TO DETERMINE FACTORS INFLUENCING LABORATORY DIAGNOSIS OF MALARIA IN LINDI REGION HOSPITALS, TANZANIA 2012

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MSc. (Epidemiology and Laboratory Management) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2013

TO DETERMINE FACTORS INFLUENCING LABORATORY DIAGNOSIS OF MALARIA IN LINDI REGION HOSPITALS, 2012

By

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A dissertation Submitted in (partial) Fulfillment of the Requirements for the Degree of Master of Science in Epidemiology and Laboratory Management of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences
25TH October, 2013

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Scienc**es** a thesis / dissertation entitled: "**To Determine Factors Influencing Laboratory Diagnosis of Malaria in Lindi Region Hospitals, 2012"** in fulfillment of the requirements for the degree of Master of Science Degree in Epidemiology and Laboratory Management of Muhimbili University of Health and Allied Sciences.

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Prof. Z. Premji

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Date: _____

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DEDICATION

This work is dedicated to To my wife Zita, and our beloved children Upendo and Fredrick

DECLARATION AND COPYRIGHT

I, **Malibiche, Theophil Clemence,** declare that this **dissertation/thesis** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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ABSTRACT

Background; Malaria remains an important public health problem. Globally it accounts for 219 Million cases and 660,000 deaths, majority under 5 years. Africa continent contributing 90% of all deaths, it is estimated that, malaria accounts for 50% of outpatient, 20% of admissions in Sub Saharan Africa. Tanzania reporting 120,000 patients annually of whom 80,000 occur in children bellow 5 years of age. This study was carried out to determine factors influencing laboratory diagnosis of malaria in hospitals.

Methods; Cross sectional quantitative study conducted from October to December 2012 in three Hospitals, Lindi Region. Patients, clinician and laboratory personnel were interviewed for their practice and quality of malaria patient management. Two thick blood smears were collected from patients, stained and examine by laboratory technologist at the study site and Bagamoyo – Ifakara research institute Laboratory.

Results: Total of 479 patients, 28 clinicians and 17 laboratory personnel were recruited, Patients mean age was 25 years ±STDev 23years, Female 288 (60.1%), Male 191 (39.9%). Clinicians mean age was 38 yrs ±STDev 10.5 years, Female 16 (57.1%) Male 12 (42.9 %) Laboratory personnel, mean age was 25 years ±STDev 10.4 years, Female 2 (11.8 %), Male 15(88.2%). Among 479 patients tested for malaria, 42 (8.8%) were positive for malaria compared to 20 (4.2%) obtained from reference laboratory with 33.3% PPV 94% NPV. Of the 17 laboratory personnel, 52% had no form of continue education in the field of malaria. There is only 26.3% of the required staff in the study area. Good prepared smear were 1.7 times likely to have given the correct results, while good staining were more likely to give correct results (P value 0.01), Correct smear microscopy was more probable to be reported by that technician who cleaned microscope before use (P value <0.001). Though 60.7% of clinicians mentioned to trust laboratory results; 4.6% of patients were given antimalarial prior laboratory test and 26.3% treated based on clinical diagnosis regardless of smear negative result.

Conclusion and Recommendations; Malaria Laboratory results are more likely to be compromised by inadequate trained and over-worked laboratory personnel. Laboratory results contribute little to the patients' management. Skilled staff could improve laboratory results and hence patient management.

ACKNOWLEDGEMENT

The processes to produce this dissertation document have been much of consultative among MUHAS members. Special thanks should go to Professor Zul Premji who worked hard to assure the quality of this dissertation, Ahmed Abade for technical advice

Lastly, I would also like to extend my sincere appreciation to officials from FELTP – Dar-Es-Salaam, RAS, RMO's office – Lindi and DMO's office Nachingwea and Ruangwa and all others facilitated the accomplishment of his valuable dissertation.

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ACRONYMS

ACT	Artemisinin-based combination therapy
CDC	Centers for Disease Control and Prevention
DMO	District Medical Officer
DNA	Deoxyribonucleic acid
HIV	Human immunodeficiency virus
HRP2	Histidine Rich Protein 2
IMCI	Integrated Management of Childhood Illness
MoHSW	Ministry of Health and Social Welfare
MUHAS	Muhimbili University of Health and Allied Sciences
PCR	Polymerase Chain Reaction
pLDH	*Plasmodium falciparum* Lactate Dehydrogenase
QT-NASBA	Quantitative Nucleic Acid Sequence based Amplification
RAS	Regional Administrative Secretary
RDT	Rapid Diagnostic Test
RMO	Regional Medical Officer
STDev	Standard Deviation
SSA	Sub Saharan Africa
TFELTP	Tanzania Field Epidemiology and Laboratory Training Program
WHO	World Health Organization
SD	Standard Deviation

CHAPTER ONE

1.0 INTRODUCTION

Malaria poses a significant impediment to social and economic development causing morbidity and mortality in tropical and subtropical regions, including parts of America, Asia and Sub Saharan Africa [1, 2, 3]. It is endemic in 108 countries, with 3 million globally estimated deaths annually, majority of deaths occurring among children under five years of age [4, 5, 6]. In sub Saharan Africa, it accounts for 50% of outpatient attendances and 20% admissions [7, 8, 9], with an estimate of 1 of every 5 of all childhood deaths occurs in Africa. Malaria causes low birth-weight, anemia, epilepsy, and learning difficulties [10].

An estimate 4.9 billion febrile events or anti-malarial treatment exposures occur each year in Africa, with most countries spending up to approximately 1.2 billion US$ annually on malaria, and this has impacted negatively towards slowed economic growth direct and indirect, such as Morbidity, mortality and loss of manpower for economic production [11].

Tanzania, as other SSA countries, reports about 120,000 cases of malaria annually, 80,000 occur in children less than 5 years of age [12].

The burden of malaria can be reduced through early diagnosis and prompt treatment, as one of the key strategies in control and case management therefore the need for accurate and prompt parasitological testing is inevitable [8,9] . Many high malaria endemic third-world countries have limited parasitological based malaria diagnosis systems and employ symptom-based diagnosis which results in a high rate of unnecessary treatment. The level of standardized expertise in malaria diagnostics in most public hospitals may vary due to heavy workload in most endemic areas, inadequate expertise and inadequate facilities.

Blood slide microscopy for decades has been a powerful tool for the routine diagnosis of febrile illnesses in many endemic areas of sub-Saharan Africa [13, 14].

Microscopic diagnosis solely depends on the expertise of the provider, with most countries in Sub Saharan Africa being faced by lower microscopy accuracies from factors like lack of technical supervision, poor condition of microscopes, and a high volume of blood slide requests. Most health facilities in remote rural areas lack electricity and health-facility resources therefore microscopy is often unavailable [12, 15]. Majority of malaria suspected cases are not well identified regardless of limited availability of microscopy for diagnosis in some third world countries, resulting in over-use of anti-malarial drugs and poor disease monitoring [8]. Various studies and report's recommendation emphasizes the importance of high-quality microscopy [8,9] or, where not available, use of quality-assured mRDTs. Changes in malaria drug policy and malaria epidemiology are aimed at targeting anti-malarials only to patients who need them, therefore, need for confirmation of malaria in all suspects [4, 5], laboratory-based diagnosis of malaria as a means to prevent the emergence of Artemisinin based Combined Therapy (ACT) resistance, a more expensive malaria combination drug for treating uncomplicated malaria [7, 8] and improve overall clinical management of febrile patients [16]. The change in drug policy, with emphasis on parasitological confirmation, combined with aggressive vector control, coincides with a decrease in malaria transmission and subsequent decline in the proportion of fevers attributable to malaria [17].

