ASSESSMENT OF MALARIA DIAGNOSTIC SERVICES IN SERENJE DISTRICT, ZAMBIA

BY

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A dissertation submitted to the University of Zambia in partial fulfilment of the requirement of the degree for Master of Public Health

The University of Zambia, Lusaka

2013

DECLARATION

I hereby declare that all the work contained in this dissertation is my own and has never been submitted for another degree in this University or any other University or institution of higher learning.

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Abstract

Zambia is one of the countries that have embarked on improved and accurate diagnosis of malaria in order to optimize the out come of malaria management. This has led to a change of policy, which emphasized the importance of accurate malaria diagnosis as one of the key interventions in malaria treatment and control. It is expected that this change in policy would lead to a more focused, efficient and cost effective malaria management programme, and overall improved malaria diagnosis and treatment. In this cross sectional, facility-based research study, aimed at assessing malaria diagnostic services in Serenje District, a semi structured questionnaire and facility check list were administered in 8 selected health facilities. A sample of 21 staff that routinely diagnosed and treated malaria for the period January to December 2011 was used and 320 case files were reviewed to collect data. Data derived from open ended questions and checklists was analysed by qualitative content analysis. Descriptive data was presented using graphs, charts and tables. Numerical data that was derived from the checklists and questionnaires was analysed using the Statistical Package for Social Sciences (SPSS) version seventeen.Prescription of antimalaria drugs was determined by the test result ($X=78.53$, $p < 0.05$ for patients under 5 years and $X=80.42$, $p<0.05$ for patients above 5 years)**.** However, 30.1% (n=43) of the patients under 5 years and 13.6% (n=16) of patients above the age of 5 who received anti-malaria prescriptions were not tested for malaria at all. Comparison of RDTs done with reported malaria cases shows a disproportionately high number of RDTs performed at 142.5% and 136.9% of total malaria cases diagnosed in patients under 5 and above 5 years respectively. Generally, the district had adequate malaria diagnostic commodities in the health facilities, most of which are malaria RDTs. Health care workers adhered to malaria guidelines by prescribing anti-malaria drugs to patients with positive RDT and rarely, in the case of a negative result. However, about a third of all children treated for malaria were treated based on clinical signs and symptoms. There was inadequate clinical assessment of patients, leading to unguided use of RDTs, consequently resulting in overuse of malaria diagnostic commodities. A study to establish factors associated with overuse of malaria diagnostic commodities in health facilities should be conducted.

Acknowledgements

I would like to sincerely thank my course supervisors, Professor Kumar S Baboo and Dr Selestine H Nzala who provided tremendous Support, guidance and advice through ought this work. To my MPH classmates, thank you for the wonderful interaction and encouragement.

I also wish to thank Provincial Medical Officer Kabwe, for the support and Serenje District Community Health Management Team for providing the enabling environment and information for my research.

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List of Abbreviations

ACT	Artemisinin based Combination Therapy
AO	Acridine Orange
BCP	Benzothiocarboxypurine
CHWs	Community Health Workers
DHMT	District Health Management Team
DNA	Deoxyribonucleic Acid
EHT	Environmental Health Technician
HMIS	Health Management Information Systems
HRP II	Histidine Rich Protein II
IMCI	Integrated Management of Childhood Illnesses
MRDTs	Malaria Rapid Diagnostic Tests
NMCC	National Malaria Control Centre
PCR	Polymerase Chain Reaction
PfHRP	*Plasmodium falciparum* Histidine Rich Protein
pLDH	Parasite Lactate Dehydrogenase
QBC	Quantitative Buffy Coat
RDT	Rapid Diagnostic Test
rRNA	Ribosomal Ribonucleic Acid
SOPs	Standard Operating Procedures
SPSS	Statistical Package for Social Sciences

UNICEF United Nations Children's Fund

WHO World Health Organization

CHAPTER ONE: BACKGROUND

Malaria is a major global public health problem that exerts a high mortality and morbidity in many countries, particularly in resource-poor countries in sub-Saharan Africa, South East Asia and Latin America, and probably contributes to keeping these countries in poverty (Roll Back Malaria Research Group, 2010). At present, 80-90% of people who should have a parasite-based malaria diagnosis do not get one (Roll Back Malaria Research Group, 2010). Some of the reasons for this include limited financial resources to procure diagnostic commodities and shortage of appropriate staff. In areas with adequate malaria diagnostic services, perceptions and practices of clinicians stand to be important barriers to effective utilization of laboratory results (Derua et al, 2011).

Inaccurate microscopy and symptomatic diagnosis of malaria occur frequently in most endemic countries (Derua et al., 2011). Malaria diagnosis based on clinical signs has resulted in over-diagnosis of malaria which results in unnecessary use of anti malaria drugs, and possible exaggeration of the burden of the disease. This is especially so with the introduction of expensive Artemisinin based combination therapy (ACTs). Equally, misdiagnosis of malaria can result in delayed appropriate treatment and sometimes death (Derua et al., 2011). Therefore, laboratory diagnosis is an important component of case management and control of malaria.

Zambia is a land-locked country in Southern Africa with a population of approximately 13.2 million (President's Malaria Initiative, 2011). The country currently has ten provinces. Zambia's key health indicators are generally positive, including under-five mortality which has fallen from 191 per 1000 live births in 1992, to 168 per 1000 in 2002, and to 119 per 1000 in 2007. Eighty-five per cent of children complete primary school and overall poverty has been declining (President's Malaria Initiative, 2011).

Serenje District is located in the Central Province of Zambia. It has an area of 240,000 square kilometers (Serenje District Health Management Team, 2011). The physical features include the Muchinga Escarpment in the east, which makes access to the valley and delivery of health services extremely difficult especially during the rainy season. To the west lie dambos and swamps of Luapula valley, contributing to the high incidence of malaria (Serenje DHMT, 2011). It is predominantly a rural District with most of the inhabitants engaged in subsistence farming and trading. The projected population for 2011 was 194,497 (Extrapolated from Demographic Health Information Survey (DHIS) database), under five population of 38,336,

expected pregnancies 9,960 with an expected annual growth rate at 3.5% (Serenje DHMT, 2011). The District has 27 rural health centres and 2 first level hospitals. Of these 27 facilities only the two hospitals have laboratory services and the capacity to do malaria microscopy. Therefore, most of the facilities use RDTs routinely for malaria diagnosis.

According to the Serenje Health Management Information System (HMIS) report, malaria was the second cause of morbidity in the district with an incident rate of 177.6/1000 and the top cause of mortality in children under five years in 2010 (Serenje DHMT, 2011).

1.1 INTRODUCTION

Malaria is a parasitic disease, which affects many parts of the world. Globally, about 109 countries are considered malaria endemic and half of these are in Africa, south of the Sahara (UNICEF, 2010).

It is estimated that in 2008, there were 250 million cases of malaria in the world and 850 000 deaths (UNICEF, 2010). In Africa, malaria causes about 20% of all child deaths (UNICEF, 2004). It is a major contributor to maternal mortality and morbidity and contributes significantly to low birth weight in Sub Saharan Africa (UNICEF, 2004). Malaria also presents a major obstacle to social and economic development on the continent. According to UNICEF, it costs Africa US $10 billion to $12 billion every year in lost gross domestic product (UNICEF, 2004).

Malaria transmission in Zambia occurs throughout the year with the peak during the rainy season, which occurs between November and April, with *Plasmodium falciparum* accounting for more than 90% of all infections (President's Malaria Initiative, 2011). In 2008, Zambia reported approximately 3 million clinically diagnosed cases of malaria, accounting for 45% of outpatient visits, 45% of hospital admissions, 47% of overall disease burden among pregnant women, and 50% of disease burden among children under five years of age (President's Malaria Initiative, 2011).

Serenje District, through the Ministry of Community Development Mother and Child Health and the Ministry of Health, has taken several steps to improve the diagnosis of malaria. Since the inception of RDTs in the District in 2006, trainings have been done on improved malaria diagnosis, and management in the District. At present, every health facility in the District has stocks of RDTs and related supplies (Serenje DHMT, 2011) There has also been an improvement in the supply and availability of antimalaria drugs in the District. It is expected

that with these interventions malaria diagnosis should improve, leading to improved management, ultimately reducing morbidity and mortality due to malaria in the District.

The District has continued to use microscopy for malaria diagnosis. However, this is only restricted to the two hospitals (Chitambo and Serenje) due lack of appropriate infrastructure and shortage of trained staff to conduct the test.

1.2 STATEMENT OF THE PROBLEM

Although the Ministry of Health has identified accurate malaria diagnosis as one of the major interventions in controlling and managing the disease, there are many obstacles to the implementation of effective diagnostic programme in Serenje District. These challenges, which range from staffing levels, staff training and inappropriate infrastructure pause a serious threat to the successful implementation of quality malaria diagnosis programme in the District (Figure 1). There is therefore great need to conduct an assessment of the programme in order to identify challenges and weaknesses and make appropriate interventions and adjustments.

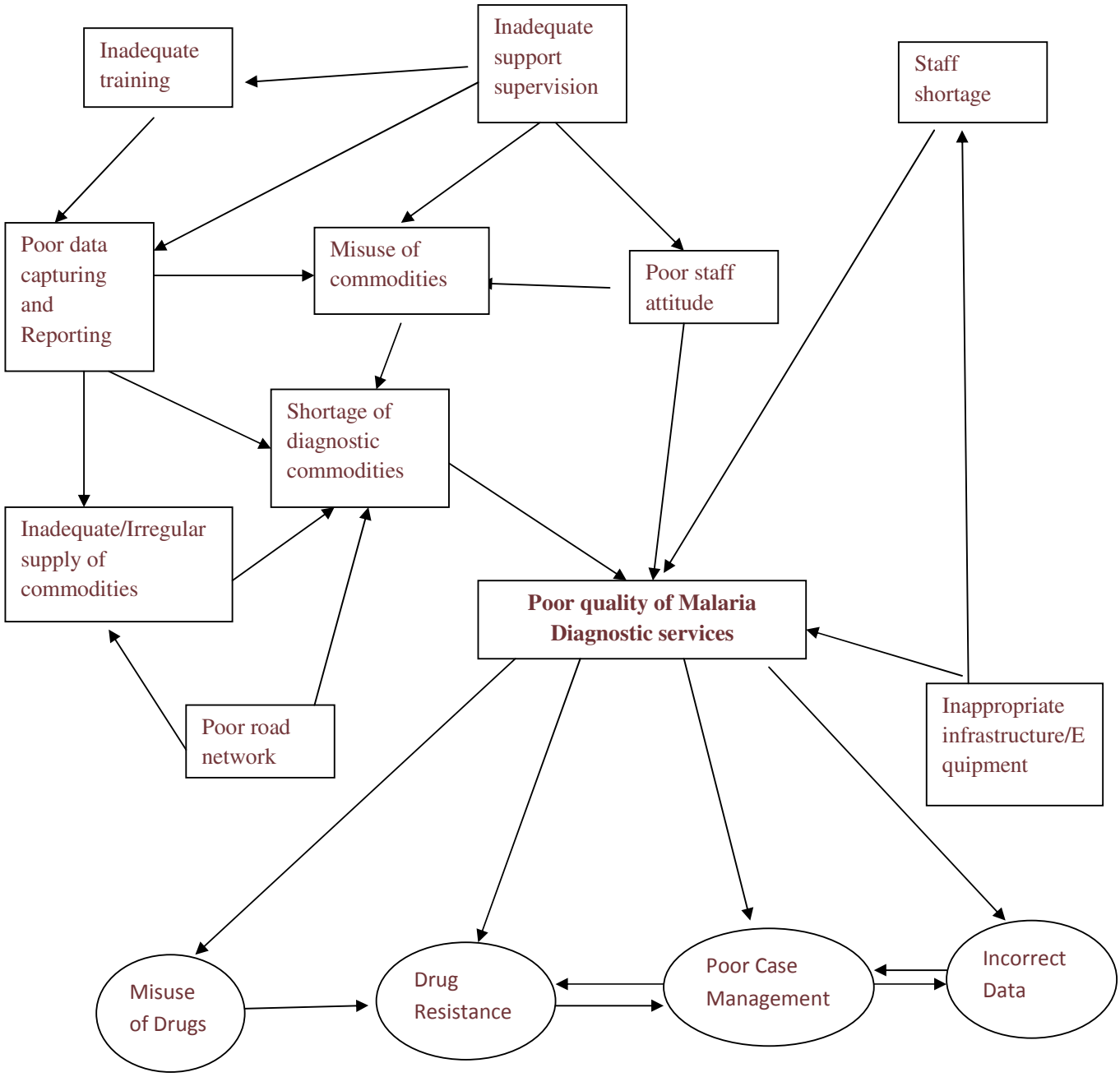
An assessment of the programme also will answer questions on the overall performance of the District malaria diagnosis programme such as level of adherence to the standard guidelines, availability of commodities for malaria diagnosis, distribution of malaria diagnostic services in the District, staff competence to carry out malaria diagnosis, interpret and adhere to test result.

1.3 STUDY QUESTIONS

1. To what extent are malaria diagnostic commodities available in health facilities in Serenje District?
2. How is malaria managed as regards to laboratory diagnosis, and in line with national guidelines?
3. What factors are associated with non- adherence to malaria diagnosis guidelines?

