.

The provider factor, being the exposure variable, has a direct bearing on the intermediate variables which include diagnosis guidelines set by the Ghana Health Service and the OTCMS facility characteristics. These aftermath influences adherence to malaria diagnosis guidelines. The provider factor being the level of education and the experience in the field of practice all contribute to the intermediate factors which leads to diagnosis adherence as the outcome variable. Wide sensitization of health providers to the malaria diagnosis guidelines improve knowledge and understanding of the national diagnosis guidelines and enhances providers' confidence level of using the RDT kit in diagnosis before treatment. Understanding of the guidelines in turn influences attitudes towards the diagnosis adherence. In a qualitative analysis by Hutchinson *et al* in 2015, it was shown that private providers would like to offer the tests because of the reputational benefits and because it enables them to offer a higher quality of care.

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OTCMS who disagree with the national diagnosis guidelines are more likely to fail to implement them in their practice. Again the educational level of the OTCMS and the monitoring and evaluation of the facility by regulatory agencies determines the facility characteristic which embraces location, the stocking of drugs and a place of conducting the test before treatment.

The on – site supportive supervision and routine inspection by the regulators, as a form of monitoring and evaluation, might enforce adherence to the diagnosis guidelines and vice versa. Regular OTCMS visits by regulatory bodies, with availability of the RDT kits, have a high tendency of increasing providers' adherence.

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1.4: The Conceptual Framework

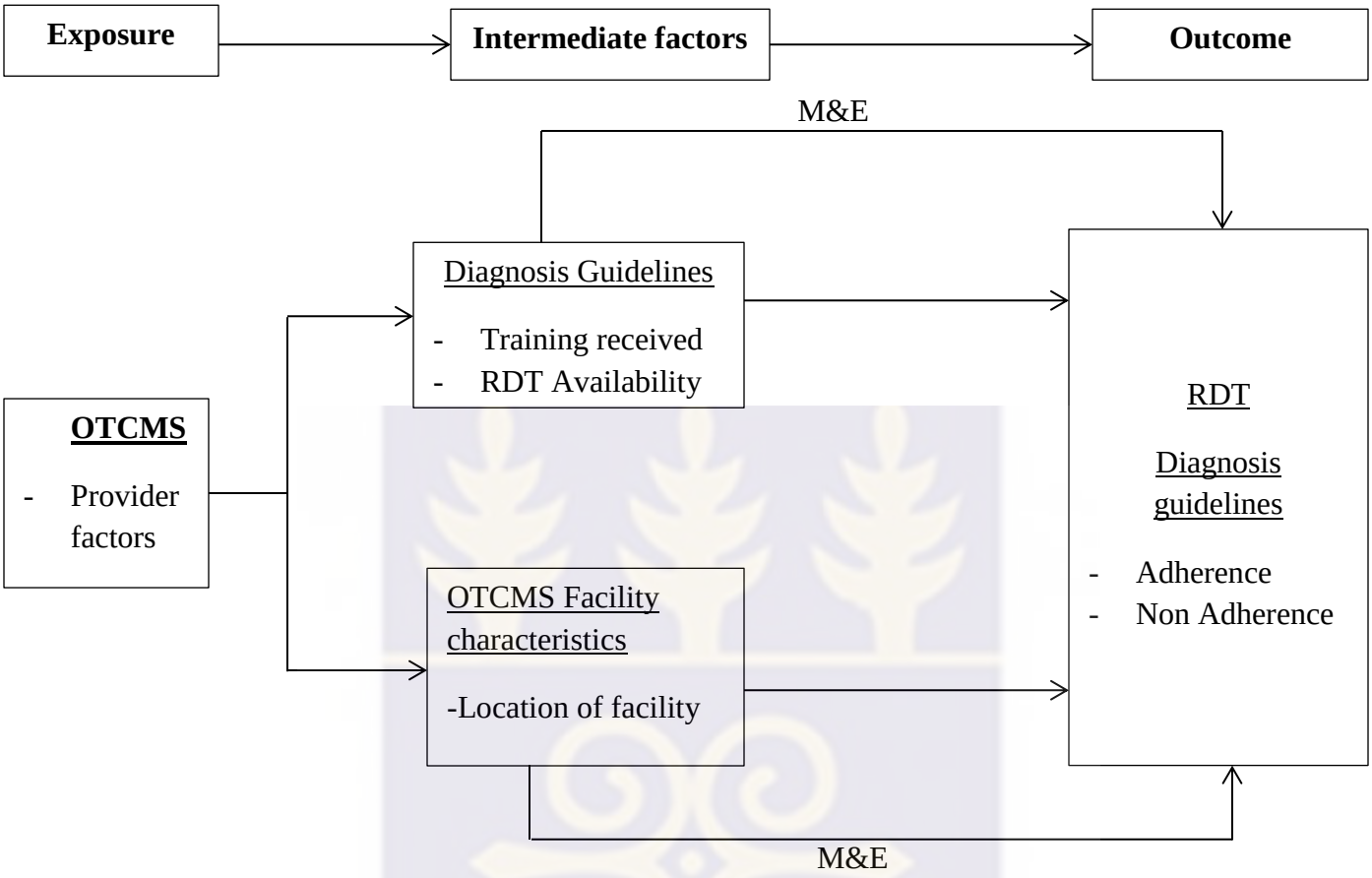


Figure 1: A conceptual framework model displaying diagnosis adherence among OTCMS

1.5: Research Question

What is the adherence of malaria diagnosis to the standard diagnosis guidelines among Over The Counter Medicine Sellers in Ledzorkuku – Krowor Municipal?

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1.6: General and Specific Objectives

1.6.1: General Objective:

The general objective of the study is to assess the adherence to malaria diagnosis guidelines among Over The Counter Medicine Sellers (OTCMS) in Ledzokuku Krowor Municipal in Greater Accra Region.

1.6.2: Specific Objectives:

The specific objectives are:

1. To determine the proportion of malaria RDT posters displayed at the OTCMS facilities
2. To determine the proportion of OTCMS providers that use the malaria RDT kits
3. To determine the testing of malaria among OTCMS providers
4. To determine the overall adherence of RDT diagnosis guidelines among OTCMS providers

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CHAPTER TWO

LITERATURE REVIEW

2.1: Uncomplicated malaria

The case definition for uncomplicated malaria denotes an individual having a fever history within the preceding 2-3 days, or is found to experience fever upon examination (with an axillary temperature 37.5°C or more or a rectal temperature 38.5°C), without any other cause will be regarded a malaria suspected case. Malaria suspected case confirmed by parasitological investigation is regarded to be "uncomplicated" malaria, in the absence of any signs of severe disease. Any symptomatic malaria parasitaemia without signs of severity or evidence of vital organ dysfunction is considered to be uncomplicated malaria (WHO, 2015). The individual patient with suspected uncomplicated malaria usually complains of fever or a history of fever within the preceding 2-3 days, rigors (shivering), chills (feeling unusually cold) and headache. Additional clinical features can comprise; generalised joint and body pain, sweating, bitterness in the mouth, nausea and/or vomiting, loss of appetite, abdominal pain (especially in children), irritability and refusal to feed (in infants). These symptoms may happen individually or in combination.

Frequent vomiting and convulsions are danger signs which indicate the onset of severe malaria.

In countries where cases of malaria are unusual, these symptoms can be associated with a cold, influenza, or other common infections, especially if malaria is not suspected. Contrarily, in countries where malaria is recurrent, citizens often recognize the symptoms as malaria and treat

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themselves without seeking diagnostic confirmation ("presumptive treatment") - (CDC Global Health, 2015).

2.2: Global malaria situation and diagnosis guidelines

Malaria is until now a public health problem worldwide, with about 3.3 billion people at risk of malaria (WHO, 2015). Before the universal testing policy, diagnosis of malaria was mainly based solely on clinically suspecting cases of malaria and detecting parasites in the blood, either parasitological or confirmatory diagnosis. For children less than the age of 5 years, all fevers were treated as malaria with ACT, without any confirmation, while over five year olds were to be tested first before commencing anti-malarials.

Following a reduction in the transmission of malaria in various parts of Africa and the burden of the disease globally, and the availability of cheaper rapid diagnostic tests (RDTs), the WHO recommended in 2010, that all suspected cases of malaria in all year groups be laboratory confirmed by microscopy or RDT before initiating anti-malarial therapy (Aregawi *et al*, 2011; Okiro *et al*, 2010). This is geared towards reducing the occurrence of drug resistance, prevent excessive use of anti-malarial drugs and encourage identification of other non-malaria febrile illnesses in the context of declining change of malaria epidemiology. Consequently, the recommended anti-malarial drugs should only be directed to patients who certainly have malaria (WHO, 2015).

In 2012, there was an extension of the treatment policy to include a track component. This component entails routine capturing and reporting of commodity stocks, malaria testing rates of

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all suspected cases and subsequent appropriate treatment of the cases through health information systems (WHO, 2012).

In accordance with GHS/NMCP policy, it is currently recommended to limit treatment to only laboratory-confirmed malaria cases. The major aim of ensuring adequate use of parasitological diagnosis with either microscopy or RDTs is to lower malaria overtreatment by guaranteeing that treatment is earmarked at only patients with true malaria infection. For uncomplicated malaria, all patients suspected to have malaria without signs of severe disease or danger signs should be tested for malaria and only those whose test results are positive be treated with the recommended ACT. Microscopy is the standard test for malaria in public health facilities across the country (GHS, 2016).

The introduction of new malaria treatment guidelines by WHO that recommend universal laboratory testing of all suspected malaria cases before treatment, led many countries, including Ghana to adopt to the policy. In the face of improvements in malaria case-management being reported and the testing rates being high, a number of patients are still being treated presumptively, i.e. being treated without a malaria test (Bilal, *et al*, 2015; Johansson, *et al*, 2014; Juma and Zurovac, 2011). A South Eastern Nigeria study conducted in 2014 revealed that utilization of ACTs for treating uncomplicated malaria in the States has progressed but laboratory confirmation of diagnosis were suboptimum (Udoh, *et al*. 2013).