Lack of specificity to the presumptive diagnosis is another major drawback to treatment of malaria with an ACT [18]. The economic implications of over diagnosis are considerable and undermine the cost effectiveness of the ACTs [19]. The World Health Organization now recommends malaria patient management based on parasite based diagnosis in all cases [7,9]. Given the challenges of implementing microscopy-based definitive diagnosis of malaria, mRDTs have been suggested as an alternative [20,21]. Antigen detecting rapid diagnostic tests (mRDT) are cost effective and feasible than molecular methods to the implementation of ACT and control strategy, forming the backbone of expansion of access to malaria diagnosis as they provide parasite-based diagnosis in areas where good quality microscopy cannot be maintained. Though several studies mention mRDT as having false positive in endemic areas and inability to monitor resistance [22]. Effective implementations of malaria patient management policies is significantly determined by health workers adherence to diagnostic

and treatment guidelines and involve parasitological testing of all febrile patients regardless of the age category [23].

Non-adherence to laboratory confirmed negative results is not unique to Tanzania and related studies such as microscopy-based have reported similar results across Africa [24, 25 26, 27, 28, 29]. Poor quality malaria routine testing and clinical guidelines and practices permit treatment of older children and adults with negative blood-slide. This hinders potential benefit of parasitological diagnosis and thus undermines the normal use of anti-malarial drugs.

1.1 PROBLEM STATEMENT

There is an enormous gap in diagnosis and management of malaria cases in Lindi with only about 16 (8%) of 196 health facilities having diagnostic tools for malaria confirmation. Malaria diagnosis is mainly based on clinical grounds. Approximately 23,754 febrile cases were reportedly treated for malaria between January and June 2010, out of which only about 10% was positive Laboratory confirmed cases [(30)]. The problem of clinical diagnosis is, it has very low specificity bellow 50% [(43)] leading to overtreatment with ACTs and potential for resistance and wastage of drugs

Microscopy remains the golden standard in the diagnosis of malaria, but with limited availability of microscopic diagnostic sites due to inadequate skilled staff, availability of reagents and electricity, there is absence of mutual team cooperation between the clinicians and laboratory personnel proceeding to patients treatment without waiting for laboratory results or ignore the results and give anti-malarial therapy in cases where no malaria parasites are demonstrated and hence gross over-diagnosis and over-treatment, ranging from 32% to 96% of febrile patients having an anti-malarial prescribed without any evidence of peripheral *P. falciparum* infection depending on background level of malaria transmission [(31)]. Currently there is little information on the factors influencing malaria diagnosis in Lindi. Documentation of the laboratory diagnosis findings will enable medical providers improve malaria diagnosis and hence provide appropriate treatment and preventive measures.

1.2 RATIONALE

Malaria is preventable, treatable and curable, and there is, therefore, a need for rapid, effective and accurate diagnosis, [8, 9] that forms a vital part of malaria case management. Delays in diagnosis and treatment of malaria are the leading causes of deaths from malaria.

Since there is wastage of drugs and patient mismanagement, there is need to determine factors influencing accuracy of laboratory diagnosis of malaria in Lindi, similarly capacity of clinicians to treat malaria can be an alternative to malaria mismanagement and thereupon improve overall management of febrile patients in malaria endemic areas, Lindi in particular. This study is therefore aiming at determining factors influencing laboratory malaria diagnosis, the obtained information will therefore be utilized to put strategies to improve malaria diagnosis, management and reduce cost implication resulting from over diagnosis and use of costly ACT. The study will also be useful to health policy makers in planning towards scaling up effective interventions to attain both coverage and National impact targets of reducing Malaria by 50% by 2013 and thus help WHO in achieving the goal of ending malaria deaths by 2015, thereby accelerating progress towards millennium Development Goals.

1.3 RESEARCH QUESTIONS

1.3.1. Is the laboratory producing accurate results for malaria diagnosis?

1.3.2. What is the level of knowledge of laboratory personnel and clinicians on malaria diagnosis and management?

1.3.3. What is the proportion of negatively confirmed malaria suspect cases prescribed with anti-malaria?

1.3.4. What is the capacity in terms of profession and number of laboratory personnel in the study area?

1.4. OBJECTIVES

1.4.1 Broad objective:

1.4.1.1To determine factors influencing malaria laboratory diagnosis in Lindi Region hospitals

1.4.2. Specific Objectives

1.4.2.1 To determine capacity of laboratory personnel and clinicians in malaria diagnosis

1.4.2.2 To determine the proportion of negatively confirmed malaria cases prescribed with anti-malarial in the study areas.