Figure 1:

PROBLEM ANALYSIS DIAGRAM FOR MALARIA DIAGNOSIS



1.4 DEFINITION OF KEY CONCEPTS

1.4.1 *Plasmodium falciparum:* A protozoan parasite, one of the species *Plasmodium* that causes malaria in humans, transmitted by the female *Anopheles* mosquito (Answers.Com).

1.4.2 Polymerase chain Reaction (PCR): A process that enables researchers to produce millions of copies of a specific DNA sequence in approximately two hours (Cold Spring Harbour Laboratory, 2011).

1.4.3 Histidine-rich Protein II (HRP II): A naturally occurring and alanine rich protein localized in several cell compartments, including the cytoplasm of *P. falciparum* (Noedl et al., 2002).

1.4.4 Malaria: A protozoan infection of the genus *Plasmodium,* transmitted through the bite of an infected female mosquito belonging to the genus *Anopheles* (Ministry of Health - Zambia, 2010).

1.4.5 DNA (Deoxyribonucleic acid): Hereditary material in humans and almost all other organisms. Most DNA is located in the cell nucleus (Nuclear DNA), but a small amount can be found in mitochondria (Mitochondrial DNA) (US National Library of Medicine, 2011).

1.4.6 Malaria Rapid Diagnostic Tests (MRDTs): Malaria Rapid Diagnostic tests, sometimes called dipsticks or Malaria Rapid Diagnostic Devices (MRDDs) or Rapid Diagnostic Tests (RDTs), assist in the diagnosis of malaria by providing evidence of presence of malaria parasites in human blood. They detect specific antigens produced by malaria parasites, which are present in the blood of infected or recently infected individuals (WHO, 2005).

1.4.7 Health Care worker: A Health Care Worker is someone who works in a hospital or health centre (Harper Collins Publishers, 2003).

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

The differentiation of malaria from other causes of fever in the absence of microscopy or RDT is difficult (Perkins et al., 2008). Early, prompt and accurate diagnosis and treatment is crucial to the management of morbidity and mortality caused by malaria and is one of the main interventions used in the global control of the disease. Rising drug costs resulting from the need to use newer medications or combination therapy, and recognition of the inaccuracy of clinical diagnosis are increasing the demand for demonstration of parasitaemia prior to therapy (Barnwell et al., 2003).

2.2 Availability of malaria diagnostic services

According to Ministry of Health structure, the District Health Management Team provides overall planning, coordination, and monitoring of malaria activities within the Districts (President's Malaria Initiative, 2011). Health Posts are intended to cover 500-1000 households and all households should be within five kilometres of a Health facility. Health Centres should be staffed by a Clinical Officer, Nurse or Environmental Health Technicians and serve a catchment population of 10,000 residents. Each District is expected to have a hospital, staffed by one or more physicians (President's Malaria Initiative, 2011).

According to the Zambia National Malaria Control Centre (NMCC), only 30% of health facilities have functional microscopy, while many health facilities in Zambia do not have Laboratories and Technicians due to a shortage of trained and qualified staff (President's Malaria Initiative, 2011).

To extend laboratory diagnosis to more peripheral levels in Zambia, the National Malaria Control Centre (NMCC) has introduced RDTs in rural health centres and villages for use by Community Health Workers (CHWs), with more than 2 million RDTs purchased and distributed during the year 2010 (President's Malaria Initiative, 2011).

In order for a malaria programme to be effective, case management and management of logistics is very important. Before an implementation plan can be drawn up, it is important that clear malaria case management policy documents and guidelines are endorsed that clearly define who will be performing the tests, which tests will be performed, when they will be performed, and at which level of the health service(WHO, 2010).

Developing policies and management guidelines in this area will require malaria programmes to liaise closely with other health management programmes, such as Integrated Management of Childhood Illnesses (IMCI), and to have adequate access to resources to train and equip health workers for management of non-malaria fever. Resources, including training, appropriate medicines, diagnostics, and referral mechanisms, will be required (WHO, 2005). Additionally, strengthening supportive supervision, training and quality control of laboratory diagnosis is expected.

2.3 Staff Training and Attitude

Staff attitude and training also play a significant role in malaria diagnosis.

A study in Tanzania showed that clinicians appeared to make malaria treatment decisions on the basis of conventional clinical logic and diagnostic algorithms on the one hand, and social factors with no obvious basis in clinical logic on the other. They also used tests to confirm their suspicions, rather than make a diagnosis or allocate treatment (Whitty et al., 2008).

Elsewhere, there was evidence of over diagnosis of malaria in the formal health-care sector in many parts of Africa. Mostly, clinicians often failed to request a diagnostic test when it was clinically appropriate. Even when clinicians chose to test, they often ignored the results (Whitty et al., 2008).

A study done in Kenya showed that overall malaria testing in public health facilities was low. Findings showed that, of the 880 febrile patients attended to in 88 facilities, 19.8% and 28.7% of children under five and patients above five years respectively had malaria test done (Juma et al., 2011). Another study done in Tanzania showed that despite the fact that laboratory malaria diagnostic services were available in all study health facilities, standard criteria for who to test was lacking and test results were underutilized in management of patients. Request for laboratory malaria test was unguided as some clinicians requested the test always while others ordered the test infrequently (Derua et al., 2011). The researchers concluded that improving the quality of malaria diagnosis in Tanzania should, therefore, take into consideration patients, clinicians and laboratory staff related factors, which most likely contribute to the performance. For example, inadequate infrastructure, consumables and poor working conditions and perceptions towards malaria diagnostic services can constrain malaria diagnostic services (Derua et al., 2011).

As in many other countries, clinicians in Zambia do not always use the results of RDTs or microscopy to guide malaria treatment decisions. Health workers prescribe antimalaria drugs even in cases where laboratory diagnoses are negative (President's Malaria Initiative, 2011).

Effective malaria programmes must also take into account training not only of existing health personnel and laboratory technicians but also of new cadres, to guarantee the availability of sufficient personnel to perform diagnostic services at all levels of the health service (WHO, 2010). These trainings must have available materials such as manuals, job aids and standard operating procedures (SOPs) and must be reinforced with continuous supportive supervision to monitor the use of diagnostic results in patient management (WHO, 2010). Health education on the reasons for changes in diagnostic and treatment practices to both the health provider and community members will promote confidence in the system and adherence to test results (WHO, 2010).

One survey done in Zambia showed that only a third of the facilities visited had at least one health worker who had received training in malaria diagnostics in the previous 12 months. Two thirds of these facilities were able to perform RDTs correctly but only 20% were able to perform microscopy correctly (President's Malaria Initiative, 2011).

Until 2006, laboratory technologists and technicians were the only cadres trained and legally authorized to perform malaria microscopic diagnosis (President's Malaria Initiative, 2011).

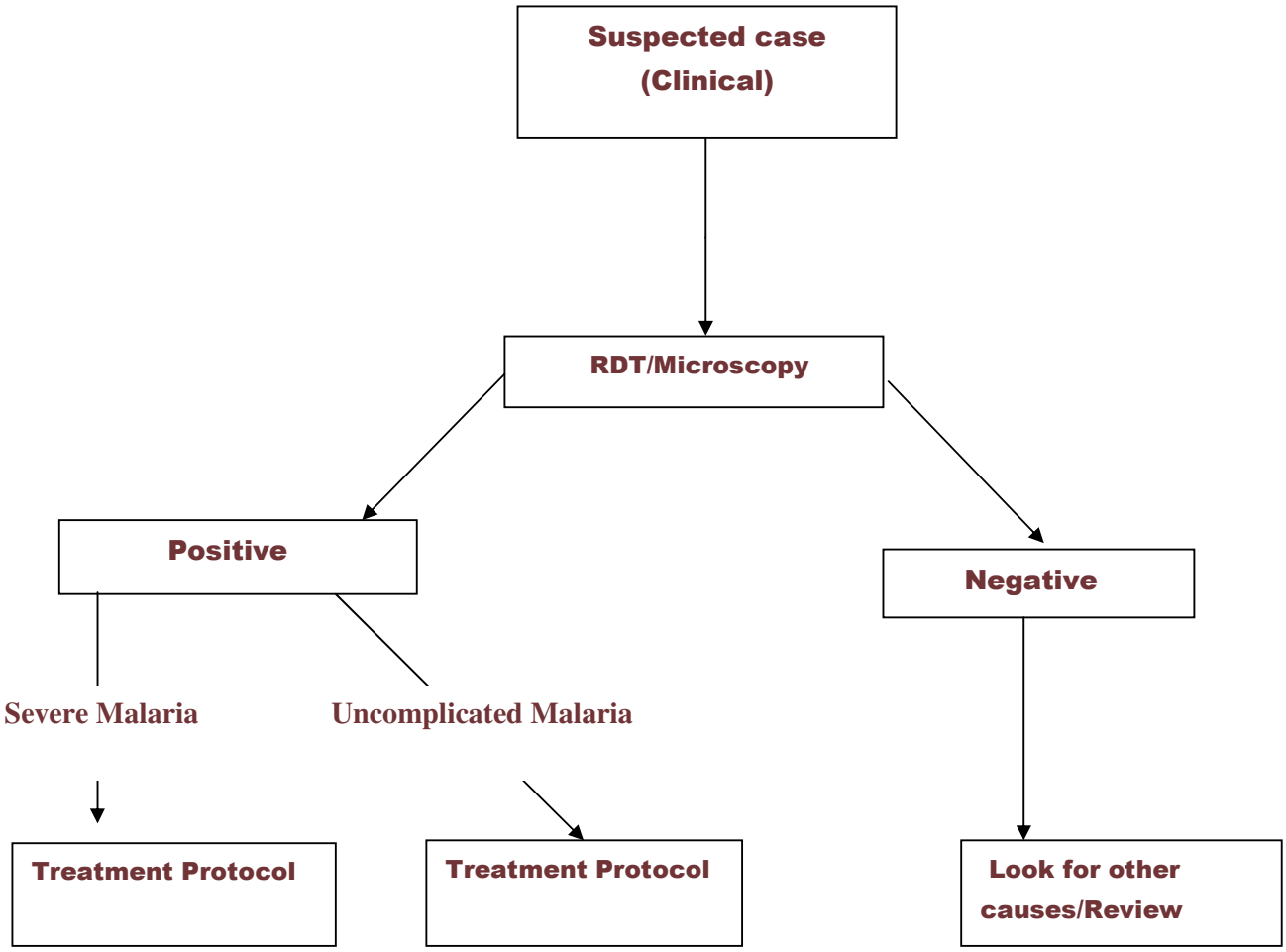
2.4 Malaria Diagnosis

Clinical diagnosis is the most widely applied method for malaria diagnosis (Barnwell et al., 2003). Among the many clinical signs and symptoms associated with malaria and used in diagnosis, the most prominent is fever, which is often associated with chills, perspiration, anorexia, headaches, vomiting and malaise. Additional signs indicating severe malaria include confusion or drowsiness. However, although clinical diagnosis is sensitive, it has poor specificity (Barnwell et al., 2003). WHO recommends that malaria case management be based on demonstration of parasites, either by RDT or microscopy, in all except exceptional circumstances. These exceptions include: children less than 5 years in areas of high transmission, established malaria epidemics where resources are limited, cases consistent with severe clinical malaria and with high suspicion whilst further investigation and management is urgently put in place and in situations where effective treatment can not otherwise be provided, while adequate diagnostic measures are being put in place (WHO, 2005).

The cost-effectiveness of any malaria programme will be substantially reduced if most of the money spent on antimalaria drugs goes to treat people who do not have malaria. This is potentially an important limitation on the long term sustainability of funding, and, in particular, of maintaining widespread political support (Whitty et al., 2008). Therefore, microscopy and rapid diagnostic tests (RDTs) represent the two diagnostics most likely to have the largest impact on malaria control today. These two methods represent the best means for accurate diagnosis as a key component of successful malaria treatment and control (Wongsrichanalai et al., 2007).

Figure 2:

Malaria Management: Algorithm for Diagnosis



Source: *World Health Organization, 2005.*

For malaria diagnosis, microscopy is the gold standard (WHO, 2009). Basic light microscopy has many advantages. This method is relatively inexpensive at US$ 0.12–0.40 per slide in countries where malaria is endemic (Barnwell et al., 2003). It is cost effective, fairly sensitive, and highly specific, can be used to differentiate between species and determine parasite density. It can also be used to diagnose many other conditions. However, the procedure is labor intensive, time consuming and requiring substantial amount of expertise (Murray et al., 2009). For microscopy, both thick and thin smears should be made. The thick smear, which increases by a factor of 20-30 the number of red blood cells per given area on the slide compared to the thin smear, is much more sensitive than the thin smear for detection of malaria parasites. The thin smear is superior to the thick smear for speciation (Moody et al., 2000). The major disadvantage of a thick smear is that it is difficult to read.

DNA-binding fluorochromes can be used to aid the detection and quantification by microscopy of parasites (Barnwell et al., 2003). Three techniques using fluorescence of the parasite for the diagnosis of malaria have been described. The quantitative buffy coat (QBC) method, the Kawamoto acridine orange process (AO) and the use of benzothiocarboxypurine (BCP) (Moody et al., 2000).

These three methods are rapid and easy to perform (when there are 100 parasites/uL) and achieve a sensitivity and specificity similar to that demonstrated by a stained thick smear (Moody et al., 2000). Both the QBC and Kawamoto methods use acridine orange (AO) as the fluorochrome to stain the nucleic acids of any malaria parasites in the sample. Kawamoto acridine orange process (AO) is nonspecific and stains nucleic acids from all cell types. Consequently, the microscopist using AO has to learn to distinguish fluorescent-stained parasites from other cells and cellular debris containing nucleic acids (Moody et al., 2000).