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Majority of health providers rely on clinical symptoms when making a diagnosis even though they are poor predictors for the disease. This practice results in malaria disease over-diagnosis hence excessive reporting of malaria cases, over-use of anti-malarial drugs, under-treatment, under-reporting and incorrect treatment of non-malarial febrile illnesses (Amexo *et al*, 2004; Nosten and Ashley, 2004). As a further matter, it leads to increased real or apparent anti-malarial drug resistance, treatment of negative test cases as malaria and inappropriate allocation of resources, including over-treatment with expensive ACTs (Reyburn *et al*, 2006). Malaria over-diagnosis and over-treatment can result in failing to treat other blood stream causes of fever (Reyburn *et al*, 2004). The standard for diagnosing and treating malaria is a positive blood smear test using microscopy or RDT in a patient with history of fever or suspected to have malaria, but in practice this is not frequently adhered to. There have been cases that show poor adherence to malaria management guidelines in many settings even though clinical guidelines are standards to be followed by health providers. For instance, not strictly following malaria slide results in treating suspected malaria cases, whereby some malaria slide positive patients are not prescribed anti-malarials (under-treatment). Malaria slide negative patients and those not tested being prescribed anti-malarials; this has led to inappropriate use of malaria drugs (Onchiri *et al*, 2015; Juma and Zurovac, 2011; Bouyou-Akotet *et al*, 2012; Mosha *et al*, 2010; Mbonye *et al*, 2015; Bilal, *et al*, 2015).

A research conducted in Nigeria found that providers perceived malaria RDTs as a major step to correct treatment, nevertheless, it was also disclosed that there were concerns as to the reliability of test results as symptoms were considered more of great significance than test results (Ezeoke *et al*, 2012). A Uganda study explored the introduction of RDTs into OTCMS and also found a

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doubt of RDT results being negative. Other associated factors reported to reduce health providers interest in adherence to RDTs usage included the cost of the test and the extra time required to be tested (Chandler *et al*, 2011). Again, in Bisoffi *et al*. (2009) study, negatives RDT results were still diagnosed and treated as malaria due to lack of confidence in the reliability of RDTs. RDTs are seen not to be ideal tools and false results could weaken the reliance of health service providers and lead to non-adherence to the new diagnosis guidelines (Olliaro, 2009; Ochola et al, 2006).

It is very critical to change from symptom-based presumptive treatment to parasitological confirmation of all patients presenting with malaria before initiation of antimalarial medications are administered. The use of parasite-based diagnosis allows for efficient utilisation of anti-malarial drugs, and provides a chance for other causes of fever to be identified early and treated appropriately (D'Acremont et al. 2009; Perkins & Bell, 2008; Msellem et al. 2009; Ishengoma et al, 2011). Efficacious uses of antimalarial medicines are critical to malaria control. It is for this reason imperative for health systems to invest in strengthening and enhancing the skills of health care providers especially those at the peripheral with appropriate guidelines and on hand training in order for them to make informed decisions.

2.3: Levels of Malaria Diagnosis in Ghana

The Ministry of Health (MoH) Ghana in the year 2012 scaled up the use of malaria Rapid Diagnostic Test (RDT) at all levels of health facilities to enhance diagnosis and ensure reasonable use of antimalarial drugs. The uptake of this policy made a significant headway over

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the years with testing rates for suspected malaria cases increasing from 14 percent in 2008 (MPR, 2013) to 73.5 percent in 2014 (NMCP, 2014).

Ghana has four categories of Malaria diagnosis which includes Community level, Primary Level, Secondary Level and Tertiary Level. Administering treatment can be different at these levels and among facilities of the same level. These categorical levels of malaria diagnosis is primarily based on the level of training and the ability of the provider to deliver the required service together with the nature of support services available for service delivery. A greater number of the reported cases of malaria are treated at the lower levels of the malaria diagnosis in Ghana. The OTCMS fall under the Community level of Malaria diagnosis in Ghana and they are to manage uncomplicated malaria using the Rapid Diagnostic Test as the recommended diagnostic test and as per the policy they are to refer all suspected severe cases to a higher level of care. To implement these guidelines, a common strategy is to provide health workers with in-service training; notwithstanding this training, health workers usually do not follow the diagnosis guidelines (Naimoli *et al*, 2006; Zurovac *et al*. 2004, 2005)

2.4: The characteristic and role of the Over The Counter Medicine Sellers (OTCMS)

Over the Counter Medicine Shops are independently owned businesses. The owners are persons authorised and licensed by the Pharmacy council of Ghana to engage in the retail supply of only over the counter drugs (i.e. Class C or OTC drugs) at a location specified in the license. They constitute one of the groups of practitioners mentioned in Part Four of the Healthcare Professions Regulatory Bodies Act, 2013, Act 857. They are classified by the Act 857 as Pharmaceutical Support Staff. They are small private outlets offering over-the-counter medicines and supplies for common illnesses, particularly in rural and hard-to-reach areas.

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In sub - Saharan Africa, OTCMS are often the most commonly used source for health services, information, and products (Wafula and Goodman, 2010). The owners of these facilities are typically literates and may or may not have some form of training such as a teachers and nurses (Seiter & Gyansa-Lutterodt, 2009).

They regularly receive training from the OTCMS Association and Pharmacy Council. Majority of them are retirees in professions like midwives, nurses and teachers with some using it as a full time enterprise and others as a part time venture where they often go to their normal daily job and opens later in the day to serve the community. They normally have white inscription indicating their name and address on a blue background as signage. They typically have storefronts, product displays, and a counter. There are more than 11,000 OTCMS facilities in Ghana (Seiter & Gyansa-Lutterodt, 2009). The effective enactment of the diagnosis and treatment guidelines led to a national training for OTCMS on the malaria case management by Pharmacy council with a support from donor agencies like the United State Agency for International Development (USAID) to improve OTCMS knowledge and practice of malaria case-management. Subsequently, distribution of job-aids to these groups through routine on-site supportive supervision and during the trainings was done.

The Ghana National Malaria Control Program Strategy aims is to have all suspected malaria cases presenting to a health provider managed according to the national malaria diagnosis guidelines before treatment. The OTCMS are licensed to provide medicines in the community. Their role in malaria control includes: (1) Educating clients on malaria prevention; (2) Diagnosis (performing malaria RDTs and recognizing symptoms) and treatment of uncompleted malaria; (3) Stocking the recommended anti-malarial commodities; (4) Dispensing anti-malarial

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medicines in accordance with the National Anti-malaria Drug Policy and (4) Referring cases to the appropriate health facilities (MOH, 2014).

This is to be achieved through training of health providers, support and supervision. The OTCMS facility can be located in almost every town within the country and provide services to a large population of the Ghanaian community.

2.5: Malaria diagnosis policy for OTCMS in Ghana

The Ministry of Health through the Pharmacy Council seeks to provide OTCMS with the skills to manage malaria efficiently and effectively in the community. As part of the Strategic Objectives for case management for National Malaria strategic plan 2014 – 2020, the country adopted the test, treat and track initiative where a provider is to conduct RDT on all febrile or suspected malaria cases, treat positive clients with appropriate and effective ACT and record actions taken respectively. The OTCMS providers are to withhold treatment of uncomplicated malaria cases from a negative result patient to a rapid diagnostic test. Further causes of fever should be investigated and suitable treatment given.

Effective diagnosing before treatment of malaria is a key intervention in response to increasing anti-malaria medicines cost and decreasing prevalence of malaria especially in urban areas of Ghana. Under this plan, all OTCMS in the country are to conduct RDT on all reported suspected malaria cases, treat only positive cases and refer negative but ill cases for further investigation at hospitals and clinics, and document and report all test conducted (MOH, 2016).

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2.6: Malaria Rapid Diagnostic Test Kit in Ghana

Parasite specific antigen is detected in a blood sample by RDTs which is a lateral flow test. Histidine-rich protein II (HRP II), a water soluble protein produced only by P. *falciparum* and specific to P. *falciparum*, based kits detect only P. *falciparum* which is the dominant parasite in the country (MOH, 2016). An RDT test demand of the provider to collect a drop of blood through a finger prick and place it onto a small plastic device called a cassette, which shows the result of the test after 15–20 minutes.

They are reasonably easy to use compared with microscopy and do not need specialised skills or laboratory equipment and reagents that are often inaccessible in rural or resource poor settings (*Hopkins et al, 2009*). Currently, in Ghana, HRP II based RDTs are acquired and supplied to peripheral areas as per the guidelines (MOH, 2016).

2.7: Standard Operating Procedures (SOPs) in malaria diagnosis

The Standard Operating Procedures (SOPs) is an essential document in a laboratory or testing sites and must be available to the provider as a reference. It gives a detail description of the complete procedure for performing tests and ensures that consistent and reproducible results are produced. The SOPs are developed to address before, during and after testing processes required for performing a malaria microscopy or rapid diagnostic test. For malaria RDTs, since each brand differs slightly, product-specific SOPs and job aids should be developed in reference to the package insert (MOH, 2016).

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To ensure the standard operating procedures are met, the OTCMS were giving all the necessary documents describing in detail the steps in conducting the rapid diagnostic testing. These documents included job aid/wall chart showing a simplified version of the procedures for performing an RDT that should be displayed in each OTCMS facility and training manuals.

2.8: Conclusion

The reviewed literature highlights compliance situations among OTCMS in managing uncomplicated malaria using malaria diagnosis test kits which must be addressed to improve adherence situation in the country to conform to the standard diagnosis guidelines. Notwithstanding the improvements in malaria case-management being reported and the testing rates being high, majority of health providers shown poor adherence to malaria management guidelines in many settings and a lot of patients are still being treated without a malaria test.