1.4.2.3 To determine proportion of cases treated relying upon clinical diagnosed malaria cases

1.4.2.4 To assess the ability of laboratory to diagnose malaria

1.4.2.5 To determine factors that influence laboratory diagnosis of malaria

CHAPTER TWO

2.0 LITERATURE REVIEW

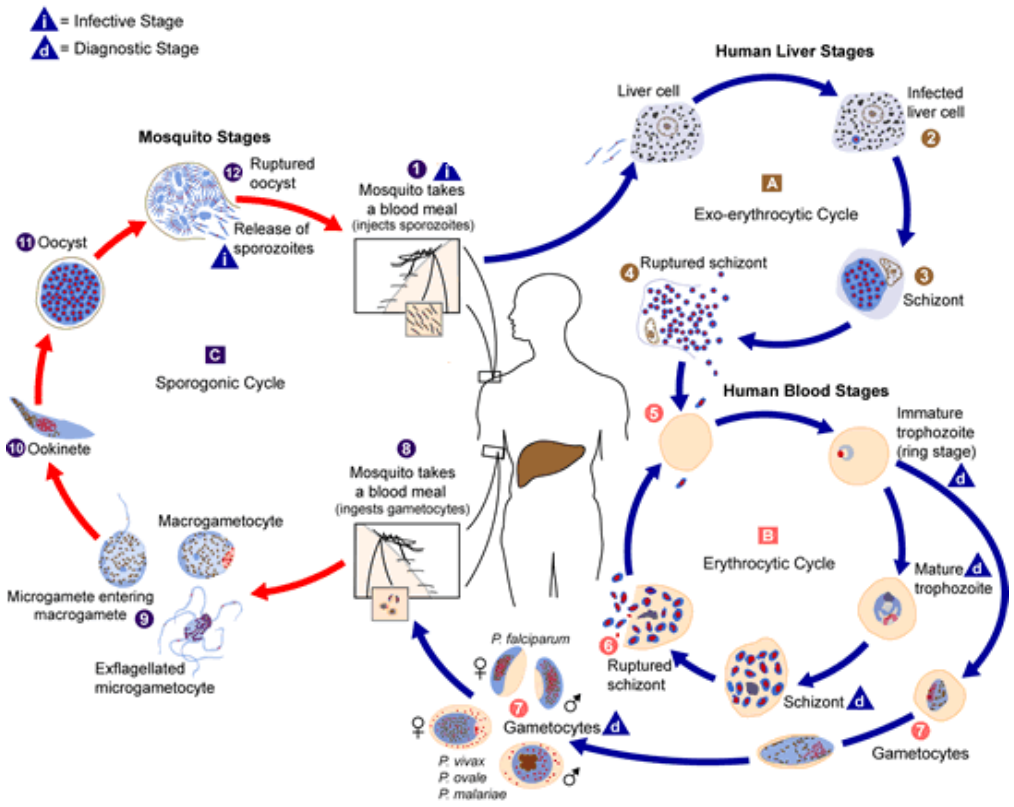
2.1. MALARIA

Malaria is a mosquito-borne infectious disease, caused by any of four species of intraerythrocytic protozoa of the genus Plasmodium (i.e., *P. vivax*, causing *vivax* or benign tertian malaria; *P.ovale*, found mainly in central Africa that causes *ovale* malaria. *P. malariae*, which causes malariae or quartan malaria and *P. falciparum*, the causative organism of falciparum or malignant tertian malaria). These parasites are transmitted by the bite of infective female Anopheles specie of Mosquito. It parasitizes human liver cells and red blood cells. *P. falciparum* is highly pathogenic and accounts for 80% of all malaria infections and 90% of all malaria deaths also associated with cerebral malaria [(32)]. *P. knowlesi* is a zoonosis and causes malaria in Macaques and man [(33)]. Malaria or a disease resembling malaria has been noted for more than 4,000 years, in 2700 BC, several characteristic symptoms of what would later be named malaria were described in the *Nei Ching*. On 6th November 1880, french army surgeon Charles Louis Alphonse Laveran, described malaria parasite in human blood and Camillo Golgi, an Italian neurophysiologist, established that there were at least two forms of the disease, one with tertian periodicity (fever every other day) and one with quartan periodicity (fever every third day). Thereafter, Giovanni Batista Grassi and Raimondo Filetti first introduced the names *Plasmodium vivax* and *P. malariae* for two of the malaria parasites that affect humans in 1890.

2.2 TRANSMISSION OF MALARIA

Female Anopheles mosquito carrying malaria-causing parasites feeds on a human and injects the parasites in the form of sporozoites present in its saliva into the bloodstream. The sporozoites travel to the liver possibly carried by kupfer cells and invade liver cells (Figure 1)

Figure 1: MALARIA LIFE CYCLE



Source: CDC

2.3 PROGRESSION WITHIN HUMAN BODY (SCHIZOGONY CYCLE)

Following mosquito blood meal, sporozoites from the mosquito saliva are transferred to either the blood or the lymphatic system of the recipient [(22)]. Migrate to the liver where they invade liver cells in the stage named as pre-erythrocytic cycle. Over 5-16 days, sack like structure is formed in which the sporozoites grow, divide, and produce tens of thousands of haploid forms, called merozoites, per liver cell (Chizonty). Some malaria parasite species remain dormant for extended periods in the liver (Hapnozoite stage), causing relapses weeks or months later. They mature into liver schizonts containing many merozoites and upon rapture releases the merozoites into blood capillaries to establish erythrocytic cycle. Some of the merozoites lodge in the pulmonary capillaries and slowly disintegrate over 48–72 hours releasing merozoites. In the erythrocytes, ring shaped forms are formed from the merozoites and mature to larger

trophozoite form. Erythrocytic schizogony stage results to production of new merozoites. Some of the merozoite lodged in blood cells leave the cycle of asexual multiplication. Instead of replicating, the merozoites in these cells develop into sexual forms of the parasite, called male and female gametocytes (Micro and Macrogametocytes respectively) [(34)]. The parasite feeds by ingesting haemoglobin and other materials from red blood cells releasing malaria pigment (Hemozoin). This multiplication can result in thousands of parasite-infected cells in the host bloodstream, leading to illness and complications of malaria that can last for months if not treated.

2.4 DIAGNOSIS OF MALARIA

2.4.1 Clinical Diagnosis

Is based on symptomatic manifestation or/ and physical examination of the patient to detect the disease as per the established case definition. Areas that cannot afford laboratory diagnostic tests use a history or presence of fever above 37.5^{0C} as an indicator of malaria with other associated symptoms like vomiting, headache, generalised malaise and joint pains. Others include eye/nail pallor and enlarged spleen.

2.4.2 Laboratory Based Diagnosis

Microscopic examination is frequently used and currently non-microscopic tests are also done for diagnosis of parasites or antigen in blood or histological tissues. Different species, forms and stages of either erythrocytic or pre-erythrocytic schizogony, antigenic components or products in the blood samples are demonstrated.

2.4.2.1 Malaria Microscopy**.**

Microscopy is the most widely used approach to confirm malaria diagnosis. It gives a comprehensive characteristic of a parasite and has always been regarded as a gold standard for malaria diagnosis. Effectiveness in its use requires an organized health system infrastructure with functioning microscopes used by trained technicians with regular provision of reagents, supervision, and quality control [(8)] Peripheral blood smear examinations, usually thin and thick films subjected to standardized Romanosky staining are used as gold standards in case management and epidemiological studies both analytical and research. Parasite density is

quantified to determine the severity of infection and malaria species are differentiated, other techniques used includes: Field staining, Acridine orange, Buffy Coat. It is sensitive, inexpensive and easy to perform, enhanced by competence of the well trained microscopist, a fine microscope and a well regulated quality assurance system. Thin films is used for species identification whereas thick blood films is more sensitive since larger blood volume is screened but distorts the appearance of the parasite, therefore not good for species characterisation [(35)]. Both thick and thin smears should be used irrespective of their odds for better microscopy.

It has been difficult to maintain good quality microscopy especially at the periphery health services, where most patients are treated in spite of the fact that the importance of light microscopy is well recognized. The current limitations of malaria microscopy include; training, supervision, reliable reagents, light source (electricity), functioning microscope, technician, time consuming and need extreme resources. Reliability of results depends on an individuals' competence and therefore most clinicians ignore laboratory confirmed blood smear results and treat clinically. Precise and reproducible parasite counts are not easy to achieve, because of intrinsic practical and human discrepancy. Inaccurate parasite density estimation may have adverse clinical and therapeutic implications for patients. Accurate interpretation of malaria smears remains problematic in many established clinical laboratories, especially those outside major referral centers. [(36)]

2.4.2.2 Immuno-Chromatography Tests.

These are also referred to as antigen detection malaria test, antigen-capture assay, dipsticks tests or rapid diagnostic tests. Antigens detected are *P. falciparum* glutamate dehydrogenase histidine rich protein 2, *P. falciparum* lactate dehydrogenase antigen and plasmodium aldolase. mRDTs are expensive compared to blood smear, but easy to use and do not need high expertise and electricity [(37)].

The mRDTs are qualitative non microscopic tests which use monoclonal or polyclonal antibodies against the parasite antigen. They are useful where there are no microscopes or experienced microscopist [(38, 39)].