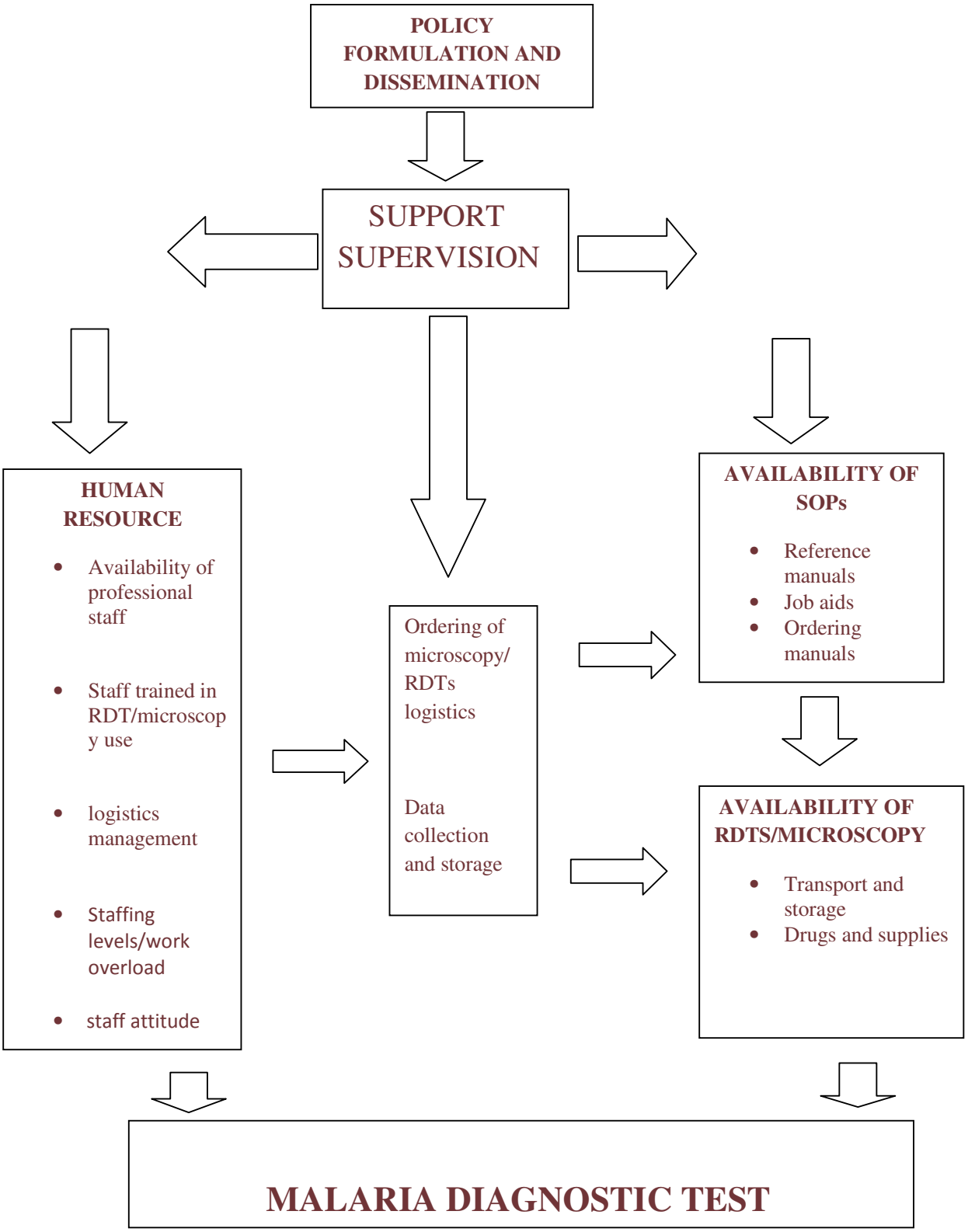
Though they should not be viewed as a replacement for microscopy where it is available, RDTs offer an effective, quick and simple way of diagnosing malaria. They are useful in low resource settings, where quality microscopy is not readily available. They detect specific antigens which are released by the parasite both sexual and asexual forms, particularly Histidine rich protein II (pfHRP II) in the case of *Plasmodium falciparum* (WHO, 2005). RDTs are generally more expensive per test than microscopy, ranging from US$ 0.60 to US$ 2.50 or more, depending on the marketing area (Barnwell et al., 2003). RDTs for the diagnosis of *Plasmodium falciparum* malaria generally achieve a sensitivity of more than 90% at parasite densities above 100/µL blood and the sensitivity decreases markedly below

that level of parasite density. The pfHRP II can remain in the blood for at least 28 days after commencement of treatment (Kakkilaya, 2003).

A study done in Nchelenge, Zambia showed that RDTs for diagnosis of *Plasmodium falciparum* malaria had a sensitivity of 96.1% (with 95%, CI of 93.7 - 98.5) but a specificity of 53.8% (at 95% CI of 45.3 – 62.3) with a positive predictive value of 80.2% and a negative predictive value of 87.6% (Baboo et al., 2008). The same study showed that correlation with pfHRP II RDTs was 100% with a parasite density above 440/µl, and a range of 50% to 98% at parasitaemia less than 440/µl.

Like any other diagnostic procedure, RDTs have limitations including inability to quantify, distinguish parasites and identify stages. This can lead to a persistent positive RDT in case of gametocytaemia. Other factors may include variations in test strips, instructions and level of training of the user (Kakkilaya, 2003).

Figure 3: Framework for Malaria RDT/microscopy



Source: *World Health Organization, 2005.*

Other approaches, such as the polymerase chain reaction (PCR) and immunological tests for malaria are also available but are useful only for research in field contexts in Africa, Asia, and South America (Whitty et al., 2008). Polymerase chain reaction (PCR) involves analysis of blood samples by amplification of parasite-specific nucleic acids. Real-time polymerase chain reaction (PCR) is reported to be highly sensitive and specific, however, the technique requires highly trained personnel, and is both time and resource intensive (Barnwell et al., 2003). Several PCR assays have been developed for the diagnosis of malaria, including the18S rRNA gene which has been used as a target for the differentiation of *Plasmodium* species by nested PCR and reverse transcription-PCR (Moody et al, 2000). The major advantage of using a PCR-based technique is the ability to detect infection in patients with low parasitaemia (5 parasites/uL) can be detected with 100% specificity and its sensitivity is greater than microscopy following treatment (Moody et al., 2000). It means therefore that this method is useful for screening and early detection of treatment failure.

Malaria antigen detection tests are also available and can detect fewer parasites within a short time. Two parasite antigens are currently used; the rapid immunochromatographic tests which are Histidine-rich protein-2 (HRP-II), a water-soluble protein which is expressed by *Plasmodium falciparum* and parasite lactate-dehydrogenase (pLDH) antigen (Moody et al., 2000).

2.5 Interpretation of Malaria test result

There is evidence that administration of antimalaria treatment to patients without malaria results in adverse outcomes and that delay in diagnosis can result in increased mortality (Hopkins, 2009). Firstly, important alternative diagnoses may be missed. Evidence from many parts of Africa as well as outside suggests that the high burden of mortality in childhood is attributable to many treatable febrile illnesses. Malaria is certainly not the only cause of death and in many settings is not even the most important (Whitty et al., 2008). Treating malaria with an antimalaria drugs is a balance of the relative risk of the drug against the very high risk of the disease, but if the great majority of those treated with an antimalaria drugs do not have the disease and therefore cannot benefit, the risk-benefit balance changes, presenting a significant safety issue for patients taking the drugs, and especially newer drugs (Whitty et al., 2008). Furthermore, the risk of increasing the potential for the emergence and subsequent spread of antimalaria drug resistance is also enhanced. Accurate diagnosis is also essential to monitor trends in malaria prevalence, monitor the impact of malaria control

interventions and target malaria control resources to areas with true need (Perkins et al., 2008).

Published evidence indicates that, in many instances, adherence to test results is very poor, and poor adherence, particularly the treatment of test-negative patients with anti-malaria drugs, has been identified in several studies as an impediment to achieving the desired impact with RDTs and microscopy (Roll Back Malaria Research Group, 2010).

One study in Kenya showed that in children under five antimalaria drugs were prescribed for 74.7% test positive, 40.4% test negative and 60.4% untested patients (Juma et al., 2011). In two studies, which were conducted in similar epidemiological settings, (One in Tanzania and the other in Zambia), approximately 99 per cent of patients with a positive diagnostic test (either microscopy or RDT) and approximately 50 per cent of those with a negative RDT were prescribed an antimalaria drug. It also stated that the great majority (more than 90 per cent) of all anti-malaria drugs prescribed were given to patients for whom the clinician had chosen to undertake a test and had received a negative result (Whitty et al., 2008).

Another study conducted in 2006, in Zambia (Chipata, Kalomo, Samfya and Chingola districts), one year after RDTs were introduced showed that 58.4% of negative smears were prescribed with antimalaria drugs and 35% of RDT negative results received treatment for malaria. In addition, 65.9% of patients with fever received antimalaria drugs without a diagnostic test (Davidson et al., 2007). The researchers concluded that there was under utilization of diagnostic services in these cases.

These examples highlight the need to make evaluation of malaria diagnosis in order to identify needy areas that require strengthening for the malaria programme to succeed.

CHAPTER THREE: STUDY OBJECTIVES

3.1 General Objective

To assess malaria diagnostic services in Serenje District, Zambia for the period January to December, 2011.

3.2 Specific Objectives

1. To describe the availability, and distribution of malaria diagnostic commodities in Serenje District
2. To establish level of adherence to Zambia national guidelines on malaria diagnosis by staff managing a patient with/suspected of malaria.
3. To describe factors associated with non adherence to malaria diagnosis guidelines

CHAPTER FOUR: RESEARCH METHODOLOGY

4.1 Introduction

Under this chapter, the following are discussed: study design, study setting, study population inclusion and exclusion criteria, pilot study, sampling, data collection and management, and study limitations.

4.2 Study Design

A cross - sectional, facility based study was conducted in selected Health Facilities in Serenje District to assess malaria diagnostic services.

4.3 Study Variables

4.3.1 Dependent Variable

- Adherence to guidelines on Malaria diagnosis (RDT and microscopy use).

4.3.2 Independent Variables

- Availability of malaria diagnostic commodities (microscopy & RDTs, references (SOPs)
- Health care workers' attitude/perceptions
- Health care workers' training and use of test results
- Support supervision.

4.4 Study Population

The Study population comprised health care workers managing malaria patients for the period January to December 2011

4.5 Inclusion Criteria

Health care workers who managed patients with malaria for the period January to December 2011

- Willingness to take part in the study
- Records of patients treated for malaria from January to December 2011

4.6 Exclusion Criteria

- Health care workers who did not manage malaria patients during the period under review
- Health care workers not willing to take part
- Patient records not covering the period under review
- Patient records for other conditions than malaria

4.7 Sampling Process

Simple random sampling was used to pick the 8 Health facilities. These were Mulilima rural health centre, Chibale rural health centre, Kabamba rural health centre, Muchinka rural health centre, Yoram Mwanje health post, Kanona health post, Malcom Moffat health post and Chitambo Hospital affiliated Health centre. For each facility, files were sampled using systematic sampling. All the eligible health care workers in the selected facilities who accepted to take part in the study were included.

- 8 health facilities were selected
- 21 Health care workers were included
- 40 patient files per facility were reviewed

4.8 Data Collection Tools

Both qualitative and quantitative data was collected using a semi structured questionnaire administered to healthcare workers and a checklist.

4.9 Pre-test

The questionnaire and checklist were pre-tested at Serenje Hospital Affiliated Health Centre and Nchimishi Rural Health Centre which were non-participating facilities.

4.10 Ethical Consideration

Ethical clearance to conduct the study was sought from the Biomedical Research Ethics Committee of the University of Zambia, School of Medicine. Written consent was obtained from Kabwe Provincial Medical Office before commencement of the study. Written consent was obtained from all participants prior to the interview. The information collected was kept confidential.

4.11 Data Analysis

Data derived from open ended questions and checklists was analyzed by qualitative content analysis. Descriptive data was presented using graphs, charts and tables and analyzed accordingly. Numerical data that was derived from the checklists and survey questionnaire was analyzed using the Statistical Package for Social Sciences (SPSS) version seventeen.

2X3 tables were drawn and Chi-square test was used to determine associations between categorical variables in the study.

CHAPTER FIVE: STUDY FINDINGS

5.1 Background Sample Characteristics

The study was done in 8 health facilities which included 1 hospital affiliated health centre, 4 health centres and 3 health posts. A sample of 21 Health care workers that routinely diagnosed and treated malaria for the period under review was used to collect the required information. Figure 3 below shows the number of participants who worked in a hospital and those who worked in health centres or health posts.