Majority of health providers rely on clinical symptoms, instead of a confirmation, when making a diagnosis even though they are poor predictors for the disease. This practice results in malaria disease over-diagnosis leading to excessive reporting of malaria cases, over-use of anti-malarial drugs, under-treatment, under-reporting and incorrect treatment of non-malarial febrile illnesses. Again, it leads to increased anti-malarial drug resistance, treatment of negative test cases as malaria and inappropriate allocation of resources, including over-treatment with expensive ACTs.

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The OTCMS, which provide healthcare at the community level in Ghana, are to manage uncomplicated malaria using the Rapid Diagnostic Test as the recommended diagnostic test and as per the policy to refer all suspected severe cases to the next level of care.

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CHAPTER THREE

METHODS

3.1: Study Design

A cross sectional survey was employed for the study where complete information from all OTCMS facilities in the Ledzorkuku-Krowor Municipality was under consideration. The data collection involved two distinct forms of surveys:

1) A mystery client survey (MCS) carried out at all the OTCMS facilities that have malaria rapid diagnostic kit in stock and
2) A face-to-face provider survey with the attendant (OTCMS or assistant) of the facility visited by the mystery client.

The MCS gave a better estimate of the policy-relevant impact - change in behavior on the part of the person who was most likely to respond to clients. The MCS took place before the provider interview. A quantitative method with structured questionnaire was used for the provider survey to interview OTCMS participants on varying issues such as provider type, sex of the provider, level of education of the provider, experience of the provider and trainings received on malaria case management as indicated in Table 1. The data collection for this retrospective study took a month, starting from first of June 2018.

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3.2: Study site

The study was conducted in Ledzorkuku-Krowor Municipal Assembly (LEKMA) in the Greater Accra region of Ghana. The municipal comprises of settlement classified according to income levels and developmental structures making it suitable for the study. LEKMA has an estimated land area of about 50 square kilometers. It is bounded to the south by the Gulf of Guinea from the Kpeshie Lagoon to the Mukwe Lagoon near Regional Maritime Academy as seen in Figure 2. The boundary extends along the Maritime Road to connect the Tema - Accra road to Nungua Police Barrier. It then turns right leading to the Ashiaman road and extends to hit the Spintex Road and runs on all the way through to Coastal Estate junction and carries on through to the Kwame Nkrumah Motorway. This then leads left along the motorway and branches south at the end of the Motorway, moves along the Tetteh Quarshie Circle and extends south along the frontiers of the Ashitey Akomfra Electoral area and towards the estuary of the Kpeshie lagoon. LEKMA lies in the Coastal Grassland zone which experiences a double maxima rainy season pattern with an average annual rainfall of about 730mm.

The municipality, according to the Ghana Statistical Service survey conducted in 2010, has a population of 227,932 representing 5.7 percent of the region's total population with 48 percent and 52 percent being males and females respectively and a sex ratio of 91.9 (GSS 2010).

Settlement system in the municipality is classified based on income levels and on development as calculated on rate imposts on the various residential properties. This provides guidance to the property rates charged in the various settlements. Based on the above, it is categorized broadly under four zones, namely First Class (Airport Hill, Teshie-Nungua Est., Regimanuel Est., Part of

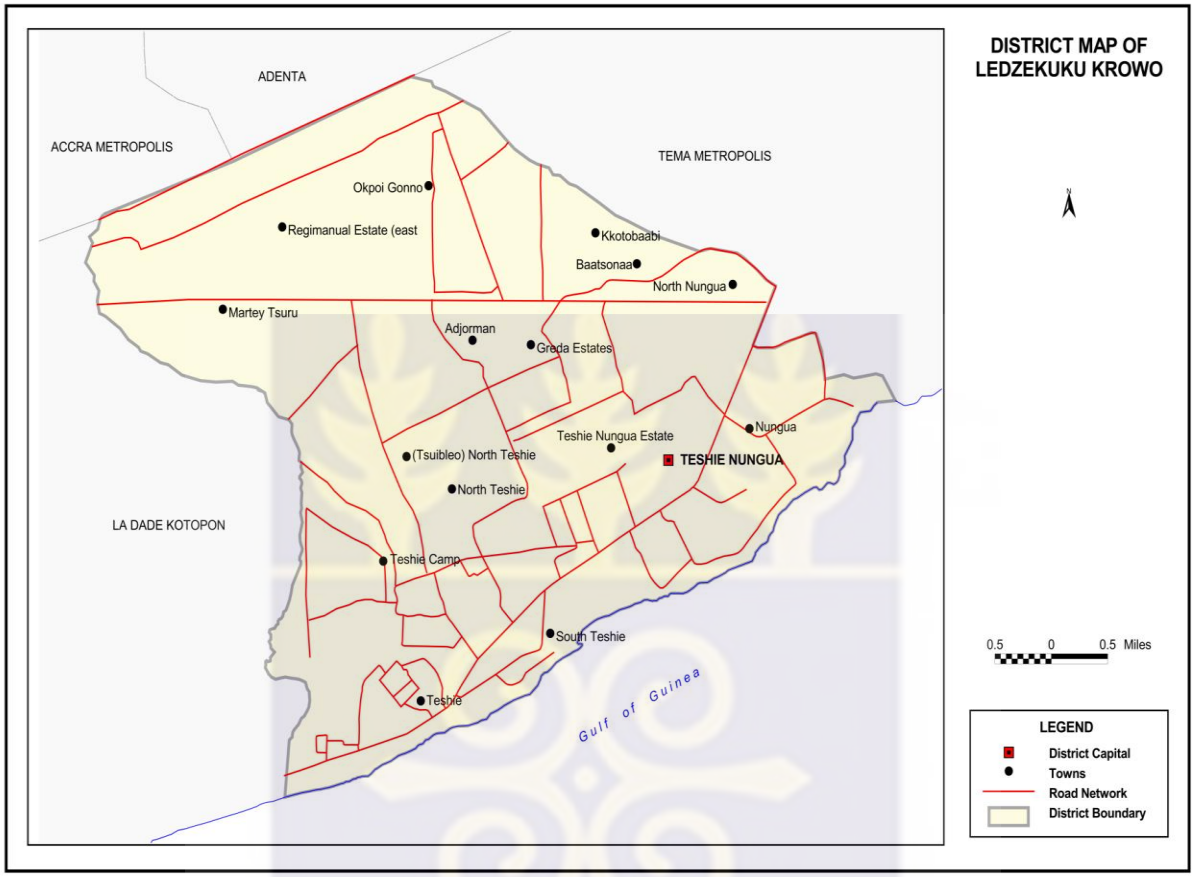
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Martey Tsuru, SSNIT Grade Est., Adzormana, Nungua Barrier etc) Second Class 'A,' (Maritime Academy area, Parakuo Est., Baatsonaa, Tebibianor, Cold store area, Penny, Teshie Fertilizer, Camp 2, Buade, Bush road etc) Second Class 'B' (Demo, First junction, Nungua new town, Teshie Dar-es-salam, Teshie Manhean etc) and Third Class (Teshie old town, Nungua Old town, Teshie Zongo and Nungua Zongo).

The age – sex structure of the municipality is similar to the national structure with a broad base comprising of concentration of children at younger ages that is characteristic of a developing country such as Ghana. 92.2 percent of the population 11 years and older are literate (GSS 2010). The municipality is also burdened with malaria as one of its top priority diseases, especially in the second quarter of 2008. There are a total of about sixty – four OTCMS facilities in the municipality.

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Figure 2: Map of LEKMA



Source: Ghana Statistical Service, GSS (2014)

3.3: Study population

The study population was Over The Counter Medicine Sellers providing services within the LEKMA area.

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Inclusion criteria:

The selection criteria for inclusion in this study was an OTCMS provider having malaria rapid diagnostic test kit in stock and consenting to be interviewed.

Exclusion criteria:

The exclusion criterion for the study was an OTCMS provider who has malaria rapid diagnostic test kit in stock but does not consent to be interviewed.

3.4: Study Variables

Outcomes of Interest:

The specific outcome of interest was the adherence to malaria diagnosis guidelines by Over The Counter Medicine Sellers (OTCMS). This was measured based on mystery client survey report as nominal scale of measurement to assess whether they adhered to or do not (Table 1).

Exposure variables

The key exposure variable, as illustrated in table 1, were the provider's factor which includes the level of education and experience in the field of practice.

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Intermediate variables

The intermediate variables were the training received on the malaria diagnosing guidelines and the characteristics of the OTCMS facility (Table 1).

Additional factor considered was the institutional regulatory body's routine visits to the facilities as a form of monitoring and evaluation.

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Table 1: Variables and scale of measurement

Variable	Operational definition	Type of variable	Scale of measurement
Provider factor - Educational level - Experience	 - Highest level of education obtained - Number of years of practice as a provider)	 Exposure	Ordinal - Primary school = 1 - JHS/Middle School = 2 - SHS/O Level/A level = 3 - Tertiary = 4 Experience - Below 5 years = low - Above 5 years = High
Monitoring & Evaluation - Regulatory body's visit to the OTCMS facility	The yearly routine on-site supportive supervision visits by the regulatory bodies(institutional support) prior to the study	Exposure	Nominal - Yes = 1 - No = 0
Malaria diagnosis guidelines - Training received	OTCMS training received on malaria case management	Intermediate	Nominal - Yes = 1 - No = 0
OTCMS facility characteristics - Location	 - The area in which the OTCMS facility is found	Intermediate	Nominal Residential type - First Class = 1 - Second class 'A' = 2 - Second class 'B' = 3 - Third class = 4
RDT Adherence	OTCMS providers compliance to national malaria diagnosis guidelines in conformity to recommended standard guidelines	Outcome	Nominal Adherence - Yes = 1 Non Adherence - No = 0

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3.5: Sample Size Determination

The study was a descriptive survey where all OTCMS facilities having malaria rapid diagnostic test kit in stock in the Municipality were recruited for the study. The OTCMS facility total was obtained from the Pharmacy Council of Ghana. There were a total of 67 OTCMS facilities in the municipality and of which 21 of these facilities had malaria RDT in stock at the time of the study period and were therefore purposively considered.