The Rapid Diagnostic Tests are sensitive and easy to perform and interpret, do not require electricity or special equipment or highly qualified personnel to perform [40]. Test procedure takes between 15-20 minutes, and the results are interpreted basing on the formation or absence of coloured stripes. During the glycolytic pathway, the enzyme is expressed and is essential for generation of ATP. Histidine-rich protein 2 of *P. falciparum* (*Pf*HRP2) is a water soluble protein. It is produced by trophozoites and gametocytes of P. falciparum, attached on the surface of the red cell membrane. It can be expressed in blood at least three weeks after commencement antimalarial treatment. Plasmodium aldolase is an enzyme expressed during the glycolytic pathway and is produced by both asexual and sexual stages of the Plasmodium falciparum. Pan-specific aldolase is an antigen common to all four species of human malaria. Parasite lactate dehydrogenase (pLDH) is a soluble glycolytic enzyme produced by the asexual and sexual stages of 4 plasmodium species. It is released from the red blood cell infected with parasites. Both quantitative and qualitative analysis can be done. mRDT examples are; Quantitative immune-capture assay, a qualitative immune-chromatographic dipstick assay using monoclonal antibodies and an immunodot. pLDH are specific to P. falciparum, and P. vivax. The weakness with mRDT is the failure to monitor resistance and or its false positive results especially in endemic areas.

2.4.2.3 Molecular Methods

These methods are expensive and only available in advanced laboratories most in referral hospitals and few regional referral hospitals, mainly for research purposes but not in clinical laboratories. Molecular methods have a higher sensitivity and specificity by their ability to detect low levels of parasitemia [41].

Real causes of fever can be determined and specific anti malarial medication provided and thus limits chances of drug resistance from over diagnosis. Examples are; QT-NASBA based on the polymerase chain reaction [42]. PCR are more accurate than microscopy and requires specialised laboratory, equipment and highly skilled personnel. Molecular methods are highly sensitive, specific and use genus or species-specific sequences of 18S subunit rRNA gene.

Whole blood is collected in anticoagulant or dry blood spot on filter paper 20 µl and DNA extracted with 1% of extracted DNA volume used in PCR reaction.

CHAPTER THREE

3.0 METHODS

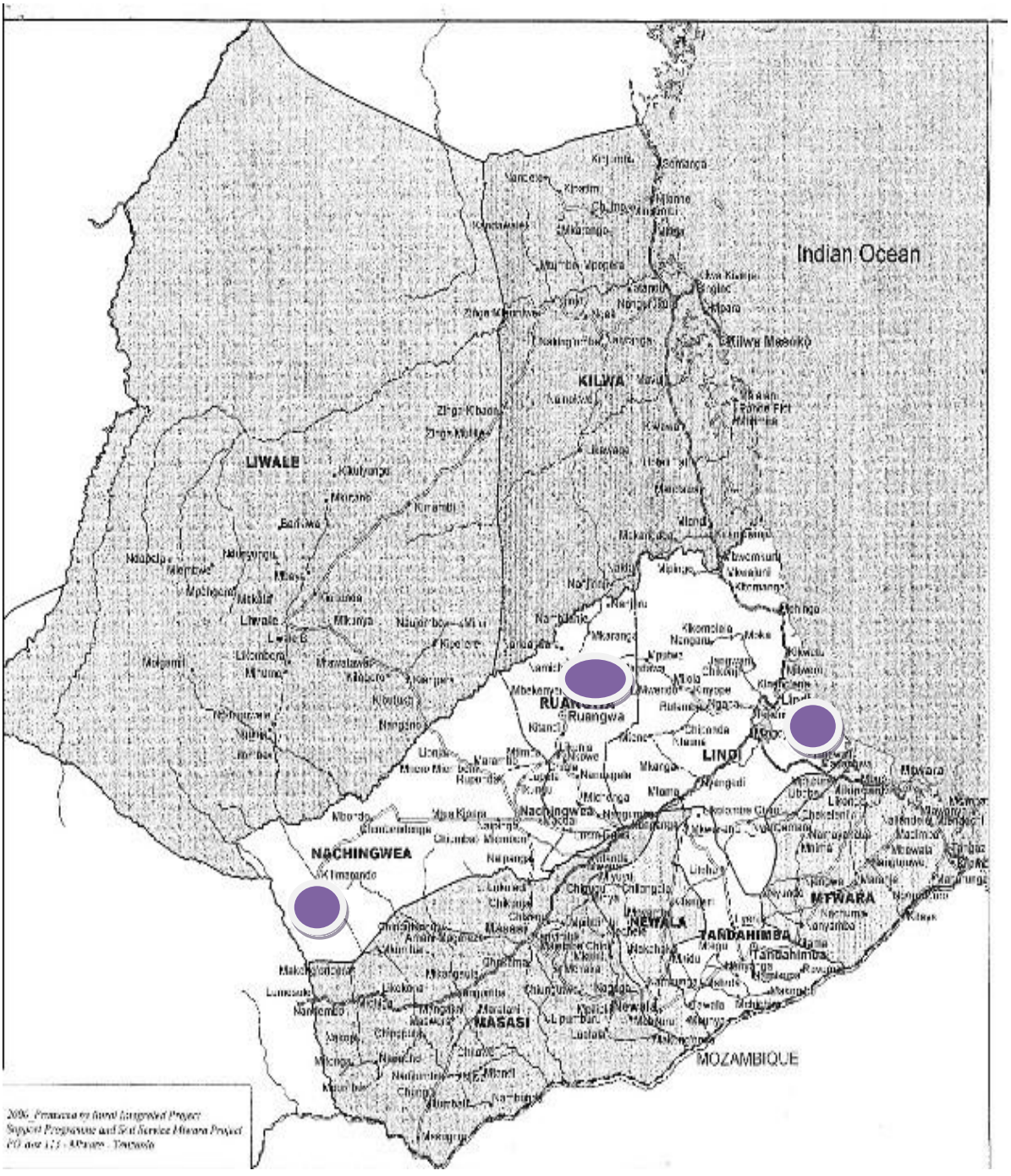
3.1 Study Area

The study was conducted in Lindi Region. The Region is located in the South-east of Tanzania bordered with the Indian Ocean on the East, Coast Region on the North, South is Mtwara Region and in the West is Ruvuma and Morogoro Regions. It lays South of Equator between latitudes 7.55 and 10 south, longitudes 36.51 and 40 East.

The Region has a total area of 67,000 sq. km of which 18,000 sq. km. (27%) is in the famous Selous Game Reserve in Liwale District. The Region's area constitutes 7.1% of Tanzania mainland making it the fourth largest Region in the Country. Administratively, the Region is divided into five Districts with six Councils, namely Lindi Municipal, Kilwa, Nachingwea, Ruangwa, Liwale and Lindi District Council. The total population by 2010 was 919,645. There are 5 District hospitals and 1 Regional referral hospital, of which 3 hospitals were sampled by rotary method for this study (Sokoine- Regional referral Hospital, Ruangwa and Nachingwea District hospitals)

Lindi region is among the leading regions with high reported malaria prevalence, others are Kagera, Mtwara, Mwanza and Dar-Es-Salaam. Lindi was selected by rotary

MAP OF LINDI REGION



= Locations in which the study was conducted

3.2 Study Design

A Cross sectional quantitative study was carried out in 3 hospitals in Lindi Region (Sokoine-Regional referral Hospital, Ruangwa and Nachingwea District hospitals). Conducted during the period of October to December, 2012.

3.3 Study Population

3.3.1 Patients who were referred to the laboratory for malaria blood test in the period of October to December 2012

3.3.1.1 Inclusion criteria; all malaria suspected patients referred to the laboratory and willing to take part in the study.