Figure 4: Type of Health Facility a respondent worked in

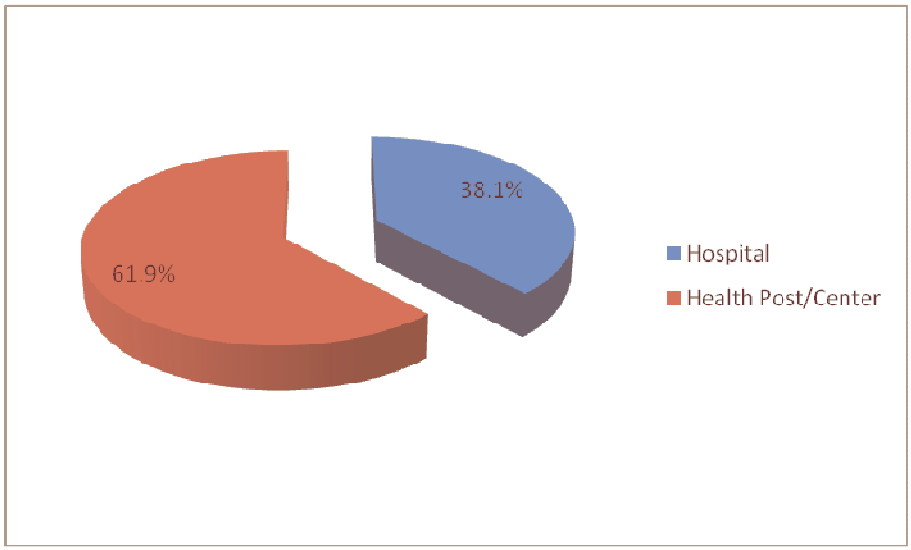
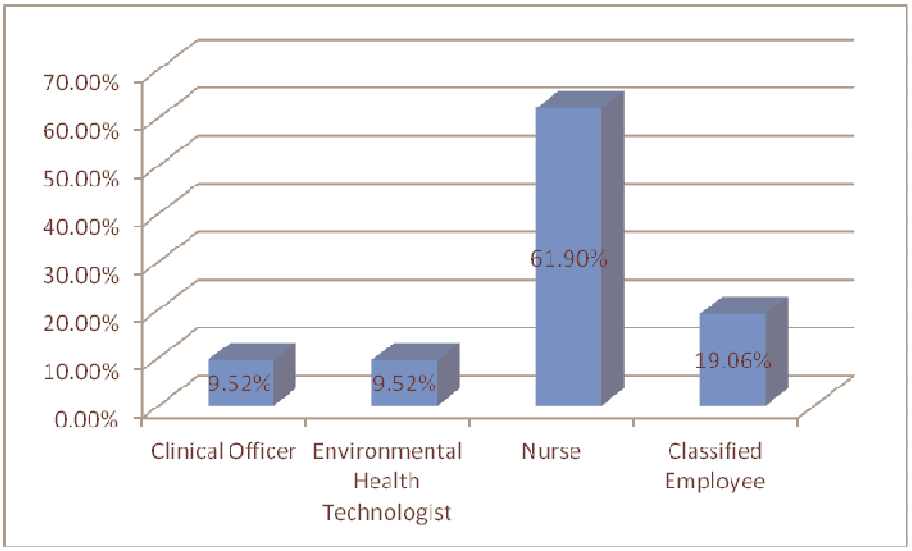


Figure 4 above shows that out of a total sample of 21 health workers, 61.9% (n=13) of them worked either in health posts or health centers, while the rest 38.1% (n=8) worked in a hospital.

5.1.1 Respondents' Distribution by profession

Figure 5: Respondents distribution by profession



From the sampled health workers, 61.9% were Nurses, while 19.06% were Classified Employees. Environmental Health Technologists and Clinical Officers were at 9.52% each.

5.1.2 How-Long a Respondent had been in Service

Figure 6: How long a respondent had been in service

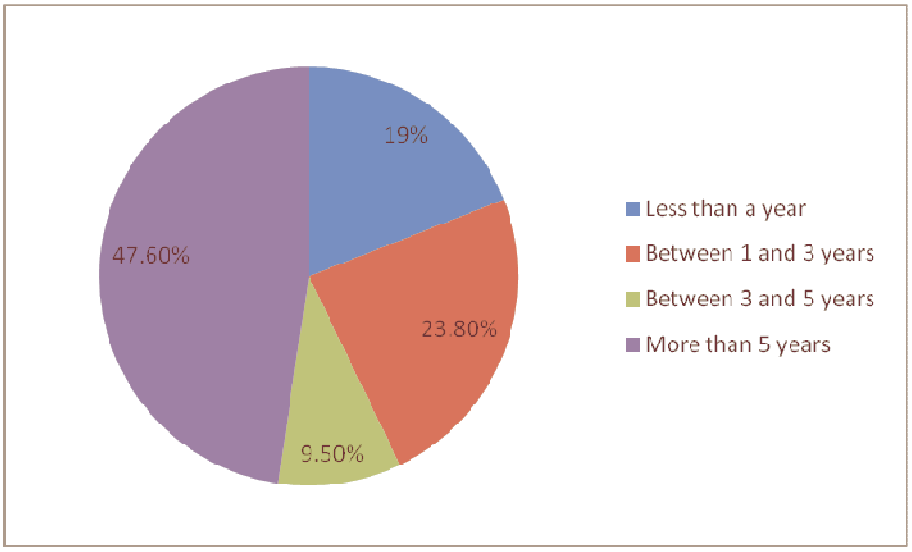


Figure 6 shows that out of the 21 sampled health workers, 47 .6 % (n=10) had worked for more than five years. 19% (n=4) had worked for less than a year at the time of the study.

5.1.3 In-Service Training in Malaria Management

Figure 7: In-service training in malaria management (Have you undergone in-service training in malaria management?)

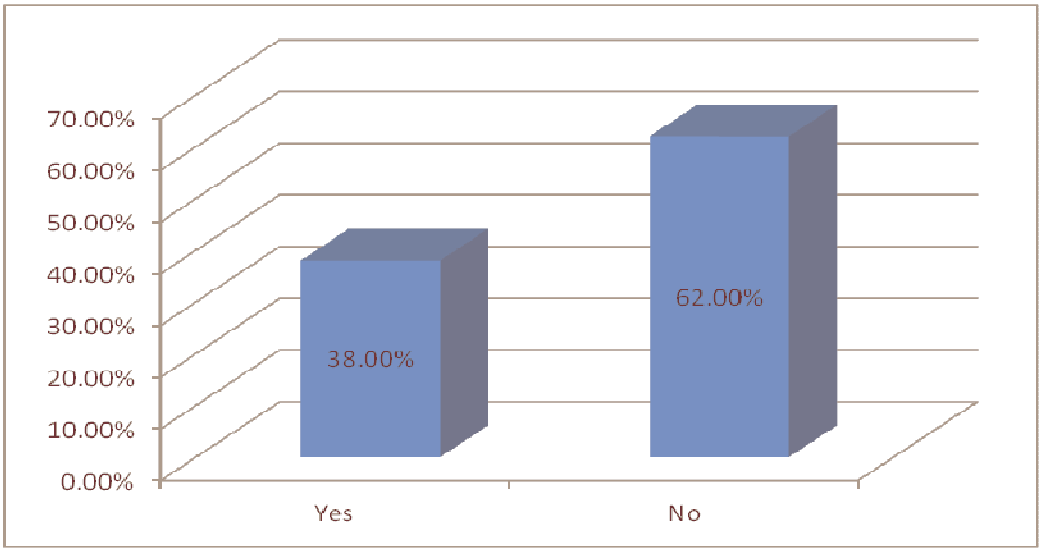


Figure 7 shows that out of the 21 respondents, 38% (n=8) had undergone in-service training in malaria management at the time of the study and 62% had not.

5.2 Availability and Distribution of Malaria Diagnostic Services

5.2.1 Distribution of healthcare workers per facility

Table 1: Distribution of healthcare workers per facility

	Facility							
Staff	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Clinical Officer	0	3	0	0	0	0	0	0
Environmental Health Technician	1	1	0	1	1	0	1	0
Nurse	1	1	2	1	1	1	1	1
Classified Employee	1	3	1	2	2	1	2	1
TOTAL	3	8	3	4	4	2	4	2

From table 1 above, out of the eight facilities, each facility had at least one Nurse and one Classified Employee. Only facility **B** had Clinical Officers (n=3). Environmental Health Technicians were available in 5 facilities namely, **A, B, D, E** and **G**.

5.2.2 Health care Workers who were able to Perform Malaria Diagnosis

Table 2: Number of healthcare workers who were able to perform malaria diagnosis

Staff Category	Total number (for eight facilities)	How many could perform RDTs?	How many could perform malaria blood slide?
Clinical Officer	3	3	0
Environmental Health Technician	5	4	1
Nurse	9	9	0
Classified Employee	13	11	1
TOTAL	30	27	2

Table 2 shows that 90% (n=27) of staff in the sampled facilities could perform RDTs, while only 6.7% (n=2) could do blood slide.

5.2.3 Availability of Malarial Reference Materials on malaria diagnosis

Table 3: Availability of malaria reference materials

Type of malarial reference material	Number of facilities in which it was available (out of eight facilities)
Standard case management/treatment guidelines	8
Programmatic treatment guidelines	6
SOP: Use of RDTs	5
Bench Aid/Job Aid: Malaria RDTs	2
Reference Books	6

Table 3 shows that standard case management and treatment guidelines were available in all the 8 facilities. Programmatic treatment guidelines were available in 6 facilities, SOP use of RDTs were available in 5 facilities, while Bench Aid/ Job Aid were available in only 2 facilities. Reference books were available in 6 facilities.

5.3 Adherence to National Guidelines on Malaria Diagnosis (Records of 320 patients treated for malaria during the period under review were used)

5.3.1 Age Distribution of Patients

Figure 8: Age distribution of patients

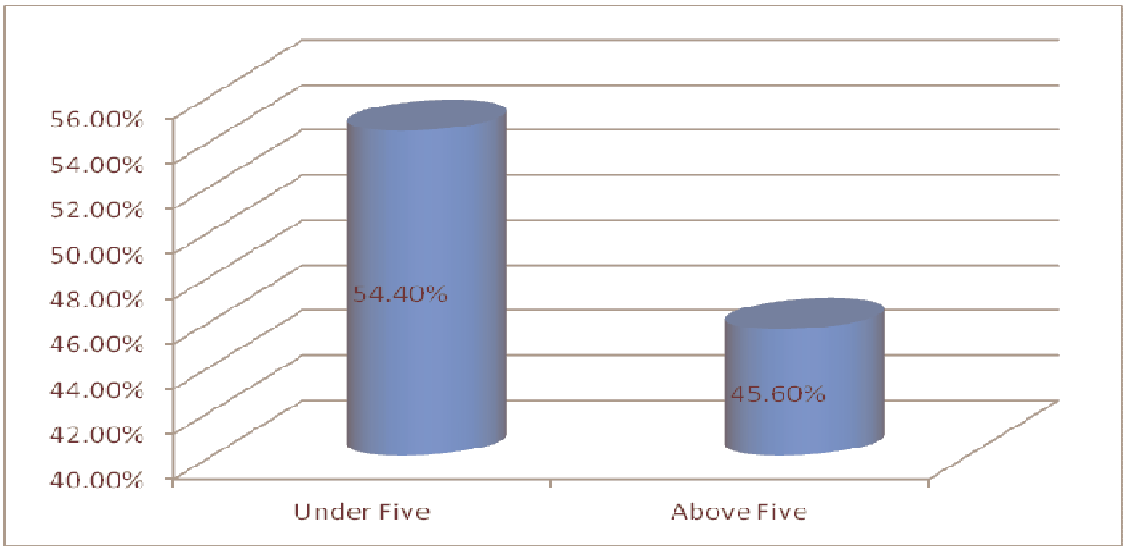


Figure 8 above shows that out of the 320 sampled records for patients who were treated for malaria, 54.4% (n=174) were under 5 years, while the rest 45.6% (n=146) were equal to or above 5 years.

5.3.2 Proportion of Patients who were tested before treatment

Figure 9: Proportion of patients who were tested for malaria before treatment

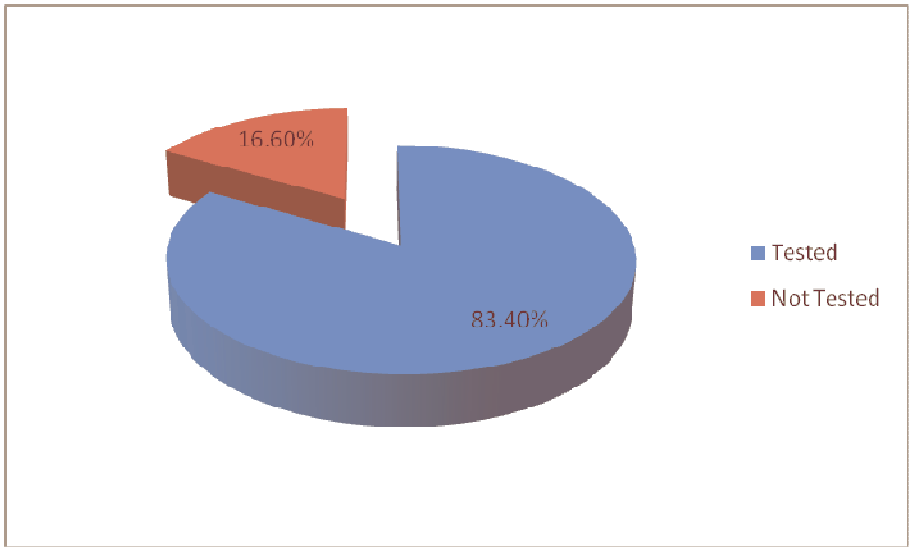


Figure 9 shows that out of the 320 patients who were treated for malaria, 83.4% (n=267) were tested before they were treated while 16.6% (n=53) were not.