In generating the possible number of case scenarios for the mystery clients, the case definition for uncomplicated malaria was set as constant for diagnosis by the provider and other related symptoms of uncomplicated malaria were then shuffled around. This was done using mathematical combination, starting with 8 combination 1, thus 8C1, 8C2, 8C3 through to 8C8 for each mystery client to have a unique case scenario to present to the provider. These were then summed up to a total of 255 possible scenarios. There were a total of 21 OTCMS facilities and 255 possible scenarios. By dividing the possible scenarios by the number of OTCMS facilities gave a total of 12.14 ~ **12.** The number 12 was therefore used for not the sample size to exceed the estimated of 255. This therefore gave a sample size of **252**.The 12 represented the total number of mystery clients used in total with each having a unique case to present to the facilities.

The symptoms of uncomplicated malaria with the exception of fever were labelled alphabetically, in no order of importance (Table 3). Each OTCMS facility was visited 12 times with different case scenarios. By using STATA to randomly select 12 from the 255 possible scenarios using the command (sample 12, count), generated the random samples of alphabets

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(ACDF, ABCEGH, ABF, ABCDFH, ACDEFG, ABH, BDFH, CDFGH, EFGH, BEG, ACG, ABDFH). This is illustrated in table 3 with each mystery client presenting with different case scenarios.

Table 2: Illustration of the sample – Simulated case scenarios for each mystery client

Mystery Client #	Sample	Sample-simulated case scenarios
1	ACDF	Chills (feeling unusually cold), Headache, General body and joint pains; Loss of appetite
2	ABCEGH	Chills (feeling unusually cold), Rigors (shivering), Headache, General joint and body pains, Nausea/vomiting, Sweating, Bitterness in the mouth
3	ABF	Chills (feeling unusually cold), Rigors (shivering), Loss of appetite
4	ABCDFH	Chills (feeling unusually cold), Rigors (shivering), Headache, General joint and body pains, Loss of appetite and Bitterness in the mouth
5	ACDEFG	Chills (feeling unusually cold), Loss of appetite, Headache, General joint and body pains, Nausea/vomiting and Sweating
6	ABH	Chills (feeling unusually cold), Rigors (shivering) and Bitterness in the mouth
7	BDFH	Rigors (shivering), General body and joint pains, Loss of appetite and Bitterness in the mouth
8	CDFGH	Headache, General body and joint pains, Loss of appetite, Sweating and Bitterness in the mouth
9	EFGH	Nausea/vomiting, Loss of appetite, Sweating and Bitterness in the mouth
10	BEG	Rigors (shivering), Nausea/vomiting and Sweating
11	ACG	Chills (feeling unusually cold), Headache and Sweating
12	ABDFH	Chills (feeling unusually cold), Rigors (shivering), General body and joint pains, Loss of appetite and Bitterness in the mouth

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Table 3: Illustration of symptoms of uncomplicated malaria with alphabets

#	**Constant**	Fever within the preceeding 2 - 3 days
1	**A**	Chills (feeling unusually cold)
2	**B**	Rigors (shivering)
3	**C**	Headache
4	**D**	General body and joint pains
5	**E**	Nausea/vomiting
6	**F**	Loss of appetite
7	**G**	Sweating
8	**H**	Bitterness in the mouth

3.6: Data Collection Technique/Instruments

A quantitative method was used for the data collection. The provider survey data was collected using face-to-face interviews with paper questionnaires that took approximately 20 minutes to be administered and the mystery client survey was recorded on a sheet upon exist from the provider's facility. The provider survey was conducted with the same attendant the mystery client met at the facility. The mystery clients were selected purposively and were all trained prior to the study. In the MCS, a recruited client visited each of the enumerated OTCMS provider's facility, posing as a client presenting with varying symptoms of uncomplicated malaria as illustrated in table 2. The recruited mystery client for this study was not in any circumstances undergo any type of diagnostic test during the visit but rather purchased the malaria test kit and

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leave the facility. The steps and the actions taken by the provider was recorded by the mystery client on exit from the facility. All the facilities visited by the MCS were made sure that they had in stock of malaria RDT available to prevent providers using stock out as an excuse of not conducting test. The specific research objective of the MCS was to determine the diagnosis guidelines were adhered to by providers in accordance with the national guidelines. The study was conducted within a month period starting in June 2018. All the 21 OTCMS facilities having malaria rapid diagnostic test kit in stock within the district were visited.

3.7: Data Processing

The administered questionnaires were cross-checked by the principal investigator and were double entered by two personnel independently into an excel spread sheet. These were then compared before transporting all to STATA. This data were then cleaned using Microsoft excel software. The research assistants and the principal investigator independently cross checked each data entry to ensure what has been entered into the excel spread sheet was accurate. Adherence to the national diagnosis guidelines was coded '1' for Yes (Adherence) and '0' for No (Non adherence). If an OTCMS provider met all the required research objectives (display of malaria RDT posters at the facility, use of the malaria RDT kits and the testing of malaria), he/she gets 'Full adherence', if he/she did not meet all but some, is 'Partial adherence' and if did not meet all, is 'Non-adherence'.

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3.8: Data Analysis

3.8.1: Background characteristics of OTCMS

In the analysis of the background characteristics of the OTCMS, the categories in the predictor variables which include the sex of the provider, the provider type, provider level of education, provider experience, provider training received on malaria case management were cross tabulated to determine the number and proportion of categories for each predictor variable. This was analyzed using STATA Version 15 after its importation. The units of analysis for all estimations were the individual OTCMS facility (including licensed OTCMS and shop assistants). Frequency distribution of responses by categories of each variable was calculated and expressed in percentages. The results were then presented in tables.

3.8.2: Determination of malaria RDT posters displayed at the OTCMS facilities

The proportion of malaria RDT posters displayed at the OTCMS facilities was analysed by cross tabulating availability of the malaria RDT poster with non-availability of the malaria RDT poster with the aid of STATA Version 15. The numbers and proportions for both availability and non-availability were determined. The unit of analysis for the estimations was the individual OTCMS facility. Tables were then used to demonstrate the results.

3.8.3: Determination of OTCMS providers that use the malaria RDT kits

The characteristics in determining OTCMS providers that used the malaria RDT kits was done by cross tabulating the use of the malaria RDT kits against those providers that do not use the malaria RDT kits. The numbers and proportions for both use and not use of the malaria RDT kits were determined. The unit of analysis for the estimations was the individual OTCMS facility.

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3.8.4: Determination of the testing of malaria among OTCMS providers

In determining the testing of malaria among OTCMS providers, those that did the testing were cross tabulated with those that did not do the malaria testing by finding the numbers and proportions of each using STATA Version 15 for the analysis. The results were then illustrated in table.

3.8.5: Determination of the overall adherence of malaria RDT diagnosis guidelines among OTCMS providers

The overall adherence to the malaria RDT diagnosis guidelines was done under three levels of adherence – full adherence, partial adherence and non-adherence. In the determination of full adherence, if all the first three specific objectives were met, a provider gets 'full adherence', if some but not all were met, a provider gets 'partial adherence' and if none were met, a provider gets 'non-adherence'. These were cross tabulated with the help of STATA. The numbers and the proportions of the three levels of adherences were then determined. The results were then presented using a pie chart. A chi square test was used to determine the significant relationship each predictor variable has with the outcome variable. The results were then presented in a table form.

3.9: Quality Control

Recruitment for data collector(s) was done based on those with a secondary or tertiary educational background and with experience to ensure quality of data collection. These collectors were trained and evaluated to ascertain their level of understanding and capability to carry out accurate assessment and obtain a true data from the providers. All questionnaires were

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entered and double checked as a standard quality control procedure. Questionnaires were critically examined at the end of each day's survey. Research assistant(s) also double checked data that were gathered by the principal investigator. As part of the quality control mechanism, pre-testing was done at Labadi town which serves communities with similar characteristics as those treated in the Ledzorkuku-Krowor Municipal. This assisted in evaluating the time needed to finish each questionnaire, filled each data abstraction form and ascertained the preciseness of questions and conduct model analysis.

3.10: Ethical Issues

3.10.1: Ethical Clearance

Prior to this study, ethical clearance was obtained from the Ghana Health Service Ethics Review Committee.

3.10.2: Study area approval

Permission was sought from the Pharmacy Council of Ghana, the main regulatory body to the OTCMS.

3.10.3: Purpose of study

The main purpose of the study was to assess the adherence to malaria diagnosis guidelines among Over the Counter Medicine Sellers in Ledzorkuku-Krowor Municipal. This was to guide and strengthen the implementation of malaria diagnosis guidelines being used in the country.

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3.10.4: Study subjects

The subjects under the study consisted solely of OTCMS providers who had malaria RDT in stock in Ledzorkuku-Krowor Municipality at the time of the study period.

3.10.5: Risk/benefits of the study

The participants were made known that there was minimal risk associated with the study in relation to information sharing. The information shared was kept confidentially and was used solely for the study purpose and not for any other. There were no consequences when someone withdrawn from the study. The benefit of the study was to guide and strengthen the implementation of malaria diagnosis guidelines used in the country.

3.10.6: Privacy/Confidentiality

Privacy was highly ensured during the interview with the providers not to interfere with their work and that patients do not see what goes on between the interviewer and the interviewee. No identifying information such as name of facility and phone number were captured through the administration of the questionnaire. Confidentiality was assured regarding the information collected and was not shared with anyone but solely for study purposes.