3.3.1.2 Exclusion criteria; all malaria suspected patients referred to the laboratory and willing to take part in the study but had taken anti-malaria within 72hrs of symptoms onset

3.3.2 Health workers attending malaria patients; all laboratory personnel and 50 % of Clinicians

3.4 Sample Size

Taking the prevalence of malaria in Lindi (48%) and assuming absolute precision of 5% and 95% Confidence Interval, the minimum sample size was calculated by the formula

$$n = \frac{z^2 * p(100-p)}{\varepsilon^2}$$

Where:-

n= sample size of the study

z = z score at standard normal deviation of 95% (z=1.96)

p = prevalence of HIV to children

ε = margin of error

$$n = 1.96^2 * \frac{48(100-48)}{5^2} \quad ; \quad n = 3.8416 * \frac{48\,(52)}{25} = 383$$

The Minimum Sample size was calculated to be 383 patients, 25% (96) added to cover for non respondent and incomplete filled forms, making a total sample size of 479 (2 Thick blood smears were collected from each patient).

3.5 Sample Collection

Two thick blood smears were collected from capillary blood from middle finger for patients above two years of age and heal of the foot in infants below 2 years of age. Sample were stained, examined at the study hospital laboratories and the second smear were examined at Ifakara malaria research institute Laboratory in Bagamoyo

3.6 Sampling Method

After determining the samples size i determine the uptake of laboratory in regarding to malaria diagnosis. I reviewed laboratory records at the three hospitals that were involved in this study and determine number of suspected malaria patients between January-December 2011 as follows

- Sokoine hospital 15072 (42.4%) patients,
- Ruangwa 5124 (14.4%)
- Nachingwea 15366 (43.2%)
- Total number from 3 hospitals 35562.

In order to allocate how many to consider from each health facility probability proportion to size was used as shown below.

Total number of Suspected case = Z

Sample size = S

Number of malaria suspect per facility = K

Sample size per each facility = N

$$N = \frac{K*S}{Z}$$

Lindi Sokoine hospital 15072*479/35563 = 203

Ruangwa 5124*479/35563 = 69

Nachingwea 15366*479/35563 = 207

In order to identify study respondent who participated in the study, simple random sampling technique was used. The random number was generated using open Epi software Consented

patients were included irrespective of age or race. Guardians consented on behalf of the children under the age of 18 years they have accompanied.

Systematic random sampling was employed to select 50% of Clinicians, sample frame was obtained from medical officer in charges of the respective hospital, sampling interval determined, the beginning point was selected by rotary and hence sample size were obtained. Seventeen (100%) laboratory personnel were recruited.

3.7 Data Collection and Management

3.7.1 Data Collection

Adhering to safety precautions, two thick blood smears were collected from 479 patients referred to the laboratory for malaria test by disinfecting the finger using70% methylated spirit, pricked by blood lancet to obtain a blood drop. The first drop wiped off to remove interstitial fluid and the consecutive drops put centrally on two slides and spread evenly using the edge of another microscope slide at an area of about 2Cm diameter. The blood slide is labeled and smear is left to dry. A set of smears were locally stained using field staining technique (Blood smear immersed three times in fied stain A, washed with water, dip in field stain B, washed in clean water, left to dry and examined using oil immersion objective lens at the study sites, while the second blood smear was examined at Ifakara research institute Laboratory in Bagamoyo. Laboratory practice was examined to ascertain adherent to the set standard operating procedures. Quality of smear, drying and microscopy practices were observed.

General laboratory quality assessment was conducted using checklist customized from WHO to establish laboratory strengths' and gaps which could compromise quality of malaria diagnosis. Documentation on laboratory results, patients' prescription and validation of blood slide smears results for both negative and positive slides. Demographics information of the patients' age, gender, reasons for requesting blood smear test, time of reporting to the laboratory and dispatch of malaria laboratory results was recorded. Malaria management data from the previous year (2011) was reviewed to establish rate of negative patients prescribed antimalarial relying on clinical bases. Proficiency test was conducted to laboratory personnel

and clinicians using self administered questionnaire. Pretesting of data collecting tools was done in a hospital setting to check the validity of tools to be used in the study.

3.6.2 Data sources

I reviewed Laboratory results, laboratory assessment reports, 2011 laboratory data review and patients' record review, treatment administered as well as interview of patients. Variables studied including number of patients tested for malaria, number for those tested positive as well as number of patients received antimalaria in relation to laboratory results, Chi square were calculated to determine the inference of the results

3.7 Ethical Considerations and Consent

Ethical clearance was obtained from the Senate Research and Publications Committee of Muhimbili University of Health and Allied Sciences, Dar-es-Salaam. This work involved patients, laboratory technicians and clinicians; there was no harm done. Concerted patient' sample were collected adhering to good laboratory practices. This work did not involve anything extra. Study number and not names was used instead to ensure confidentiality

CHAPTER FOUR

4.1 RESULTS

During the study period a total of 479 patients, 28 clinicians and 17 laboratory personnel were recruited. Mean age of the patients was 25 years with a standards deviation of 23 years. The median age was 20 years with youngest patient being1 month while the oldest patient was 87 years. Female contributed 60.1%.

Of the 479 patients who were enrolled, age group 16-30 years contributed 103 (21.5%) while less than 1 year contributing to 60 (12.5%). As shown in Table 1.

Table 1A: Socio demographic characteristic of patient by gender, Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012. (n-479)

Socio demographic characteristic	Number	Percentage (95% CI)
Gender		
Male	191	39.9 (35.5-44.4)
Female	288	60.1(55.0-64.5)
Age Group		
Less than 1Yr	60	12.5 (9.8-15.9)
1-5	93	19.4 (16.0-23.3)
6-15	50	10.4 (7.9-13.6)
16-30	103	21.5 (18.0-25.5)
31-50	89	18.6 (15.3-22.4)
Above 50	84	17.5 (14.3-21.3)

Based to education level, the predominating group was those having primary education 189 (39.5%) while participants having tertiary education contributing the lowest 19 (4%) number of participants. Among recruited patients, 188 (39.2%) participants had informal employment. Table 1B summarize the findings

Table 1B: Level of education and occupation of patient, Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012. (n-479)

Socio demographic characteristic	Number	Percentage (95% CI)
Level of Education		
Under School age	165	34.4 (30.2-38.9)
Primary Education	189	39.5 (35.1-44.0)
Secondary Education	62	12.9 (10.16.4)
Tertiary Education	19	4 (2.5-6.2)
No education	44	9.2 (6.8-12.2)
Occupation		
Child	162	33.8 (29.6-38.3)
Student	69	14.4 (11.4-17.9)
Formal employment	60	12.5 (9.8-15.9)
Informal employment	188	39.2 (34.9-43.8)

Laboratory personnel

The mean age of Laboratory personnel who were recruited was 41 years, standard deviation was 10.4. The median age was 41 year with youngest being 25 years while the oldest laboratory personnel were 60 Years. Males contributed to 88.2% while 35.3% of the study respondents were aged between 41-50 years. Among recruited laboratory personnel, 12 (70.6%) had an ordinary level education, 3 (17.6%) 'A 'Level secondary education, while 9 (11.8%) had standard seven education (table 2A)

Table 2A: Socio demographic characteristic of Laboratory personnel, Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012. (n-17)