5.3.3 Test Type Used

Figure 10: Test type used

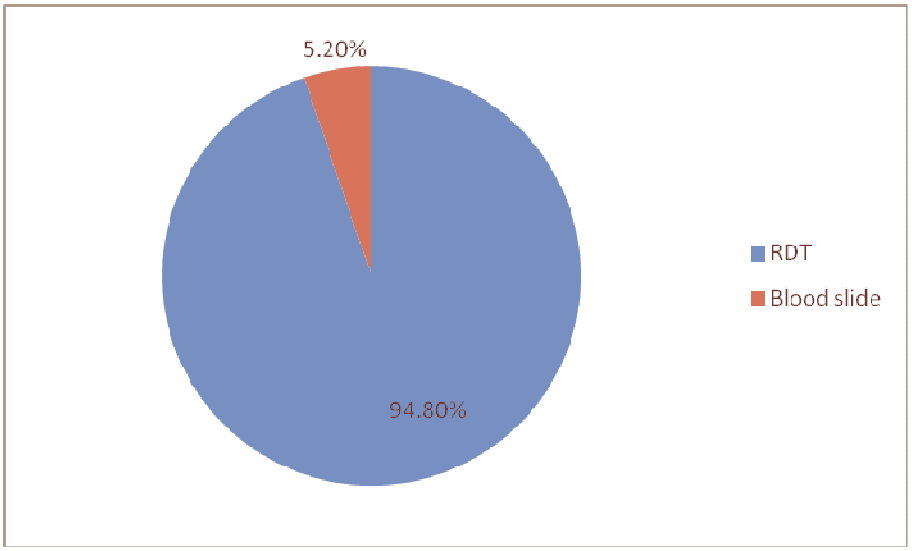


Figure 10 above shows that out of the 267 patients who were tested for malaria before treatment, 94.8% (n = 253) of them were tested by RDT, while 5.2 % (n = 14) took a blood slide*.

** The proportion of patients who took a blood slide was very minimal (5.2%) and could be ignored without compromising the validity of the findings. Therefore, more emphasis will be put on RDT test results.*

5.3.4 Confirmed against all malaria diagnoses and number of RDTs done

Figure 11: Comparison of number of RDTs done with number of malaria diagnoses and number of positive RDTs. (under five)

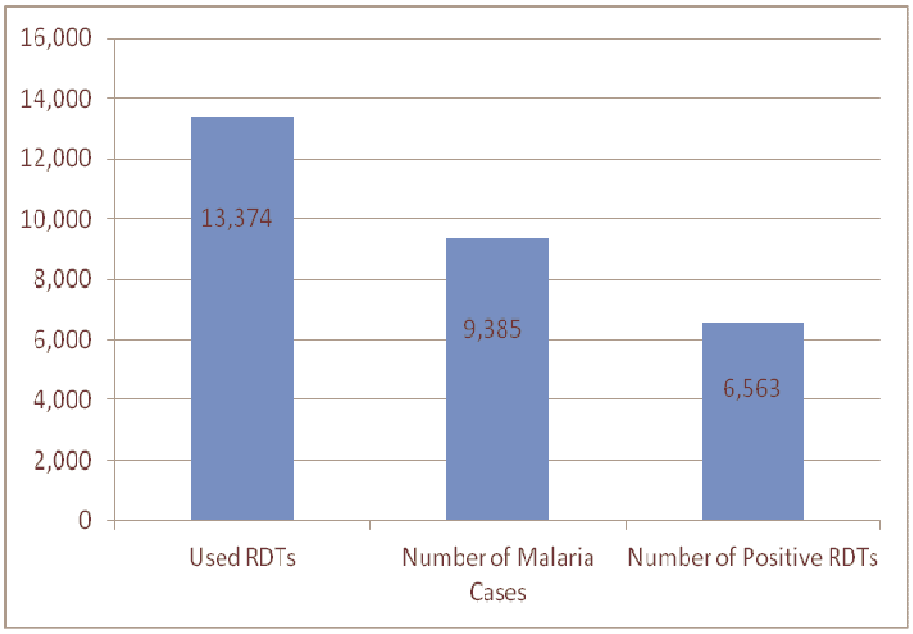


Figure 11 shows that during the period under review, 13,374 RDTs were used on patients under the age of five. Out of these used RDTs, only 6,563 came out positive. However, during this period, there were only 9,385 recorded malaria cases (both confirmed and clinical) for patients under the age of five.

Figure 12: Comparison of the number of RDTs done with the number of malaria diagnoses (clinical and confirmed) and number of positive RDTs (above five)

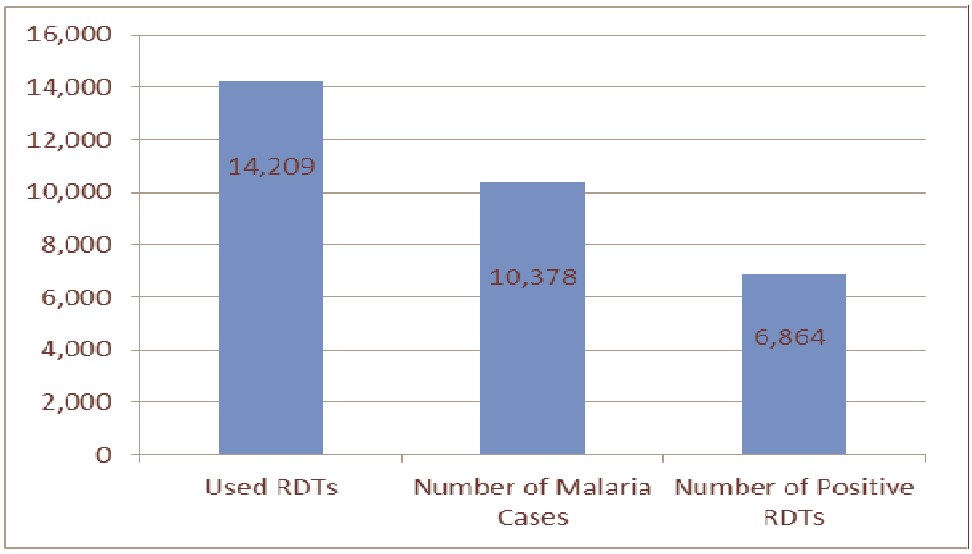


Figure 12 shows that during the period under review, 14,209 RDTs were used on patients above the age of five. Out of these used RDTs, only 6,864 came out positive. During this period however, there were only 10,378 recorded malaria cases (both clinical and confirmed) for patients above the age of five.

5.3.5 Interpretation of Malaria Test Results

Table 4: RDT test results cross tabulated with antimalaria prescription (Patients under 5 years)

	ANTIMALARIA PRESCRIPTION			
TEST RESULTS	Prescribed	Not Prescribed	**TOTAL**	P-Value
Positive	89 (97.8%)	2 (2.2%)	91 (100%)	
Negative	11 (31.4%)	24 (68.6%)	35 (100%)	0.000
Not Tested	43 (89.6%)	5 (10.4%)	48 (100%)	
TOTAL	143 (82.2%)	31 (17.8%)	174 (100%)	

With reference to the contingency table above, a chi-square analysis was used to determine whether there was a significant relationship between malaria test results and antimalaria prescription for patients below five years of age. The obtained chi-square value of **(x (2), N-174=78.53** was statistically significant **(p < 0.05)**. The strength of the relationship was found to be moderate **(V= 0.67)**. Frequencies indicated that patients with positive malaria test results were more likely to have antimalaria drugs prescribed to them than those with negative results.

Table 5: RDT test result cross tabulated with antimalaria prescription

(Patients above 5 years)

	ANTIMALARIA PRESCRIPTION			
TEST RESULTS	Prescribed	Not prescribed	**TOTAL**	P-Value
Positive	91 (100%)	0.0 (0.0%)	91 (100%)	
Negative	11 (30.6%)	25 (69.4%)	36 (100%)	0.000
Not Tested	16 (84.2%)	3 (15.8%)	19 (100%)	
TOTAL	118 (80.8%)	28 (19.2%)	146 (100%)	

In the above contingency table to determine whether there was a significant relationship between malaria test results and antimalaria prescription for patients above five years, the obtained chi-square value of **(x(2), N-146=80.42)** was statistically significant **(p < 0.05)**. The strength of the relationship was found to be high **(V= 0.74)**. Frequencies indicated that patients with positive malaria test results were more likely to have antimalaria drugs prescribed than those with negative results.

5.3.6 Anti-Malaria Drugs Prescribed

Figure 13: Anti malaria drugs prescribed

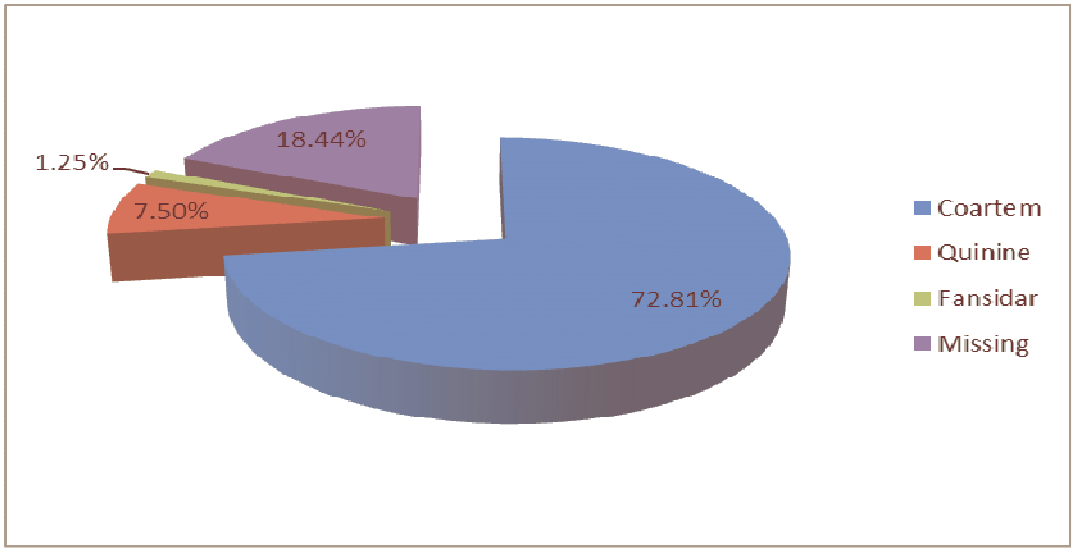


Figure 13 above shows that out of a total of 320 prescriptions, Coartem represented 72.81% (n=233), Quinine 7.5% (n=24) and Fansidar 1.25% (n=4).

Drug specification for 18.44% (n= 59) was missing.

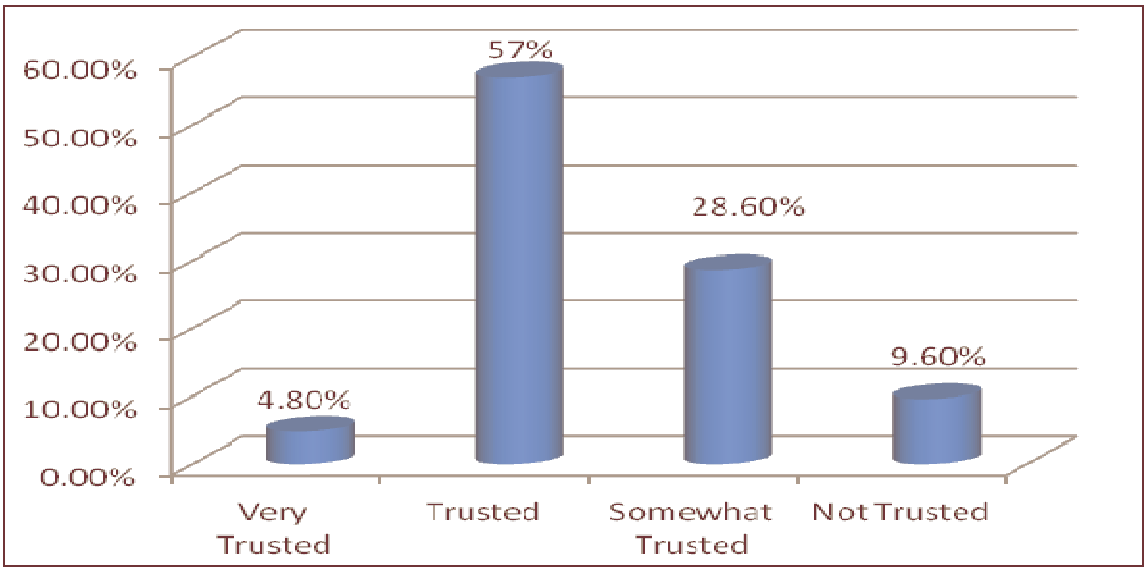
5.4 Health Care Workers' Perceptions of Malaria Diagnostic Test Results

5.4.1 Result for negative RDT –above five years

Figure 12 below shows the results when respondents were asked how trusted they thought a negative RDT test result for malaria would be in a patient above five years of age.

How trusted do you think a negative RDT test result for malaria would be in a patient above five?

Figure14: Results for negative RDT – Above five years



All the 21 sampled health workers responded to this question. The results were as follows: Only 4.8% (n=1) respondent felt that a negative RDT result for malaria in a patient above five would be very trusted, 57.1% (n=12) felt that it would be trusted, 28.6% (n=6) felt it was somewhat trusted and 4.8% (n=2) felt it would not be trusted.