3.10.7: Voluntary withdrawal

All OTCMS providers were made aware that they were of liberty to withdraw from the study at any point if they felt uncomfortable. They were made known that some of the information already obtained before withdrawal from the study will be used in analysis. The data cannot be linked to their names and may be used in study reports and publications as the total number of people who refused to participate.

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3.10.8: Description of consenting process

The OTCMS providers were made known of the potential risk and benefits of the study associated with their work while they participated in the study. They were again assured that the information gathered from them was to be used solely for research purposes. Confidentiality and privacy were highly assured. The providers were also made aware that data security, storage and usage would be well protected and limited to the principal investigator and supervisor.

They were informed of the fact that they can choose to participate in the study or withdraw at any time. When inform consent was granted by the OTCMS provider upon request, they signed a consent form to concur to the interview and the questionnaire being administered.

3.10.9: Data security, storage and usage

Information obtained from OTCMS providers were kept in a locked file cabinet. Accessibility to these was limited to the principal investigator and supervisor of the study. The softcopy of the data obtained was password protected.

3.10.10: Compensation

There was no compensation for OTCMS providers participating in the study.

3.10.11: Declaration of conflict of interest

The principal investigator had no conflict of interest for the study.

3.10.12: Research funding information

The study was funded entirely by the Principal Investigator.

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CHAPTER FOUR

RESULTS

4.1: Introduction

This results section is organised into sections, the first section demonstrates the background characteristics of the OTCMS. The second section of the work is on determining the proportion of OTCMS providers that use the malaria RDT test. The third section focuses on the testing of uncomplicated malaria among the OTCMS providers and the last section is determination of the overall adherence to malaria diagnosis guidelines among OTCMS providers.

4.2: Background characteristics of OTCMS

The response rate for the study was 98.8 percent. The table 4 shows that there were 38.1 percent (96/252) of the OTCMS owners and 61.9 percent (156/252) assistants in all the OTCMS facilities visited during the study period. There were 33.3 percent (84/252) of the attendants who have worked as a provider for less than or up to 5 years whereas about 66.7 percent (168/252) have had more than 5years working experience as an OTCMS provider. There was no provider with primary school as his/or her highest level of education. The JHS/Middle school recorded 9.5 percent (24/252), the Senior High School/A & O levels with 71.4 percent (180/252) and Tertiary level with 19.1 percent (48/252). In the residential type, the first class recorded 14.3 percent (36/252) whereas the second class 'A' and third class residential type recorded 66.7 percent (168/252) and 19.1 percent (48/252) respectively. There was no location recorded for residential

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type second class 'B'. Providers trained on malaria case management were 76.2 percent (192/252) as against those not trained were 23.8 percent (60/252).

Table 4: Predictor variables of OTCMS providers frequencies with proportion

ITEMS	Number	Percent (%)
Sex of provider		
Male	108	42.9
Female	144	57.1
Provider type		
OTCM Owner	96	38.1
Assistant	156	61.9
Experience of provider		
≤ 5 years	84	33.3
> 5 years	168	66.7
Educational level		
JHS/ Middle school	24	9.5
SHS/ A&O levels	180	71.4
Tertiary	48	19.1
Provider RDT Training		
Have not received training	60	23.8
Received training	192	76.2
Residential type		
First class	36	14.3
Second class 'A'	168	66.7
Third class	48	19.1
Total	252	100.0

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4.3: Determination of malaria RDT posters displayed at the OTCMS facilities

There were 8.3 percent (21/252) of the OTCMS providers that had malaria RDT posters displayed at their facilities whereas 91.7 percent (231/252) of the OTCMS providers had not displayed their malaria RDT posters as indicated in table 5.

Table 5: Proportion of malaria RDT posters displayed at the OTCMS facilities

Malaria RDT posters	Number	Percent
Not available	231	91.7
Available	21	8.3
Total	252	100.0

4.4: Determination of OTCMS providers that use the malaria RDT kits

The proportion of OTCMS providers that use the malaria RDT kit was 21.8 percent (55/252) and providers that do not use the malaria RDT kits was 78.2 percent (197/252) as shown in table 6.

Table 6: Proportion of OTCMS providers that use the malaria RDT kits

	Number	Percent
Do not use RDT kits	197	78.2
Use RDT kits	55	21.8
Total	252	100.0

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4.5: Determination of testing of malaria among OTCMS providers

The table 7 shows that there was 7.1 percent (18/234) of the OTCMS providers that did the malaria testing with 92.9 percent (234/252) of the providers not doing the testing of malaria.

Table 7: Testing of malaria among OTCMS providers

	Number	Percent
No malaria testing	234	92.9
Malaria testing	18	7.1
Total	252	100.0

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4.6: Determination of the overall adherence to malaria RDT diagnosis guidelines among OTCMS

4.6.1: Determination of the overall adherence using the three levels

About 2.8 percent (7/252) of the OTCMS providers fully adhered, 24.6 percent (62/252) partially adhered and 72.6 percent (183/252) did not adhere to the malaria diagnosis guidelines as indicated in the figure 3.

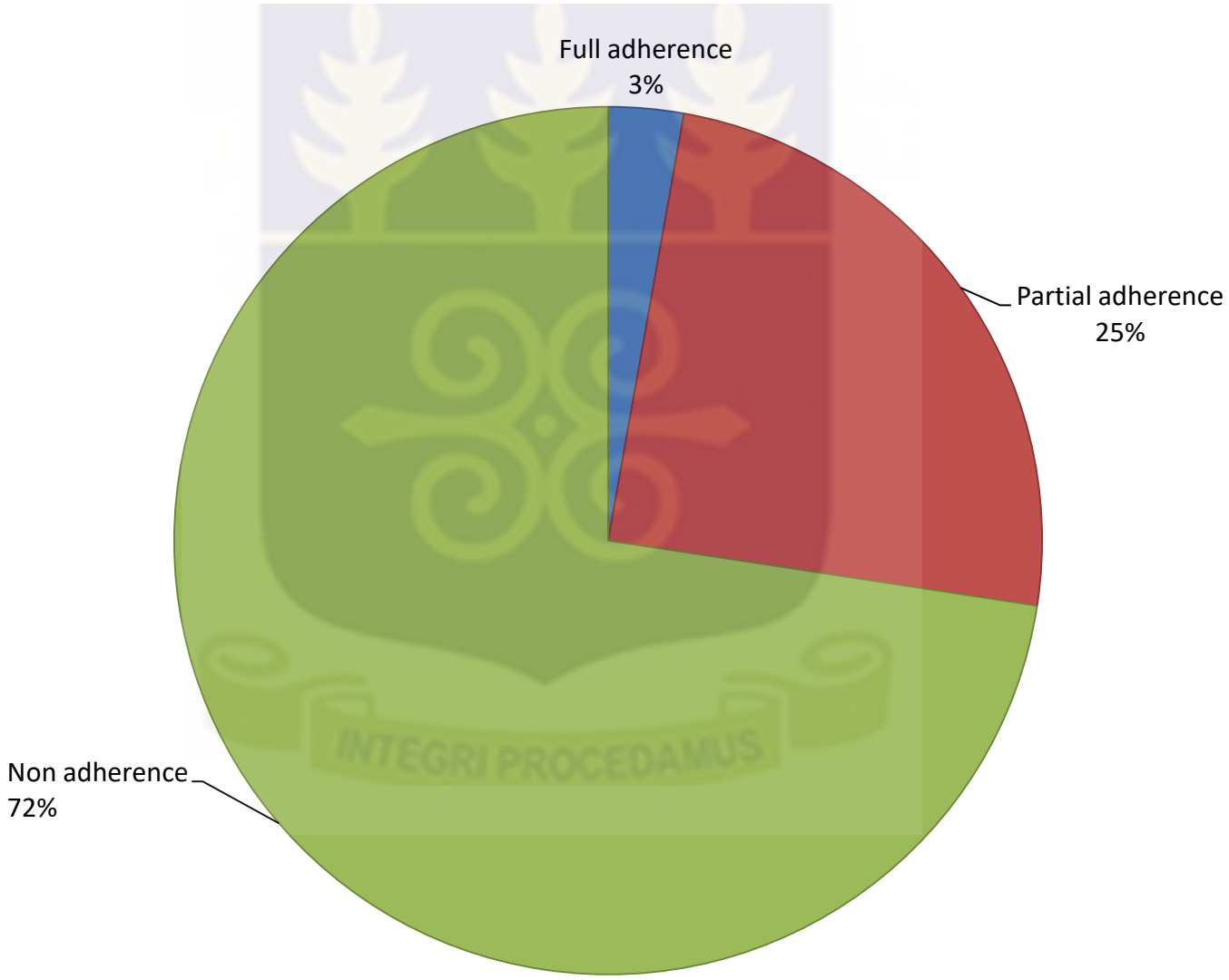


Figure 3: Level of adherence among OTCMS providers

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4.6.2: Determining the significances of the overall adherence with predictor variables

The test for significant association shows that the sex of the respondent, the provider type and the educational level of the provider had some level of association with adherence to the malaria RDT diagnosis guidelines as shown in table 8. The Male respondents showed 6.5 percent (7/108) full adherence, 36.1 percent (39/108) partial adherence and 57.4 percent (62/108) non-adherence to the malaria RDT diagnosis guidelines whereas the Female respondents were 0.0 percent (0/144) for full adherence, 16.0 percent (23/144) partial adherence and 84.0 percent (121/144) non-adherence to the malaria RDT diagnosis guidelines as shown in table 8.

The OTCMS providers showed 7.3 percent (7/96) full adherence, 24.0 percent (23/96) partial adherence and 68.8 percent (66/96) of non-adherence whereas the assistants showed 25.0 percent (39/156) partial adherence and 75.0 percent (117/156) of non-adherence as indicated in table 8.