Socio Demographic Characteristic		Number	Percentage (95% CI)
Gender			
	Male	15	88.2 (63.6-98.5)
	Female	2	11.8 (1.5-36.4)
Age Group			
	20-30Yrs	3	17.6 (3.8-43.4)
	31-40Yrs	5	29.4 (10.3-56.0)
	41-50Yrs	6	35.3 (14.2-61.7)
	51-60Yrs	3	17.6 (3.8-43.4)
Education			
	STD VII	2	11.8 (1.5-36.4)
	Form IV	12	70.6 (44.0-89.7)
	Form VI	3	17.6 (3.8-43.4)

Among 28 laboratory personnel recruited in this study, laboratory technicians (Diploma in Laboratory Science) contributed to 58.8% while 5 (29.4%) and 2 (11.8%) were Laboratory Assistants and laboratory Attendants respectively. Fifty two percent of the respondent reported to have never had any form of continue education in the field of malaria since employment. Laboratory personnel working experience was detrmined and it was observed that; 5(29.4%) recruited in this study had less than 1 years working experience, 3(17.7%) had working experience of more than 20 years as presented in table 2B

Table 2B: Professional, Malaria training and work experience among Laboratory personnel, Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012. (n-17)

Socio demographic characteristic	Number	Percentage (95% CI)
Professional level		
Lab Attendant	2	11.8 (1.5-36.4)
lab Assistant	5	29.4 (10.3-56.0)
Lab Tech	10	58.8 (32.9-81.6)
Duration post Malaria Training		
None	9	52.9 (27.8-77)
Less than 1Yr	5	29.4 (10.3-56)
2Yrs	1	5.9 (0.1-28.7)
3Yrs	1	5.9 (0.1-28.7)
Above 3Yrs	1	5.9 (0.1-28.7)
Work experience		
Less than 1Yr	5	29.4 (11.0-58.7)
1-5Yrs	2	11.7 (1.6-38.3)
6-10Yrs	4	23.5 (6.0-47.9)
11-20Yrs	3	17.7 (4.0-45.6)
Above 20Yrs	3	17.7 (4.0-45.6)

Clinicians

Mean age for Clinicians recruited in this study was 38 years, standard deviation 10.5 years. The median age was 36 years with the youngest being 25 year while the oldest were 53 Years. Female contributing to 57.1% sixteen (57.1%) clinicians had professional level of Assistant Medical Officer, as it is shown in Table 3A.

Table 3A: Socio demographic characteristic of Clinician. Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012 . (n-28)

Socio demographic characteristic		Number	Percentage (95% CI)
Gender			
	Male	12	42.9 (24.9-62.8)
	Female	16	57.1 (37.2-75.5)
Age Group			
	20-30Yrs	10	35.7 (18.6-55.9)
	31-40Yrs	5	17.9 (6.1-36.9)
	41-50Yrs	9	32.1 (15.9-52.4)
	51-60Yrs	4	14.3 (4.0-32.7)
Education			
	Form IV	16	57.1 (37.2-75.5)
	Form VI	12	42.9 (24.5-62.8)
Professional level			
	Clinical Officer	11	39.3 (21.5-59.4)
	AMO	16	57.1 (37.2-75.5)
	Specialist	1	3.6 (0.1-18.3)

Of the 28 clinicians, 15 (53.6%) were trained on IMCI, however 11 (39.3%) clinicians had no continuing education specific on malaria management since their employment also more than 50% of clinicians had working experience of more than 6 years as it is presented in table 3B

Table 3B: Training and Working experience of Clinician. Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012. (n-28)

Socio demographic characteristic	Number	Percentage (95% CI)
Work experience		
Less than 1 Years	5	17.9 (6.1-36.9)
2-5 Years	7	25 (10.7-44.9)
6-10 Years	6	21.4 (8.3-41.0)
11-20 Years	6	21.4 (8.3-41.0)
More than20 Years	4	14.3 (4.0-32.7)
Trained on Integrated Management of Childhood Illness (IMCI)		
Yes	15	53.6 (33.9-72.5)
No	13	46.4 (27.5-66.1)
On job Training on Malaria Management		
No Training	11	39.3 (21.5-59.4)
Less than 1 Year	5	17.9 (6.1-36.9)
1-2 Years	4	14.3 (4.0-32.7)
3-5 Years	1	3.6 (0.1-18.3)
More than 5 Years	7	25 (10.7-44.9)

Quality and practice of laboratory personnel to the laboratory results produced were determined; twelve (70.6%) participants interviewed responded to be producing accurate, reliable malaria laboratory test results. Of the 17 laboratory personnel interviewed, 10 (58.8%) reported not performing quality control on daily bases, Laboratory personnel 8 (47.1%) agreed that; health workers do not trust laboratory results, regardless of the method used for testing. Low skill was reported as the main source for poor Laboratory results by 53.8% of study respondents as it is summarized in table 4A.

Table 4A: Capacity of laboratory personnel on malaria diagnosi Sokoine, Ruangwa and Nachingwea Hospital – Lindi Region, October to December 2012. (n-17)

Factors		Number	Percentage [95% CI]
Perform QC in routine work			
	Yes	7	41.2 (18.4-67.1)
	No	10	58.8 (32.9-81.6)
Trust of lab Malaria results by other H/Workers			
	Yes	8	47.1 (23.0-72.2)
	No	8	47.1 (23.0-72.2)
	I don't know	1	5.9 (0.1-28.7)
Reasons for poor lab results			
	Low Skills	7	53.8 (25.1-80.8)
	Negligence	1	7.7 (0.2-36.0)
	Poor reagent available	5	38.5 (13.9-68.4)
Result reliability			
	Reliable	12	70.6 (44.0-89.7)
	Not reliable	2	11.8 (1.5-36.4)
	I don't know	3	17.6 (3.8-43.4)

Quality of laboratory supplies was determined, only 2 (11.8%) mentioned to be using new microscope slides in malaria microscopy, mentioning Unavailability of new microscope slides were mentioned by 70.6% of the laboratory personnel as the reason for reusing microscope slides. On the other hand, more than 50% of laboratory personnel were fulfilled with stain used in terms of skills and output. (Table 4 B)

Table 4B: Availability of supplies for malaria diagnosis Sokoine, Ruangwa and Nachingwea Hospital – Lindi Region, October to December 2012. (n-17)

Factors		Number	Percentage [95% CI]
Satisfaction with reagent used			
	Yes	9	52.9 (27.8-77.0)
	No	8	47.1 (23.0-72.2)
Type of Microscope slides used			
	Always new	2	11.8 (1.5-36.4)
	Old and new	15	88.2 (63.6-98.5)
Reasons for reusing Microscope slides			
	Not always available	15	70.6 (56.6-96.2)
	No reason	3	17.6 (3.8-43.4)

The performance of laboratory personnel on smear microscopy in the study hospitals was assessed, the sensitivity was found to be 70% and Specificity of 92%, as shown in table 5

Table 5: Performance of smear microscopy from Sokoine, Ruangwa and Nachingwea Hospitals lindi Region laboratories as compared to reference laboratory, October to December 2012: (n-479)

		Reference Lab results		
		Positive	Negative	Total
Lindi results	Positive	14	28	42
	Negative	6	431	437
	Total	20	459	479

PPV 33.3%, NPV 70%

Sensitivity = 70% Specificity 92%

In average, a clinician can attend 14 malaria patients a day with SDev of 4.8 patients, Median 15, Range 6-27. Malaria laboratory results was said to be inaccurate to 11(39.3%) clinicians, low skills to laboratory personnel (36.4%) and inaccuracy (36.4%) of test method, mRDT in particular; were reasons for poor laboratory results.