5.4.2 Results for positive RDT - above five years

How trusted do you think a Positive RDT test result for malaria would be in a patient above five years?

Figure15: Results for positive RDT - above five years

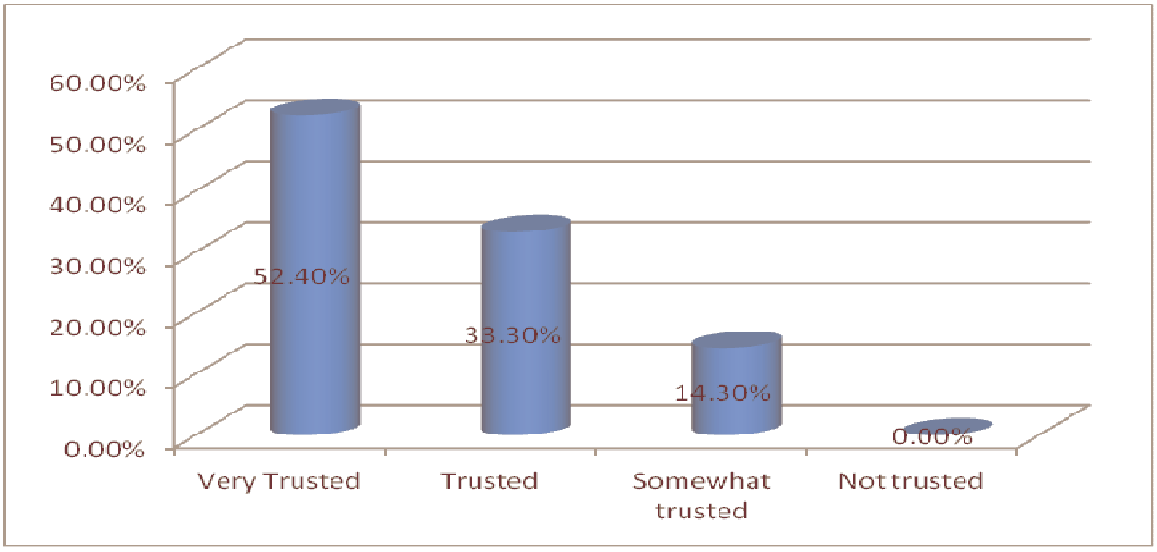
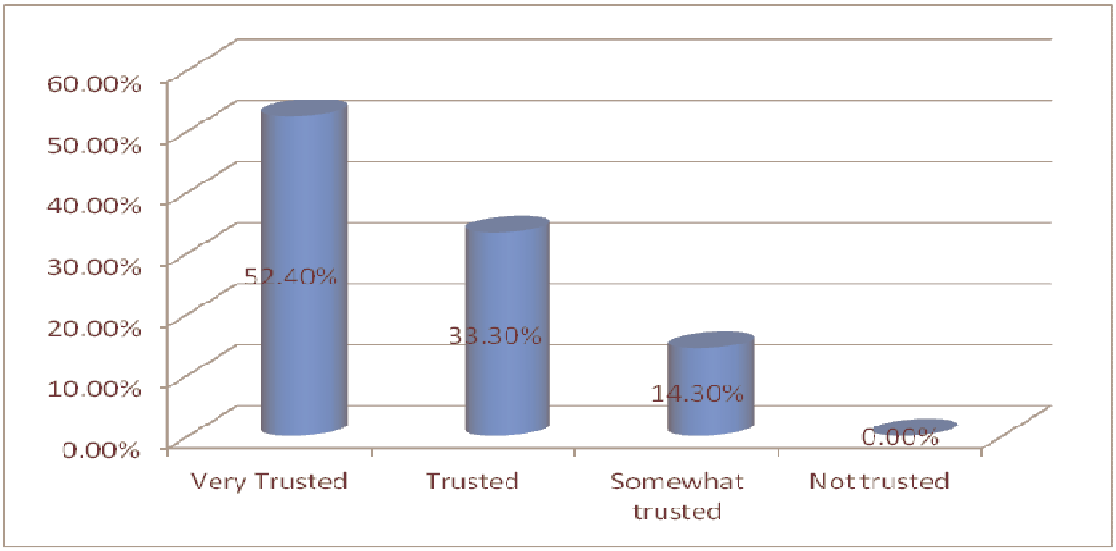


Figure 15 above shows that out of the 21 respondents, 52.4% (n=11) of them felt that a Positive RDT test result for malaria in a patient above five years would be very trusted, 33.3% (n=7) of them felt it would be trusted and 14.3% (n=3) felt it would be somewhat trusted.

5.4.3 Results for positive RDT – under five years

How trusted do you think positive RDT test result for malaria in a child under five would be?

Figure16: Results for positive RDT – under five years



With regard to how trusted a positive RDT malaria test result in a patient under five years would be, 52.4% (n=11) felt it would be very trusted, 33.3% (n=7) said it would be trusted and 14.3% (n=3) felt the result would be somewhat trusted as shown in figure 16 above.

5.4.4 Results for negative RDT – under five years

How trusted do you think a negative RDT test result for malaria in a child under five would be?

Figure17: Results for negative RDT – under five years

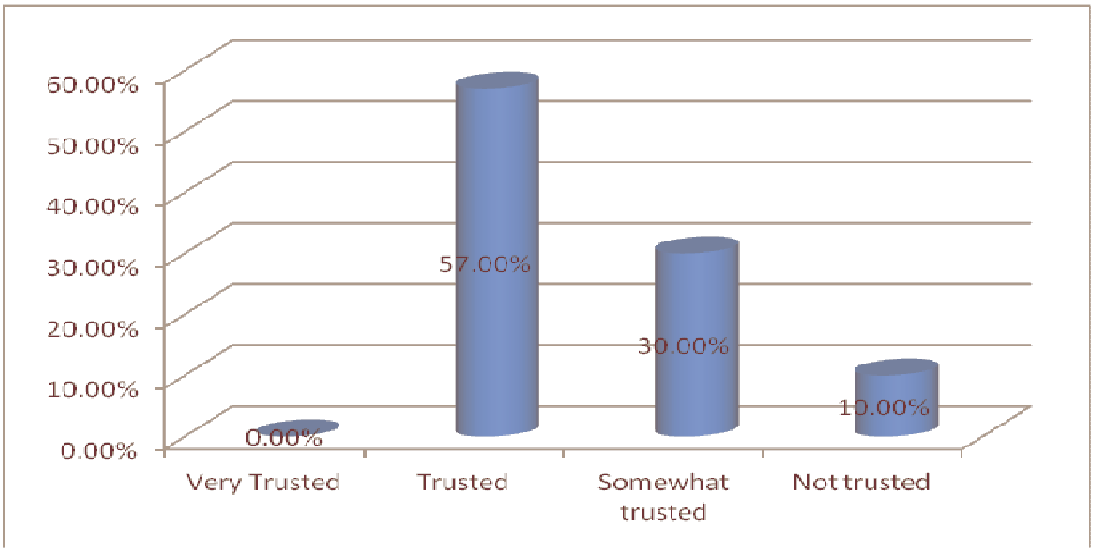


Figure 17 above shows that 57% (n=12) of the respondents felt that a negative RDT test result for malaria in a child under five would be trusted, 33% (n=7) felt it would be somewhat trusted and only 10% (n=2) felt that it would not be trusted.

5.5 Level of Support Supervision and Mentorship on Malaria Diagnosis

Figure 18: Support Supervision and Mentorship on Malaria Diagnosis

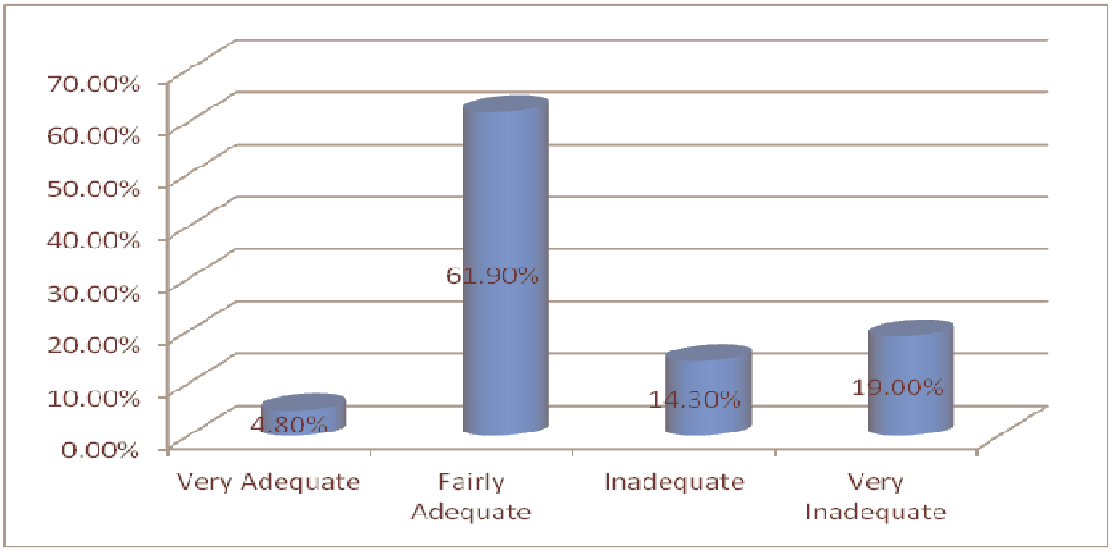


Figure 18 above shows that with regard to the level of support supervision and mentorship on malaria management respondents received from the District Medical Office, 4.8%(n=1) of the respondents felt that it was very adequate, 61.9%(n=13) felt it was fairly adequate, 14.3%(n=3) felt that it was inadequate and 19%(n=4) felt that it was very inadequate.

CHAPTER SIX: DISCUSSION

6.1 Background Characteristics of Respondents

From the 8 facilities, there were a total of 30 healthcare workers, of which 21 participated in the study. Out of a total of 21 respondents, 61.9% (n=13) were nurses, 9.52% (n=2) were clinical officers, 19.05% (n=4) of them were Classified Employees and 9.52% (n=2) were Environmental Health Technicians (Figure 5). Of the Healthcare workers that were sampled, 81% reported to had been in service for at least a year, 57.1% had been in service for at least 3 years while 47.6% had been in service for more than five years. Only 19% reported to have been in service for less than a year (Figure 6). Out of the 5 Environmental Health Technicians in the facilities, 4 could perform RDT, while only one could do malaria blood slide. With regard to Nurses, all the 9 could perform RDT, though none of them was able to do malaria blood slide. Out of 13 Classified Employees, 11 were able to do RDT and only one could do malaria blood slide. These findings conform to the National Malaria Control Centre statistics that malaria microscopy services in Health facilities are Zambia is very low (President's Malaria Initiative, 2011)

6.2 Availability and distribution of malaria diagnostic services in Serenje District

The results from the study indicate that the district had commodities for malaria diagnosis, including reference materials on malaria diagnosis in all the health facilities (Table 3). Each facility had at least one member of staff who could perform malaria test and 90% of health care workers in the sampled facilities were able to test for malaria at the time of study (Table 2). All the facilities sampled were using RDTs for malaria diagnosis, except for the hospital which used both microscopy and RDTs.

Although most health care workers could perform malaria test, only 38% of the sampled respondents had received formal training in malaria diagnosis and management in 2011(Figure 7). These findings conform to another study conducted in Zambia which showed that only a third of the facilities visited had at least one health worker who had received training in malaria diagnostics in the previous 12 months (President's Malaria Initiative, 2011). However, this situation is contrary to WHO recommendations which emphasize formal in-service training for all health care workers to be competent in malaria diagnosis (WHO, 2010).

The most commonly used test for malaria was RDT accounting for 94.8% (n=253) of malaria tests done while blood slide accounted for only 5.2% (n=14) (figure 10). This could be attributed to the fact that RDT is most appropriate to use in facilities without electricity and laboratory staff which is the case with Serenje district where only two health facilities have laboratory staff.

6.3 Adherence to National Guidelines on malaria diagnosis

The results from the review of records show that of the patients treated for malaria, 83.4% were supported by laboratory confirmation. Only 16.6% were not tested (Figure 9). This is in line with the national target which requires a minimum of 80% patients to have malaria confirmed before treatment. Nevertheless, this result is contrary to a study done in Kenya which showed that of the 880 febrile patients at 88 facilities, only 19.8% and 28.7% for children under five and patients above five years respectively had malaria test done (Juma et al., 2011).

When RDT test results were cross tabulated with anti-malaria drug prescription (Tables 4 and 5), it was found that patients (both under five and above five) with negative RDT test results seldom had anti-malarial drugs prescribed, compared to those with positive RDT test results. Of all patients under five years who tested positive for malaria, 97.8% (n=89) had anti-malaria drugs prescribed for them while only 31.4% (n=11) of those with negative result had an anti-malaria drug prescribed. For children under five, the obtained chi-square value of **(x (2), N-174 =78.53)** and asymptotic significance of **(p < 0.05)** suggested a significant relationship between the dependent variable (Antimalaria prescription) and the independent variable (Test result). This further shows that there was a correlation between a positive RDT result for a patient and prescription of anti-malaria drugs for that patient. As evidenced in table 4, the Correlation for patients under five years was moderate (**V= 0.67**). For patients above five years, all the patients with positive RDT (n=91) received anti-malaria prescription, while only 30.6% (n=11) of those with negative results received anti-malaria prescription (Table 5). The obtained chi-square value of **(x (2), N-146 = 80.42)** and the asymptotic significance of **(p < 0.05)**, showed a relationship between a positive RDT result and the prescription of an anti- malaria drug for that patient. The Correlation was high, with **(V= 0.74)**.