The educational level of the providers, as shown in table 8, indicates that all those with junior high school level/middle school recorded 100.0 percent (24/24) non-adherence. Those with senior high school/ A&O levels had 3.9 percent (7/180) of full adherence, 25.0 percent (45/180) of partial adherence and 71.1 percent (128/180) of non-adherence. 35.4 percent (17/48) and 64.6 percent (31/48) recorded for partial adherence and non-adherence respectively for providers with tertiary education (Table 8).

The OTCMS providers that received RDT training, as indicated in table 8, had 0.0 percent (0/60) full adherence, 30.0 percent (18/60) partial adherence and 70.0 percent (42/60) non-adherence whereas those that received RDT training had 3.7 percent (7/192) full adherence, 22.9 (44/192) partial adherence and 74.4 percent (141/192) non-adherence.

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Table 8: Determining the significances of the overall adherence with predictor variables

VARIABLES	Full adherence n (%)	Partial Adherence n (%)	Non adherence n (%)	Row total (N)	P-value
Sex of provider					
Male	7 (6.5)	39 (36.1)	62 (57.4)	108	0.0001*
Female	0 (0.0)	23 (16.0)	121 (84.0)	144	
Provider type					
OTCM Owner	7 (7.3)	23 (24.0)	66 (68.8)	96	0.003*
Assistant	0 (0.0)	39 (25.0)	117 (75.0)	156	
Experience of provider					
≤ 5 years	0 (0.0)	25 (30.0)	59 (70.0)	84	0.084
> 5 years	7 (4.2)	37 (22.0)	124 (73.8)	168	
Educational level					
JHS/ Middle school	0 (0.0)	0 (0.0)	24 (100.0)	24	0.007*
SHS/ A&O levels	7 (3.9)	45 (25.0)	128 (71.1)	180	
Tertiary	0 (0.0)	17 (35.4)	31 (64.6)	48	
Provider RDT Training					0.202
Have not received training	0 (0.0)	18 (30.0)	42 (70.0)	60	
Received training	7 (3.7)	44 (22.9)	141 (73.4)	192	
Residential type					
First class	0 (0.0)	9 (25.0)	27 (75.0)	36	0.312
Second class 'A'	7 (4.2)	38 (22.6)	123 (73.2)	168	
Third class	0 (0.0)	15 (31.3)	33 (68.7)	48	

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CHAPTER FIVE

DISCUSSION

5.1: Introduction

The overall study discussion detailed on the displayed malaria RDT posters at the OTCMS facilities, the use of the malaria RDT kits, the testing of malaria among OTCMS providers, the overall adherence to malaria RDT diagnosis guidelines and the limitation to the research. A significant proportion of the OTCMS providers were not adhering to the malaria diagnosis guidelines by not displaying malaria RDT posters, not using the malaria RDT kits and not testing for malaria.

5.2: Determination of malaria RDT posters displayed at the OTCMS facilities

The analysis of the results showed that the display of the malaria RDT posters in the OTCMS facilities were far less compared to OTCMS facilities that have not displayed the malaria RDT posters. This was a contributory factor to their adherence to the malaria diagnosis guidelines. The malaria RDT poster as part of the standard operating procedures in malaria diagnosis was to describe in detail the complete procedure for performing the test as recommended by the Ministry of Health. In reference to this, all OTCMS providers were given these malaria RDT posters to display at their facilities during the training as part of the diagnosis guidelines to aid them in performing the rapid diagnostic test. Despite these in-service trainings and provision of standard operating procedure materials to the OTCMS providers, a highly insignificant number of them displayed the malaria RDT posters at their facilities. It is possible to see how Naimoli et

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al (2006) agrees with Zurovac et al (2004) that in spite of the trainings with materials received, health providers often do not follow guidelines. This could be due to the fact that most of them have renovated their facilities, as some of them were found to have done so during the data collection period or might have relocated their operation to another area after the workshop which was organised for them four years ago and therefore did not display them after the renovation.

5.3: Determination of OTCMS providers that use the malaria RDT kits

It was also found that OTCMS providers that use the malaria RDT kits were 78.2 percent compared to 21.8 percent of providers that do not use the malaria RDT kits. This indicates that OTCMS providers are less likely to use the malaria RDT kits. This could be as a result of the cost of the malaria test in addition to the cost of the antimalarials to administer. This might seem too expensive, especially to clients who live in second class and third class residential types. Chandler et al (2011) makes the point that, factors that may reduce health provider's interest in the use of the malaria test kits included the cost of the test. This could be one of the many reasons why some of the OTCMS providers were not using the malaria test kits. Ezeoke et al (2012) also made this point in their study that, there were concerns as to the reliability of test results with symptoms being deemed more significant than test results among health service providers which could be due to their previous experiences in their field of practice.

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5.4: Determination of testing of malaria among OTCMS providers

The observations made during the analysis for the testing of malaria among OTCMS providers demonstrates that a high significant number of them were more likely not to test for malaria than to do the test for malaria using the diagnostic test kits. This significant difference among providers could be as a result of their previous experience with uncomplicated malaria case management. Likewise, Amexo, Nosten and Ashley (2004) make the case in their research that majority of the health service providers rely on clinical symptoms when making a diagnosis even though they are poor predictor for the disease. Conversely, Hutchinson et al (2015) argues in their qualitative research that, private health service providers may want to offer the test because of the reputational benefits and because it allows them to offer a high quality of care. This should have been the ideal situation under normal circumstances but it was different in this regard. The residential type of the OTCMS facility could also be among the reasons for them not conducting the test due to low income level among the residences and also most of the facilities were found at these settings in the municipality.

Majority of the OTCMS providers not testing for malaria could also be due the fact that they do not have confidence in the reliability of the malaria RDT test kits as most of the results might be negative even though the patient might be experiencing some symptoms of malaria. Researchers who agree with this assertion are Olliaro (2009) and Ochola et al (2006), made it clear in their research that most health service providers do not see the malaria RDT kits as an ideal tool and therefore could reduce the trust of health providers.

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5.5: Determination of the overall adherence to malaria RDT diagnosis guidelines among OTCMS

The overall full adherence to the malaria RDT diagnosis guidelines from the analysis was 24 times less compared to providers that did not adhere and about 8 times less compared to those that showed partial adherence to the malaria diagnosis guidelines. This demonstrates that a very high significant number of the OTCMS providers are not adhering to the malaria diagnosis guidelines as recommended by the Ghana Health Service and the Ministry of Health. This could be as a result of the cost of the malaria test kits and the trust in the reliability of the malaria rapid diagnosis test kits. Chandler et al (2011), in their research, make the point that, factors that may reduce health provider's interest in adherence to malaria RDTs usage included the cost of the test. It has also been mentioned in a research conducted by Bisoffi and Van den Ende (2008) that, the outcome, the accuracy and the reliability of the malaria test kits may be a significant determinant of the adherence to the malaria diagnosis guidelines.

The results also showed that the provider type and the educational level of the provider were significantly associated with the level of adherence to the malaria diagnosis guidelines as their p-values were ($p = 0.003$) and ($p = 0.007$) respectively. The OTCMS providers are to manage uncomplicated malaria using the Rapid Diagnostic Test as the recommended diagnostic test and as per the policy they are to refer all suspected severe cases to a higher level of care. To implement these diagnosis guidelines, a common strategy was to provide them with training which was carried out by their regulatory body, the Pharmacy Council of Ghana. In line with the conceptual framework model, the educational level of the provider under provider factor and training received were to aid in their adherence to the diagnosis guidelines as recommended by

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the National Malaria Control Program of Ghana Health Service. However, the training received by the OTCMS providers was not statistically significant, thus not aiding to their adherence to the malaria diagnosis guidelines. Naimoli et al (2006) and Zurovac et al (2004) stated in their submissions that, despite the trainings received with educational level; health service providers often do not follow the diagnosis guidelines. Moreover, various studies have stated cases where healthcare providers presumptively treat patients as having malaria without a diagnostic test, or with negative test results with anti-malarials as reported by Olliaro (2009), Ochola et al (2006) and Naimoli et al (2006) in their research work. This could be that the health service providers do not have enough trust in the malaria RDT test results and false results could lessen their reliance.

The primary goals of the country adopting a strategic approach in fighting malaria cases, according to Ghana Health Service National Malaria Control Program, are to immediately confirm diagnosis and effectively treat only positive malaria cases to avoid advancement to severe disease, reduce the duration of disease and minimize the risk of developing and spreading drug-resistant parasites. One of the Strategic objectives for the case management outlined in the revised National Malaria Strategic Plan 2014 – 2020 is to provide parasitological diagnosis to at least 90 percent of all suspected malaria cases. Thus, the country aims to provide access to instant and effective treatment so as to test 90 percent of all suspected malaria cases at all health facilities. However, the adherence level recorded from the study was 87.2 percent less than the strategic plan objective of achieving at least 90 percent of all suspected malaria cases. This was related to OTCMS provider's educational level with trainings received and the provider type.

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5.6: Limitations of the study

The major limitation of the study was that it was conducted at a period where most of the OTCMS facilities in the municipality and across the country were not having malaria RDT but only a selected few had them. Due to this limitation, most of the OTCMS facility distributions according to residential type were not evenly done as most of them were concentrated at the second class 'A' residential type and a few in the first class and third class.

Another limitation was the fact that the mystery clients did not undergo any medical procedure; the OTCMS providers could not collect information on provision of these services.

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CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1: Conclusion

The findings of this study clearly show that a very high significant number of the OTCMS providers are not adhering to the malaria diagnosis guidelines as recommended by the Ghana Health Service and the Ministry of Health. There was a high remarkable difference between the strategic objective outlined in the national malaria strategic plan 2014 – 2020 and the adherence level among OTCMS providers to the diagnosis guidelines. It can be deduced from the results findings again, that majority of the OTCMS providers will not conduct the test for uncomplicated malaria cases presented to them on daily basis but rather treat their patients presumptively even though they have the malaria diagnostic test kits at their facilities and have received trained on malaria case management by the regulatory body.