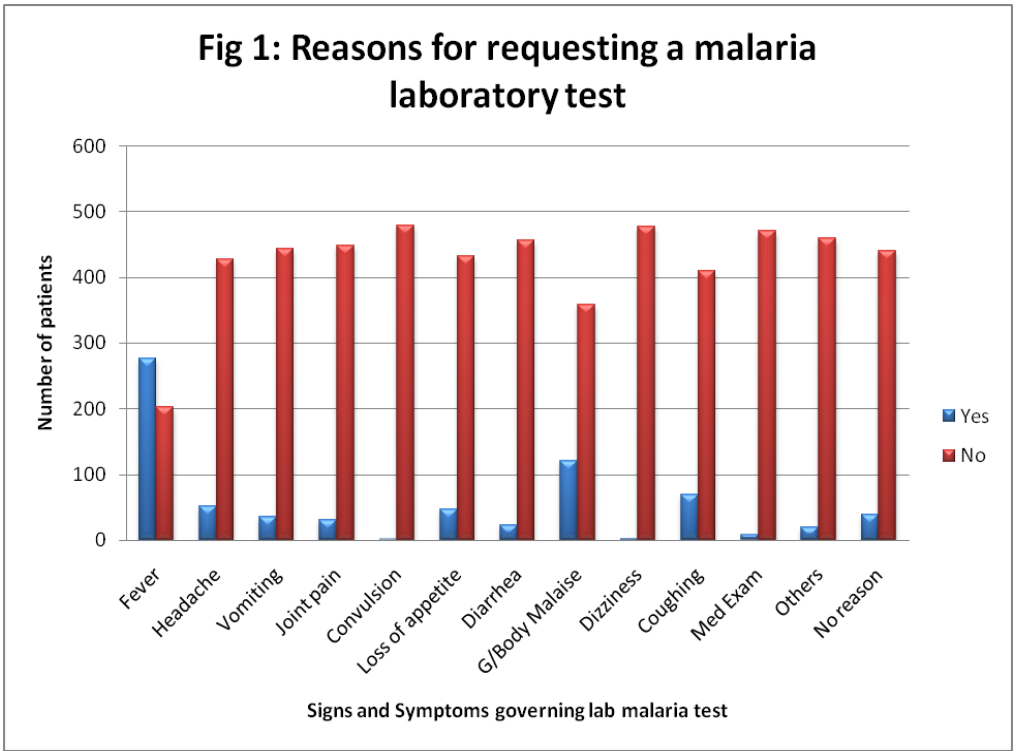
Reasons for not respecting mRDT results were mentioned to be inaccurate (39.3%) in relation to patient clinical presentation, also 17 (60.7%) of the clinicians responded to be trusting laboratory results as being the golden standard in malaria management; Table 6

Table 6: Capacity of clinicians in malaria management - Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012 (n-28)

Factors	Number	Percentage [95% CI]
Trust on Malaria lab test results		
Yes	17	60.7 (40.6-78.5)
No	11	39.3 (21.5-59.4)
Reasons for not trusting lab malaria test results (n-11)		
Low skills to Lab personnel	4	36.4 (10.9-69.2)
MRDT inaccurate	4	36.4 (10.9-69.2)
Overloaded laboratory	3	27.3 (6.0-61.0)
Ranking of MRDT in comparison with BS		
Best	8	26.8 (13.2-48.7)
No difference	4	14.3 (4.0-32.7)
poor	16	57.1 (37.2-75.5)
Reasons for accepting MRDT or not		
Need Little skills	3	10.7 (2.3-28.2)
Quick	6	21.4 (8.3-41.0)
False positive to treated patients	1	3.6 (0.1-18.3)
No quantification	5	17.9 (6.1-36.9)
Not accurate	11	39.3 (21.5-59.4)
Others	2	7.1 (0.9-23.5)

Factors governing laboratory test request were determined during interview with clinicians recruited in the current study. Fever was ranked higher (57.8%) governing test request among clinicians attending malaria patients as it is summarized in Figure 2.

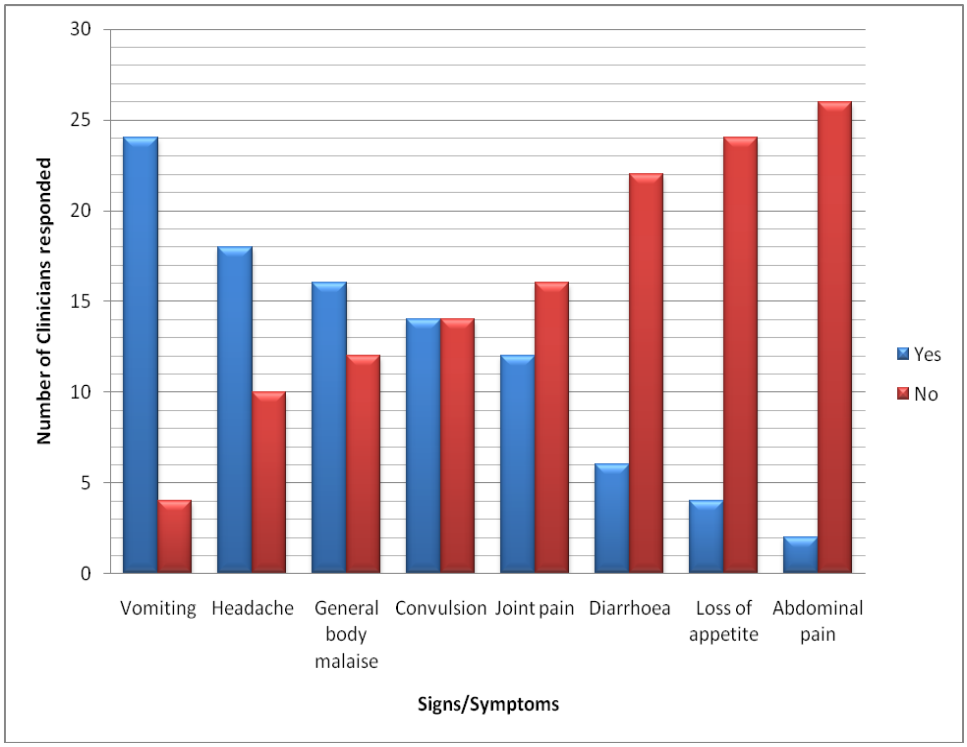
Figure 2: Reasons for Requesting a Malaria Laboratory Test Sokoine, Ruangwa and Nachingwea Hospital – Lindi region, October to December 2012 (n-479)



Of the 28 clinicians who were interviewed, 24 (85.7%) and 18 (64.3%) reported being governed by Vomiting and headache respectively as their cardinal signs for prescribing antimalarial before testing. The criteria used do not conform to the WHO case definition which states that "***Clinical case definition:*** *Uncomplicated Malaria; Fever or history of fever associated with symptoms such as nausea, vomiting and diarrhoea, headache, back pain, chills, myalgia, where other infectious diseases have been excluded, while; Severe Malaria case definition states that; Fever and symptoms as for uncomplicated malaria but with*

associated signs such as disorientation, loss of consciousness, convulsions, severe anaemia, jaundice, haemoglobinuria, spontaneous bleeding, pulmonary oedema, shock" The findings are summarized in figure 3.