The differences in the table were significant enough to justify the claim that anti-malaria prescription was determined by the RDT test result and the decision to accept the claim for existence of a relationship was supported by the asymptotic value of .000 for both age

groups, which was less than the probability value (P-value) of 0.05, suggesting that the decision to prescribe an antimalaria drug to a patient was determined by malaria test results. This is contrary to a study done in Kenya which showed that the great majority (more than 90 per cent) of all antimalaria drugs prescribed were given to patients for whom the clinician had chosen to undertake a test and had received a negative result (Whitty et al., 2008).

However, 30.1% (n=43) of the patients under five years and 13.6% (n=16) of patients above the age of five who received anti-malaria prescriptions were not tested for malaria at all. This data shows that children under the age of five years are two times more likely to be treated for malaria based on clinical signs and symptoms than adults.

Comparison of RDTs done with reported malaria cases shows a disproportionately high number of RDTs performed at 142.5% and 136.9% of malaria cases (both confirmed and unconfirmed) in patients under five and above years respectively (Figures 11 and 12). Of all RDTs performed, only 49.1% and 48.3% were positive in patients under five and above years respectively. This indicates an overuse of RDTs, most likely due to poor or lack of clinical assessment of patients or inadequate clinical skills by health care workers. These findings are similar to a study done in Tanzania which established a lack of adherence to standard criteria to request for malaria test and unguided use of malaria laboratory tests by health workers (Derua et al., 2011). As a result, RDTs were routinely used to 'screen' patients for malaria instead of confirming a suspected case of malaria. Additionally, health care workers would more likely be inclined to ensuring that every patient treated for malaria has a test done than assess a patient to ascertain the likely hood of malaria due to the emphasis on "test before treating" and not "test when you suspect" malaria. Another factor could be the relatively long waiting time it takes for an RDT result to be ready (at least 15minutes) for which the overwhelmed health care worker cannot afford to wait. It is evident therefore that, the decision to do a malaria test on a patient is not based on the clinical suspicion of malaria, but rather the desire to have every prescription given to a malaria patient supported by a test result. These findings are similar to a study done in Tanzania which showed that request for laboratory malaria test was unguided in most cases (Derua et al., 2011). However, the contrast with the Tanzanian study was that that despite the fact that laboratory malaria diagnostic services were available in all study health facilities, standard criteria for who to test was lacking and test results were underutilized in management of patients as opposed to overutilization (Derua et al., 2011).

When respondents were asked how trusted they thought a negative RDT test result for malaria would be in a patient above five years of age, 4.8% (n = 1) reported that the result would be very trusted, 57.1% (n = 12) felt it would be trusted, 28.6% (n = 6) felt the result would be somewhat trusted while 9.6% (n = 2) felt it would not be trusted (Figure 14). However, when the same question was asked for a positive RDT test result, 52.4 % felt the result would be very trusted, 33.3 % felt that the result would be trusted while only 14.3 % thought that the result would somewhat be trusted (Figure 15). None of the respondents felt the result would not be trusted. With regard to a child under five with positive RDT test result for malaria, 52.4% respondents felt that the result would be very trusted, 33.3% felt that the result would be trusted while 14.3% felt that the result would be somewhat trusted. None of the respondents felt the result would not be trusted (Figure 16). The results were similar for a negative RDT test result.

6.4 Factors associated with lack of adherence to national guidelines on malaria diagnosis

Generally, the level of support supervision by District Medical Office was found to be fairly adequate. 14% of the respondents reported to have received inadequate support supervision and technical assistance on malaria diagnosis while 61.9% reported it to be fairly adequate (Figure 18). The level of in- service training by health care givers was generally low, standing at 38% at the time of the of study (Figure 7).

The sampled health care workers were asked to give opinions on: “When is a health care giver likely to treat a patient for malaria without performing RDT or microscopy?” In response to this question, the majority cited a patient who had a ‘fever’. Another response that appeared frequently was “when a patient is coming from a malaria infested area.” Furthermore, a good number of the health staff reported vomiting as one of the factors that could make a health care giver treat a patient for malaria without performing RDT or microscopy. Other factors that were mentioned, though less frequently included: nausea, malaise, headache, joint pains and absence of RDTs/ microscopy.

The sampled health care workers were also asked to give opinions on the question: “when is a health care giver likely to treat a patient for malaria with RDT/microscopy negative results?” Similarly, the most frequent responses were: If a patient was coming from malaria “infested area”, a fever and if a patient was vomiting. Other factors such as nausea and joint pains were also mentioned on a small scale.

From the above, it appears that fever, Vomiting and coming from malaria “infested areas” are the major factors that make health care givers treat patients for malaria without malaria test or with negative test results. Lack of or shortage of commodities was not considered a factor.

6.5 Limitations of the study

Due to the involvement of health care workers, there is a possibility of bias as they could have perceived it to be a fault finding exercise. The quality of malaria test techniques was not assessed.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

Generally, the district had adequate malaria diagnostic services in the health facilities, most of which are malaria RDTs. Health care workers adhered to malaria guidelines by prescribing anti-malaria drugs to patients with positive RDT and rarely, in the case of a negative result. However, about a third of all children treated for malaria were treated based on clinical signs and symptoms.

There was inadequate clinical assessment of patients leading to unguided use of RDTs, resulting in overuse of malaria diagnostic commodities. Factors associated with lack of adherence to national guidelines in malaria diagnosis included low proportion of healthcare workers who had received formal training in malaria diagnosis and management, low level of support supervision by District Medical Office and strong association of malaria with fever and vomiting in a patient, and high malaria endemicity by health care workers.

7.2 Recommendations

The following recommendations if implemented could address the weaknesses identified and subsequently improve malaria diagnostic services in the district:

- The Ministry of Health and Ministry Community Development Mother and Child Health through District Community Medical Office to plan for and formally train all health care workers (including Classified Employees) in Health Centres in Malaria diagnosis and management.
- District Community Medical Office to equip health care workers with basic clinical skills (history taking and examination).
- District Community Medical Office to provide regular and quality mentorship and support supervision to health facility staff on malaria diagnosis and management.
- Ministry of Health to revise the performance evaluation tool to include assessment of the clinical rationale by healthcare workers to perform malaria test, and not merely checking on whether a treated patient was tested for malaria.

References

American Heritage Stedman's Medical Dictionary, (2011) Retrieved from, www.Answers.com

Baboo K.S, Ndayambanje I, Chizema E.K, et al., (2008) **Effectiveness of Rapid Diagnostic Test for Malaria Diagnosis in Children under 15 Years of Age of Nchelenge District in the Luapula Province.** Medical Journal of Zambia Vol. 35 No. 4. Zambia Medical Association. Lusaka, Zambia.

Barnwell J W, Causer L, Bloland P (2003) **Strategies for Improved Diagnostics For Malaria, Including Rapid Diagnosis**. National Center for Infectious Diseases Centers for Disease Control and Prevention Atlanta, Georgia. USA.

Cold spring Harbour Laboratory (2011). **DNA learning Centre- Preparing Students and families to thrive in the gene age.** Cold spring Harbour Laboratory Press.

Davidson H, Ndhlovu M, Zurovac D et al., (2007) **Improved Diagnostic Testing and Malaria treatment practices in Zambia**. Pub Med Central. U.K.

Derua YA, Ishengoma DR, Rwegoshora R et al., (2011) **Users' and health service providers' perception on quality of laboratory malaria diagnosis in Tanzania.** Malaria journal, 2011. National institute for Medical Research, Tanga Centre, Tanzania.

HarperCollins Publishers (2003) **Collins Co build English Dictionary for Advanced Learners 4th edition.** HarperCollins Publishers.

Hopkins H. (2009) **Malaria Case Management, From Presumptive Treatment to Definitive Diagnosis**

Juma E**,** Dejan Z (2011) **Changes in health workers' malaria diagnosis and treatment practices in Kenya.** Malaria journal Vol. 10 National Malaria control programme. Nairobi, Kenya.

Kakkilaya BS (2003) **Rapid diagnosis of Malaria**. Lab. Medicine 8(34) 602 -608. Medical Journal of Zambia Vol. 35 No. 4. Zambia Medical Association. Lusaka, Zambia.

Ministry of Health - Zambia (2010) **Guidelines for the Diagnosis and Treatment of Malaria in Zambia.** USAID-Zambia. Lusaka, Zambia

Moody AH, Chiodini PL (2000) **Methods for the detection of blood parasites**Hospital for Tropical Diseases. London, UK

Murray CK, Bennett JW (2009) **Rapid diagnosis of malaria**. Infectious Diseases Service Brooke Army Medical Center.Houston Texas,USA

Noedl H, Wernsdorfer HW, Miller RS et al., (2002) **Histidine-Rich Protein II: a Novel Approach to Malaria Drug Sensitivity Testing**. American Society for Microbiology

Perkings MD and Bell DR (2008) **Working without a blindfold: The critical role of diagnosis in Malaria control.** Malaria Journal 7(suppl) BioMed Limited

President's Malaria Initiative (2011) **Malaria Operational Plan-Zambia.** Us Global Malaria Coordinator

Roll Back Malaria Research Group, International Federation of Red Cross and Red Crescent Societies (2010) **Optimizing control of infectious diseases in resource-poor countries: Malaria diagnosis, fever home-based management and new tools.** Brussels, Belgium

Serenje District Health Management Team (2006) **Health Management Information System Report.** Serenje DHMT Serenje, Zambia

Serenje District Health Management Team (2009) **Health Management Information System Report.** Serenje DHMT Serenje, Zambia

Serenje District Health Management Team (2010) **Health Management Information System Report.** Serenje DHMT Serenje, Zambia

Serenje District Health Management Team (2011). **Health Management Information System Report.** Serenje DHMT Serenje, Zambia

Serenje District Health Management Team (2012) **Health Management Information System Report.** Serenje DHMT Serenje, Zambia

Steketee R.W, Sipilanyambe N, Chimumbwa J et al., (2008) **National Malaria Control and Scaling Up for Impact: The Zambia Experience through 2006.** American society of Tropical Medicine and Hygiene

UNICEF (2010) **World Malaria day 2010: Africa update**

UNICEF (2004) **Malaria a major cause of child death and poverty in Africa**

US National Library of Medicine (2011) **Genetic Home reference-Your Guide to understanding genetic conditions.** National institutes of Health ,USA

Whitty C, Hopkins H, Ansah E et al., (2008) **Opportunities and Threats in Targeting Antimalarials -The Role of diagnostics.** The Affordable Medicines Facility. Washington, DC

Wongsrichanalai C, Barcus MJ, Muth S et al., (2007) **A Review of Malaria Diagnostic Tools: Microscopy and Rapid Diagnostic Test (RDT).** American Society of Tropical Medicine and Hygiene

World Health Organization (2005) **Action on the result of an RDT.** Geneva,

Switzerland

World Health Organization (2005) **what is an RDT?** Geneva, Switzerland

World Health Organization (2005). **Introducing RDT-Based Malaria Diagnosis into National Programmes.** Geneva, Switzerland

World Health Organisation (2007) **Malaria Microscopy Quality Assurance manual Version 1.**Geneva, Switzerland

World Health Organisation (2011) Diagnosis **of Malaria.** Geneva, Switzerland

World Health Organisation (2010) **WHO Guidelines for the treatment of malaria.** Geneva, Switzerland

APPENDICES

APPENDIX (I)

QUESTIONNAIRE

A STUDY TO EVALUATE MALARIA DIAGNOSTIC SERVICES IN SERENJE DISTRICT

HEALTH WORKER QUESTIONNAIRE

Instructions: Attempt to answer all questions. Where options have been provided, circle the most appropriate answer. Spaces have been provided for open ended questions. Write your answer clearly.

DO NOT WRITE YOUR NAME OR ID ON THIS QUESTIONNAIRE.

SECTION A: Background information

(I) What type of Health Facility do you work in?

1. Hospital
2. Health centre
3. Other (specify) _____

(ii) What is your profession? (Circle the most appropriate)

1. Clinical Officer
2. Doctor
3. Nurse
4. Environmental Health Technician/technologist
5. General worker
6. Other (specify) _____

(iii) For how long have you been in service?

1. Less than a year
2. Between one and three years
3. Between three and five years
4. More than five years

SECTION B: Malaria Training and Diagnosis

(iv)Describe the level of support supervision and mentorship on malaria management you receive from the District Medical Office (circle the **one** most appropriate answer)

1. Very adequate
2. Fairly adequate
3. Inadequate
4. Very Inadequate

(v) Have you ever undergone any in-service training in malaria management?

1. Yes
2. No

(vi) If the answer to (a) above is yes, when were you trained?