It is known that presumptive malaria treatment causes irrational use of ACTs that are costly. The majority of the OTCMS providers' not conducting test on their patients presenting with uncomplicated malaria cases will increase transmission of the infection to others by increasing the infectious reservoir and enhancing the emergence and spread of resistance to anti-malarial medicines. If the objectives set by the country are to be achieved, then practice has to align with policies. OTCMS providers' adherence to malaria diagnosis guidelines is, therefore, very critical for the successful implementation of case-management policy and prevention of drug resistance since they are known to handle a lot of the uncomplicated malaria cases at the peripheral level of malaria diagnosis in the country.

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6.2: Recommendation

Based on this study, I will recommend the following as outlined below;

1) It is required of health systems to invest in strengthening and improving the skills of those providing care especially OTCMS providers at the peripheral with supportive supervision and re-enforcement in order for them to comply with the policy. The Pharmacy Council of Ghana together with the National Malaria Control Program will therefore have to encourage OTCMS providers documenting all malaria diagnostic tests conducted at their facilities in a reporting form and NMCP and other suppliers to demand from the OTCMS of their reporting form before other consignments are issued.

2) The Pharmacy Council of Ghana should consider the educational level of the applicant in the selection of the OTCMS. This will help increase the testing of all suspected malaria cases before treatments are administered and thereby assisting to solve the problem of non-adherence among the OTCMS service providers in the country.

3) More studies are needed on prescribers' adherence and reasons why they do not comply, in order to find ways to correct this. This will in effect reduce resistance to antimalarial medicines.

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REFERENCES

Ansah, E. K., Narh-Bana S., Epokor M., Akanpigbiam S., Quartey A. A., Gyapong J., et al (2010). Rapid testing for malaria in settings where microscopy is available and peripheral clinics where only presumptive treatment is available: a randomised controlled trial in Ghana. *BMJ*.;340:c930.

Ahorlu , C. K., Koram, K. A., Ahorlu , C., & De Savigny , D. W. (2006). Socio-cultural determinants of treatment delay for childhood malaria in southern Ghana. *Trop Med Int Health*, 11,1022–31.

Amexo, M., Tolhurst, R., Barnish, G., & Bates, I. (2004). Malaria misdiagnosis: effects on the poor and vulnerable. *Lancet*, 364.

Aregawi , M., Lynch , M., Bekele , W., Kebede , H., & Jima , D. (2014). Time series analysis of trends in malaria cases and deaths at hospitals and the effect of antimalarial interventions, 2001-2011. *PLoS One*, 9(11): p. e106359.

Bilal, J. A. (2015). Poor adherence to the malaria management protocol among health workers attending under-five year old febrile children at Omdurman Hospital, Sudan. *Malar J*, 14(1), p. 34.

Bisoffi, Z., & Van den Ende, J. (2008). Costs of treating malaria according to test results. *PubMed/NCBI*, 336, 168–169.

Bouyou-Akotet, M. K. (2012). Complicated malaria and other severe febrile illness in a pediatric ward in Libreville, Gabon. *BMC Infect Dis*, 12, p. 216.

University of Ghana http://ugspace.ug.edu.gh

Center for Disease Control and Prevention. (2015). Retrieved from Global Health – Division of Parasitic Diseases and Malaria: https://www.cdc.gov/malaria/malaria_worldwide/index.html

Chandler , C., Whitty, C. J., & A, E. (2010). How can malaria rapid diagnostic tests achieve their potential? A qualitative study of a trial at health facilities in Ghana. *Malaria Journal*, 9(95). doi:10.1186/1475-2875-9-95.

Chandler, C. I., Hall-Clifford , R., Asaph , T., & Pascal, M. (2011). Introducing malaria rapid diagnostic tests at registered drug shops in Uganda: limitations of diagnostic testing in the reality of diagnosis. *Social Science & Medicine*, 72, 937-944. 10.1016.

Chandler, C. I., Hall-Clifford, R., & Asaph, T. (2011). Introducing malaria rapid diagnostic tests at registered drug shops in Uganda: limitations of diagnostic testing in the reality of diagnosis. *Social Scien*.

Cohen, J., & Dickens, W. (2015). Adoption of Over-the-Counter Malaria Diagnostics in Africa: The Role of Subsidies, Beliefs, Externalities and CompetitionIn The Value of Information Methodological Frontiers and New Applications for Realizing Social Benefit Edited. *Malarial Journal*, 1 - 10.

D'Acremont , V., Lengeler , C., Mshinda , H., & Mtasiwa D, D. (2009). Time To Move from Presumptive Malaria Treatment to Laboratory-Confirmed Diagnosis and Treatment in African Children with Fever. *PubMed/NCBI*, 6(1): e252.

University of Ghana http://ugspace.ug.edu.gh

English , M., Reyburn , H., Goodman , C., & Snow, R. W. (2009). Abandoning Presumptive Antimalarial Treatment for Febrile Children Aged Less Than Five Years—A Case of Running Before We Can Walk? *PLoS Med*, 6(1), P 0007 - 0008.

Ezeoke , O. P., Ezumah , N. N., Chandler , C. C., & Mangham-Jefferi. (2012). Exploring health providers' and community perceptions and experiences with malaria tests in South-East Nigeria: a critical step towards appropriate treatment. *Malarial Journal*, 11, 368 - 10.1186/1475 - 2875-11-368.

Frankline, M. O. (2015). Frequency and correlates of malaria over-treatment in areas of differing malaria transmission: a corss-sectional study in rural Western Kenya. *Malarial Journal*, 14(1) P 97.

G. H.S (2010). *Annual Report.* Accra - Ghana: National Malaria Control Program.

GHS (2014). *Malaria Control and Case Management handbook for Over The Counter Medicine Sellers.* Ghana: Ministry of Health

G. H.S (2016). *National Guidelines for Diagnosis, Treatment and Prevention of Malaria.* Ghana: National Malaria Control Program.

Goodman , C., Brieger , W., Unwin, A., Mills , A., & Meek, S. (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(Suppl 6), 203–218.

G. S.S (2011). *The Multiple Indicator Cluster Survey (MICS)* . Accra - Ghana: Ghana Statistical Service.

G. S.S (2014). *Population and Housing Census, District Analytical Report 2010.* Accra - Ghana:

University of Ghana http://ugspace.ug.edu.gh

Ghana Statistical Service.

Hopkins, H., Asiimwe , C., & Bell, D. (2009). Access to antimalarial therapy: accurate diagnosis is essential to achieving long term goals. *BMJ, PubMed*, 339, b2606.

Hutchinson , E., Chandler , C., Clarke, S., Lal, S., Magnussen, P., Kayendeke, M., et al. (2015). Crit Public Health. *Malar J*, 25(1), 48-62.

Ishengoma , D. S., Francis , F., Mmbando, B. P., & Lusingu, J. P. (2011). Accuracy of malaria rapid diagnostic tests in community studies and their impact on treatment of malaria in an area with declining malaria burden in north-eastern Tanzania. *Malar J*, 10, 176.

Johansson, E. e. (2014). Diagnostic testing of pediatric fevers: meta-analysis of 13 national surveys assessing influences of malaria endemicity and source of care on test uptake for febrile children under five years. *PLoS One*, 9(4), p. e95483.

Juma, E., & Zurovac, D. (2011). Changes in health workers' malaria diagnosis and treatment practices in Kenya. *Malarial Journal*, 10, p. 1.

Malaria and biomarker. (2011). Retrieved from Ghana Statistical Service - Malaria Indicator Cluster Survey: http://www.statsghana.gov.gh/docfiles/publications/MICS4_MAIN_REPORT.pdf

Mbonye, A. K., Ndyomugyenyi, R., Turinde, A., & Magnussen P., C. S. (2010). The feasibility of introducing rapid diagnostic tests for malaria in drug shops in Uganda. *Malarial Journal*, P 1 - 5.

Mosha, J. F. et al. (2010). Cost implications of improving malaria diagnosis: findings from north-eastern Tanzania. *PLoS One*, 5(1), p. e8707.

University of Ghana http://ugspace.ug.edu.gh

Msellem , M. I., Mårtensson , A., Rotllant , G., & Bhattarai , A. (2009). Influence of Rapid Malaria Diagnostic Tests on Treatment and Health Outcome in Fever Patients, Zanzibar – A Crossover Validation Study. *PLoS Med 6(4), PubMed/NC*, e1000070.

Mwenesi H.A. , H. A. (2005). Social science research in malaria prevention, management and control in the last two decades: an overview. *Acta Trop*, 95:292–7.

Naimoli, J., Rowe , A. K., Lyaghfouri , A., Larbi , R., & Lamrani, L. A. (2006). Effect of the Integrated Management of Childhood Illness strategy on health care quality in Morocco. *International Journal for Quality in Health Care*, 18, 134–44.

Nosten , F., & Ashley, E. (2004). The detection and treatment of Plasmodium falciparum malaria: time for change. *J Postgrad Med*, 50(1), p. 35-9.

Ochola, L. B., Vounatsou , P., Smith , T., & Mabaso, M. L. (2006). The reliability of diagnostic techniques in the diagnosis and management of malaria in the absence of a gold standard. *Lancet Infect Dis*, 6, 582–588.

Okiro, E. A. et al. (2007). The decline in paediatric malaria admissions on the coast of Kenya. *Malar J*, 6: p. 151.

Okiro, E. A. et al. (2010). Changing malaria intervention coverage, transmission and hospitalization in Kenya. *Malar J*, 9: p. 285.

Olliaro , P. (2009). Management of fever and malaria – policy and practice. *Trop Med Int Health - PubMed*, 14,488–490.