1. Three years ago
2. Two years ago
3. One year ago
4. Any other (specify) _____

(vii) In your opinion, when is a health care giver likely to treat a patient for malaria without performing **RDT/microscopy** test (give three reasons)

1. _____

2 _____

3. _____

(viii) In your opinion, when is a health care giver likely to treat a patient for malaria with **RDT/microscopy negative** test result (give three reasons)

1. _____

2 _____

3. _____

(ix) Comment on how **doubtful** you would feel about the **correctness/accuracy** of the following malaria test result? (Tick **one** answer for each result)

Test Result	**Always**	**Often**	**Some times**	**Never**
Adult with **negative microscopy(mps)** test result				
Adult with **positive microscopy(mps)** test result				
Child under five with **positive microscopy(mps)** test result				
Child under five years with **negative microscopy(mps)** Result				

(x) By ranking the scores below, how **trusted** do you think the following test results for malaria would be (Tick the **one** answer for each result)

Test Result	**Very trusted**	**Trusted**	**Some** **What trusted**	**Not trusted**
Adult with **negative RDT** test result				
Adult with **positive RDT** test result				
Child under five with **positive RDT** test result				
Child under five years with **negative RDT** Result				

Thank you

APPENDIX (II)

Malaria Diagnosis and management - facility check list (Adapted from Presidential Malaria Initiative standard check list)

Health Facility information

Name of Health Facility			
Province			
District			
Level of facility	☐ Health Centre	☐ 1st Level Hospital	☐ Health Post

Malaria Diagnostic services

Does this facility use RDTs?	☐ Yes	☐ No	☐ Unknown
Are RDTs currently out of stock?	☐ Yes	☐ No	☐ Unknown
If yes, where does this facility receive its RDTs?			

Does this facility use MPs?	☐ Yes	☐ No	☐ Unknown
Are MFs currently out of stock?	☐ Yes	☐ No	☐ Unknown
If yes, where does this facility receive its MPs?			

Human Resource-Facility staff

Note the number of staff who are able to perform malaria Diagnosis				
	No.	RDT	MPS	
Clinical Officers				
Medical Officers				
Nurses				
Classified Employees				

Formal Training for clinical staff in Malaria diagnosis

Clinical staff who attended a formal training (including refresher training) in laboratory malaria diagnostics (microscopy, RDT) during the previous calendar year (January to December). Fill out as completely as possible. For the "Type of Training", use "Y" for "Yes, topic trained" or "N" for "No, topic not trained". See abreviations at bottom for types. If trainings other than the ones listed in the types occurred, specify them.

	Profession of Staff Member	Gender		Units	Type of Training (Select All That Apply)					If Other: Specify
		Male	Female		MM	RDT	CM	QA	BLP	
1)										
2)										
3)										
4)										
5)										
6)										
7)										
8)										
9)										
10)										
11)										
12)										
13)										
14)										
15)										

Are more than 15 clinic staff trained? ☐ Yes ☐ No

** If Yes, attach an additional page detailing all names w/ gender, units and training type included **

*__MM__ - Malaria Microscopy; __RDT__ - Rapid Diagnostic Tests; __CM__ - Case Management including adherence to test results; __QA__ - Quality Assurance including OTSS; __BLP__ - Best Lab Practices; __Other__ - specify other topics discussed, including Data management for OTSS or MMRT

Clinical Documentation

Indicate with a tick the status of the following clinical documents			
Daily outpatient registers	☐ Available, properly maintained	☐ Available, improperly maintained	☐ Unavailable
Daily inpatient registers	☐ Available, properly maintained	☐ Available, improperly maintained	☐ Unavailable
	☐ Not Applicable		
Reports	☐ Available, properly maintained	☐ Available, improperly maintained	☐ Unavailable
Drug stock cards	☐ Available, properly maintained	☐ Available, improperly maintained	☐ Unavailable

Malaria Reference Materials

Only tick "YES" if you can verify that the following materials are physically available				
Standard case mgmt/treatment guidelines	☐ Yes	☐ No	If "yes", location	
Programmatic treatment guidelines	☐ Yes	☐ No	If "yes", location	
SOP: use of RDTs	☐ Yes	☐ No	If "yes", location	
Bench Aid/Job Aid: Malaria RDTs	☐ Yes	☐ No	If "yes", location	
Reference books	☐ Yes	☐ No	If "yes", location	
Have the SOPs been reviewed/updated within the past 12 months?	☐ Yes	☐ No	☐ Unknown	

Prescriber Adherence to Negative Malaria test result –Under five

Test type		Antimalarial prescribed			
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	

Prescriber Adherence to Negative Malaria test result – Above five

Test type		Antimalarial prescribed			
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	
☐ RDT	☐ Blood Slide	☐ Yes	☐ No	If prescribed, name of drug	

Quarterly Report on confirmed and unconfirmed malaria cases

PATIENTS Under 5 Years		PATIENTS 5 Years and Older	
Total # of malaria cases (HMIS)		Total # of malaria cases (HMIS)	
# of RDTs (RDT registers)		# of RDTs (RDT registers)	
# of positive RDTs (RDT registers)		# of positive RDTs (RDT registers)	
# of MPs (Lab register)		# of MPs (Lab register)	
# of positive MPs (Lab register))		# Of positive MPs (Lab register)	

Stock outs of malaria diagnostic commodities

Did this health facility experience a stock-out lasting 7 or more consecutive days during the last three months that prevented the facility from carrying out malaria diagnostic tests

☐ Yes ☐ No ☐ Unknown

If yes, please indicate which commodities were missing

1) _____

2) _____

3) _____

APPENDIX (III)

Information Sheet

Introduction

My name is **Tiza Mufune.** I work for the Ministry of Health as a Medical Doctor, with Serenje District Health Management Team. I'm currently pursuing a Master of Public Health Degree at the University of Zambia. As a requirement for this degree, I'm expected to conduct a research study. My research is entitled: **A study to assess Malaria Diagnostic Services in Serenje District, Zambia.**

Objective of the study

The main objective of the study is to carry out an assessment of malaria diagnostic services in the district and ascertain the level of adherence to national guidelines on malaria diagnosis. It will discuss among other things, the availability and distribution of malaria diagnostic commodities and describe factors associated with non adherence to the national malaria diagnosis policy.

Procedure

For purposes of this study I intend to collect information using a questionnaire. It has a few questions and I would encourage you to answer all of them if you can.

Confidentiality

You are not obliged to reveal any personal details as a participant to this study. Therefore no personal details should be written on the questionnaire or anywhere therein. All the information that you will provide will be used strictly for purposes of the study and will be treated with strict confidentiality.

Voluntary Participation

Please note that participation in the study is voluntary and that you are free to decline participation in the study. Once you decide to take part in the study you are free to seek clarification and withdraw from the study anytime. If you feel uncomfortable to answer some questions, you may not answer them.

Benefits/Risks

The information that we will get from this study will be used to improve on the health service delivery, especially in the area of malaria diagnosis and management in Serenje. It will be used to identify challenges to improved malaria diagnosis and appropriate recommendations will be made where necessary. There are no anticipated risks to your participation in the study.

For any clarification, please feel free to contact me using the details below:

Name: Tiza Mufune

Address: Serenje DHMT, P.O. Box 850095

Serenje

Telephone: 05 - 382097

Fax: 05 - 382186

Cell: 0979-442224

E-mail: mufunetiza@yahoo.com

Principal Investigator: Tiza Mufune **Sign:** _____

If you understand the information provided above and you are willing to participate in the study, please fill in and sign on the form provided.

APPENDIX (IV).
Informed Consent form

I_____ (**Participant's names**) agree to take part in this study. The aim of this study has been explained to me and I understand the purpose, the benefits, risks and discomforts that may be involved.

I further understand that, my taking part in this study is voluntary, that I can withdraw from the study at any time without having to give an explanation or seeking permission, that all the information I will give will be used solely for purposes of the study and that it will be treated strictly as confidential.

Signed: _____ (**Participant's signature/ thumb print**) Date: _____

Signed: _____ (**Witness**) Date: _____

Signed: _____ (**Researcher**) Date: _____

Persons to contact for clarification

1. **Dr. Tiza Mufune**, University of Zambia School of Medicine, Department of Community Medicine, P.O. Box 50110, Lusaka. Cell: 0979-442224.
2. **Prof. KS Baboo**, University of Zambia School of Medicine, Department of Community Medicine P.O. Box 50110, Lusaka. Cell: 0978-774068
3. **Dr. SH Nzala**, University of Zambia School of Medicine, Department of Community Medicine P.O. Box 50110, Lusaka. Cell:0979-176779
4. **The Chairperson**, Biomedical Research Ethics Committee, University of Zambia, Ridgeway Campus, P.O. Box 50110, Lusaka.

APPENDIX V
Work Schedule

ACTIVITY	APR 2012	MAY 2012	JUN 2012	JUL 2012	AUG 2012	SEP 2012	OCT 2012	NOV 2012	DEC 2012	JAN 2013	FEB 2013
Proposal Development	*	*	*								
Presentation G/ forum				*							
Ethics Committee						*					
Data Collection							*	*			
Data analysis/ Report writing									*		
Submission of draft report										*	
Submission final report											*

APPENDIX VI.

Budget

The total budget for the research is **K26 037 000**. Funding will be from my sponsors (Ministry of Health) and own resources.

ITEM	QUANTITY	UNIT COST (ZMK)	TOTAL COST (ZMK)
Stationary	4 reams	30 000	120 000
Bond paper	1	800 000	800 000
Printer Toner	1	750 000	750 000
Flash Disk	2	100 000	200 000
Binding	5 reports	30 000	150 000
Secretarial services	-	-	**4 000 000**
Pens	box	50 000	50 000
Pencil	box	30 000	30 000
Erasers	10	30 000	30 000
Stapler	2	30 000	60 000
Staples		100 000	100 000
Perforator	2	70 000	70 000
Note books	6	20 000	120 000
Folders	10	8 000	80 000
Bags	6	60 000	360 000
Scientific calculator	5	200 000	1 000 000
Fuel	1500 litres	7 000	10 050 000
Accommodation	20	285 000	5 700 000
SUBTOTAL			**23 670 000**
Contingency (10%)			
GRAND TOTAL		2 367 000	1 367 000 **26 037 000**

APPENDIX (VII)

GRADUTE FORUM PERMISSION LETTERS

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE

Telephone: 252641
Email: shnzala@unza.zm

PO Box 50110
Lusaka

7th February 2012

Dr. T Mfune, Computer # 529003962
Department of Community Medicine
School of Medicine

Re: GRADUATE PROPOSAL PRESENTATION

Dear Dr. Mfune

Following the Graduate Proposal Presentation Forum (GPPF), held on Thursday, **2nd February 2012** in the Main Lecture Theatre (UTH) at 14:00 hrs, I wish to inform you that your research proposal titled **'A study to evaluate malaria diagnostic services in Serenje District, Zambia'** towards the **MPH** was approved by the Board of Graduate Studies of the School of Medicine. The average mark of the assessors was **53%.**

The comments by the assessors were:

- Suggest change title to reflect that this is not an evaluation (which has very specific definition) but to something like assessment etc.
- Ensure that the statement of the problem is succinctly presented.
- Ensure research questions, hypotheses and objectives are consistent.
- Ensure that the tools and variables match.
- Also, ensure the independent and dependent variables are not confused with one another.
- Justify why purposive sampling.
- Suggest that instead of assessing files from 2010, use 2011 malaria data if available.
- Suggest reduce number of files to review.

This proposal is judged as a **Pass** subject to the above corrections.

Dr. S.H. Nzala
Assistant Dean, Postgraduate

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
24 FEB 2012
ASSISTANT DEAN (PG)
P.O. BOX 50110, LUSAKA

cc Director, Research and Graduate Studies
Head, Department of Community Medicine
Professor KS Baboo (Supervisor), Dr. S Nzala (co-Supervisor)

APPLICATION LETTER ETHICS COMMITTEE

The Assistant Dean – Post Graduate Studies

University of Zambia,

School of Medicine,

Ridgeway Campus,

P.O. Box 50110,

Lusaka.

28th March, 2012

Dear Sir,

Re: Submission of Research Proposal for Ethical approval

Following the presentation of my research proposal entitled **"A study to evaluate malaria diagnostic services in Serenje District"** to the Graduate Proposal forum (GPPF), held on Thursday 2nd February 2012, in the main lecture theatre, the following corrections have been made based on comments from the assessors:

1. Title has been changed, instead of reading: "A study to **evaluate** Malaria Diagnosis in Serenje District" It shall read: "A study to **assess** Malaria Diagnosis in Serenje District"
2. Statement of the problem has been revised to include statistics for 2009, 2010 and 2011.
3. Study questions, objectives and variables have been revised and realigned
4. The study period has been changed from **2010** to **2011**
5. The sample size for record review has been reduced from **720** to **320.**

I now forward the proposal for approval by the University of Zambia Research Ethics Committee.

Yours faithfully,

Dr Tiza Mufune

APPROVAL LETTER ETHICS COMMITTE

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
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E-mail: unzarec@unza.zm
Assurance No. FWA00000338
IRB00001131 of IORG0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

8th June, 2012.

Your Ref: 012-02-12.

Dr. Tiza Mufune,
School of Medicine,
Department of Community Medicine,
PO Box 50110,
Lusaka.

Dear Dr. Mufune,

RE: SUBMITTED RESEARCH PROPOSAL: **"A STUDY TO ASSESS MALARIA DIAGNOSTIC SERVICES IN SERENJE DISTRICT, ZAMBIA"**

The above mentioned research proposal was submitted to the Biomedical Research Ethics Committee for ethical review on 1st June, 2012. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr. J.C Munthali
CHAIRPERSON

Date of approval: 08 June, 2012 **Date of expiry**: 07 June, 2013