University of Ghana http://ugspace.ug.edu.gh

Organisation, W. H. (2002 - 2016). *Global Health Observatory country views, Ghana profile statistics summary*. Retrieved from World Health Organisation: http://apps.who.int/gho/data/node.country.country-GHA

Organisation, W. H. (2015). *Ghana Health Topics, World Health Organisation, Regional Office for Africa*. Retrieved from World Health Organisation: http://www.who.int/malaria/publications/country-profiles/profile_gha_en.pdf?ua=1

Organisation, W. H. (2017). *Malaria health topics diagnostic testing*. Retrieved from World Health Organisation : http://www.who.int/malaria/areas/diagnosis/en/

Organization, W. H. (2015). *World malaria report 2015.* Geneva: World Health Organization.

Organization, W. H. (2017). *Malaria health topics, Drug resistance and response* . Retrieved from World Health Organization: http://www.who.int/malaria/areas/drug_resistance/en/

PC. Gazette of pharmaceutical facilities, 2012. Accra: Pharmacy Council; 2012

Perkins, M. D., & Bell, D. R. (2008). Working without a blindfold: the critical role of diagnostics in malaria control. *Malar J*, 7: (Suppl 1)S5.

Program, N. M. (2010, 2014). *National Malaria Control Program annual report.* Accra - Ghana: National Malaria Control Program.

Program, N. M. (2016). *National Malaria Control Program annual report.* Accra - Ghana: National Malaria Control Program.

University of Ghana http://ugspace.ug.edu.gh

Program, N. M. (2016). *National Malaria Microscopy and Rapid Diagnostic Test Quality Assurance Manual.* Ghana: National Malaria Control Program.

Programme, N. M. (2016). *National Guidelines for Diagnosis, Treatment and Prevention of Malaria.* Accra - Ghana: Ghana Health Service.

Rao , V. B., Schellenberg , D., & Ghani, A. C. (2013). Overcoming health systems barriers to successful malaria treatment. *Trends Parasitol*, 29,164-80.

Reyburn, H., & et al. (2004). Overdiagnosis of malaria in patients with severe febrile illness in Tanzania: a prospective study. *BMJ*, 329(7476): p. 1212.

Reyburn, H., & et al. (2006). The contribution of microscopy to targeting antimalarial treatment in a low transmission area of Tanzania. *Malar J*, 5, p. 4.

Seiter, A., & Gyansa-Lutterodt , M. (2009). *Policy note: the pharmaceutical sector in Ghana.* Washington DC: World Bank.

Smith, F. (2009). Private local pharmacies in low and middle-income countries: a review of interventions to enhance their role in public health. *Trop Med Int Health*, 14, 362–372.

Smith, F. (2009). The quality of private pharmacy services in low and middle-income countries: A systematic review. *Pharm World Sci*, 31, 351–361.

Udoh , E., Oyo-Ita , A., Odey , F., Effa , E., Esu, E., Oduwole, O., et al. (2013). Management of uncomplicated malaria in underfives in private and public health facilities in South-eastern Nigeria: a clinical audit of current practices. *Malar Res Treat*.

University of Ghana http://ugspace.ug.edu.gh

Wafula, F. N., & Catherine, A. G. (2010). Are Interventions for Improving the Quality of Services Provided by Specialized Drug Shops Effective in Sub-Saharan Africa? A Systematic Review of the Literature. *International Journal for Quality in Health care*, 22(4), 316 - 23.

World Health Organisation. T3: Test. Treat. Track. Scaling up diagnostic testing, treatment and surveillance for malaria. (2012). Geneva: World Health Organization.

Zurovac , D., Rowe , A. K., & Ochola, S. A. (2004). Predictors of the quality of health worker treatment practices for uncomplicated malaria at government health facilities in Kenya. *International Journal of Epidemiology*, 33, 1–12.

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Appendix 1: Provider Survey Questionnaire Form

ADHERENCE TO MALARIA DIAGNOSIS GUIDELINES AMONG OVER THE COUNTER MEDICINE SELLERS (OTCMS) IN LEDZORKUKU-KROWOR MUNICIPAL – GREATER ACCRA REGION, GHANA

IDENTIFICATION
QUESTIONNAIRE N° |___|___|___|___| (DO NOT FILL)
TOWN/ VILLAGE : _____ OTCMS FACILITY NAME: _____
START TIME /___/___/___/___/ [24HR FORMAT]

No	**Questions**	**Responses**	**Codes**	**Skip To**
1	What is your name?			
2	What is your age?	Age in years |__|__|		
3	What is the respondent's sex (observe)	Male Female	1 2	
4	Are you an OTCMS or a Shop Assistant?	OTCMS Shop Assistant	1 2	
5	For how many years have you worked as OTCMS/assistant?	Years |__|__|	≤ 5yrs ☐ > 5yrs ☐	

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6	What is your level of education?	Primary school Junior Secondary School/ Middle school Senior Secondary school/O level / A level Tertiary: Training college, nursing college, polytechnic, university	1 2 3 4	
7	Have you attended any workshop/training on malaria case management before?	Yes No	1 0	**If No skip to Ques 9**
8	When did you have the training?	Year [……/……/……]		
Characteristics of the OTCMS				
9	Location of the facility	First class Second class 'A' Second class 'B' Third class	1 2 3 4	
10	Do you have a place to conduct the test	Yes No	1 0	

Thank you for participating in this study!

END TIME /___/___/___/___

END OF PROVIDER QUESTIONNAIRE

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Appendix 2: Mystery Client Form

ADHERENCE TO MALARIA DIAGNOSIS GUIDELINES AMONG OVER THE COUNTER MEDICINE SELLERS (OTCMS) IN LEDZORKUKU-KROWOR MUNICIPAL – GREATER ACCRA REGION, GHANA

IDENTIFICATION
QUESTIONNAIRE N° |___|___|___| **MYSTERY CLIENT CODE** |___|___|___|
TOWN/ VILLAGE : _____ LOCATION TYPE : |_| First class |_| Second class 'A' |_|Second class 'B' |_|Third class OTCMS FACILITY NAME: _____ SEX OF RESPONDENT: |_| Male |_| Female MYSTERY CLIENT NAME: _____ SEX OF MYSTERY CLIENT: |_| Male |_| Female AGE OF MYSTERY CLIENT: |___| Years
START TIME /___/___/___/___/ [24HR FORMAT]

No	Questions and Filters	Responses	Codes
1	Did you find any malaria RDT poster during your visit to the facility?	Yes No	1 0
2	Did the provider bring out the malaria RDT to conduct the test upon presentating with simulated case of uncomplicated malaria?	Yes No	1 0
3	Did the provider insist you do a test before treatment upon presentating with simulated case of uncomplicated malaria?	Yes No	1 0

Please record any additional information about your visit to this OTCMS facility below:

_____

_____

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Appendix 3: Participant Information Sheet

ADHERENCE TO MALARIA DIAGNOSIS GUIDELINES AMONG OTCMS RESEARCH

Confidential: Data used for research purposes only

This is a sheet that we provide to all participants to explain the study and provide with points of contact in case you have any questions.

PROCEDURES

Your facility has been counted as part for the interview because you find yourself in the Municipality. If you agree to take part, some of the questions that we ask will be about health practices and malaria diagnosis. The interview will take about 20 minutes to complete.

RISKS/DISCOMFORTS

Whatever information you provide will be kept confidential. Your name and the name of your facility will never be shared with anyone outside of the study team. You do not have to answer any questions that you are not comfortable with, and you may stop the discussion at any time.

BENEFITS

There is no direct benefit to you from being in this study other than information. However, the information we collect will go a long way to help develop better programs and health services for people in Ghana.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study, and you may change your mind at any time.

- If you have questions about the study and your rights as a study participant, you may contact the pharmacy council head office. They will answer any questions or address any concerns you may have.
- You can also contact Ms. Hannah Frimpong of Ghana Health Service Ethics Review Committee on 233 9(0) 243235225 / +233(o)507041223

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You were interviewed by: _____ (**Interviewer:** write your name here for their reference)

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Appendix 4: Consent Form

ADHERENCE TO MALARIA DIAGNOSIS GUIDELINES AMONG OTCMS RESEARCH

Confidential: Data used for research purposes only

Good morning/afternoon. My name is …… I am a master's research student from University of Ghana School of Public Health - Legon. I am conducting a survey on adherence to Ghana's malaria diagnosis guidelines by health providers in Ledzorkuku – Krowor Municipal in the Greater Accra - Ghana. The main objective of this census study is to assess the level of adherence to malaria diagnosis guidelines among Over The Counter Medicine Sellers (OTCMS) in Ledzokuku Krowor Municipal in Greater Accra Region. Understanding the level of adherence of malaria diagnosis policy among OTCMS will guide and strengthen the implementation of malaria diagnosis guidelines being used in Ghana. This will in the long run lead to an improvement in the quality of healthcare through further research, investment in focused training, regular supervision and development of informed policies. This information will be used to inform policy makers in the health sector to identify the possible measures to improve adherence to the malaria diagnosis in the country.

May I speak to you for a few minutes about your experience treating uncomplicated malaria? I would like to ask a few questions in regards to malaria diagnosis guidelines. The information gathered here will remain confidential. I will not take your name, and you do not have to answer any questions that you do not want to. Your participation is voluntary and you will not be affected in any way if you decide not to participate.

You do not have to agree to be in this study, and you may change your mind at any time. If you have questions about the study and your rights as a study participant, you may contact the pharmacy council head office. They will answer any address any concerns you may have. You

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can also contact Ms. Hannah Frimpong of Ghana Health Service Ethics Review Committee on 233(0)243235225 / +233(0)507041223.

PERMISSION TO PROCEED

If you agree to participate, the interview will take about 30 minutes.

Do you have any questions about the survey? Yes/No **(If yes, answer questions)**

Do I have permission to interview you now? Yes / No

Interviewer: If no, thank the respondent and end the questionnaire.

Signature of OTCMS …….

Signature of interviewer …….