Figure 3: Signs and symptoms supporting malaria clinical diagnosis in Sokoine, Ruangwa and Nachingwea Hospitals lindi Region, October to December 2012. (n-28)



Among 479 test request forms reviewed; 22 (4.6%) were prescribed with antimalaria before test, of which, only 6 (27.3%) found to be having malaria by laboratory test. Similarly; 115 (26.3%) were given antimalaria even with negative malaria test results.

Of the 479 blood samples which were tested, 47 (9.8%) were processed and examined within 20 minutes after specimen collection, while 31 (6.5%) specimens were examined above 60 minutes (Normal TAT is 20-60 minutes) 83.7% of malaria test met the Turnaround Time as it is displayed in Table 7

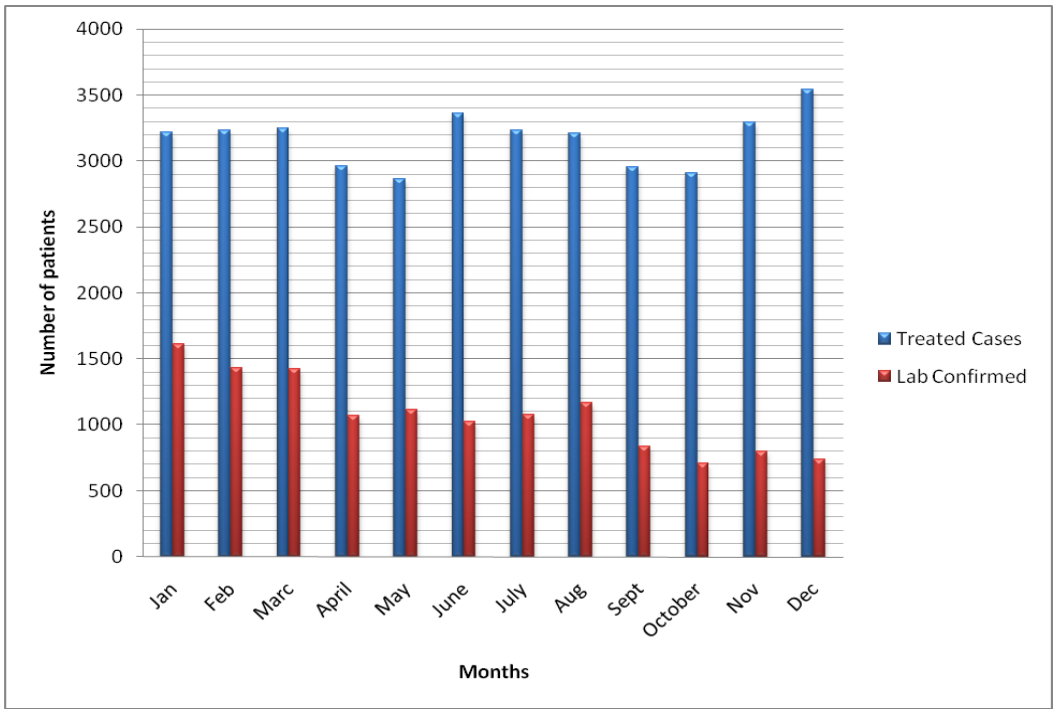
Table 7: Malaria patient management in relation to laboratory test in Sokoine, Ruangwa and Nachingwea Hospitals lindi Region, October to December 2012. (n-479)

Factors	Number	Percentage (95% CI)
Malaria test results		
Positive	42	8.8 (6.5-11.8)
Negative	437	91.2 (88.2-93.5)
Time taken from sample collection to result submission		
Less than 20 minutes	47	9.8 (7.4-12.9)
21-40 Minutes	313	65.3 (60.9-69.6)
41-60 Minutes	88	18.4 (15.1-22.2)
More than 60 minutes	31	6.5 (4.5-9.2)
Prescription of antimalaria before lab test		
Yes	22	4.6 (3.0-7.0)
No	457	95.4 (93.0-97.0)
Lab results among patients given antimalaria before test (n-22)		
Positive	6	27.3 (10.7-50.2)
Negative	16	72.7 (49.8-89.3)
Malaria test smear negative patient given antimalaria		
Yes	115	26.3 (22.3-30.8)
No	322	73.7 (69.2-77.7)

Of the 437 patients with smear negative, 112 (25.6%) were given antibiotic, 117 (26.8%) antipyretic, whereby 80 (18.3%) received both

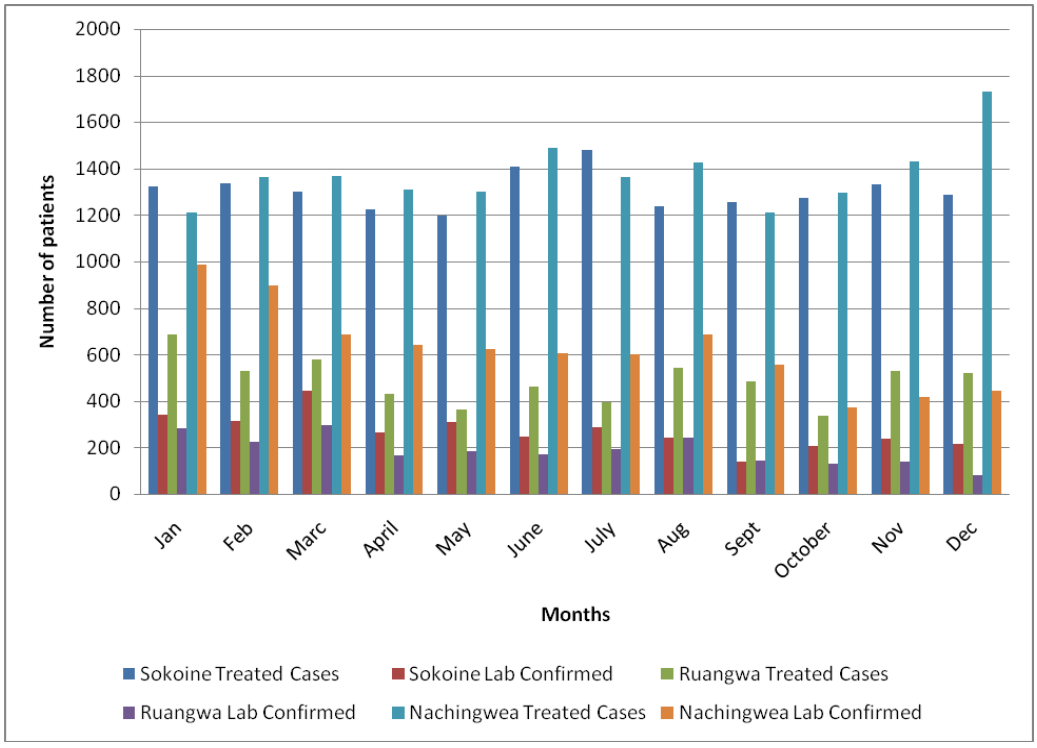
Among 38014 patients records that were attended as malaria patients for the year 2011, 25003 (65.7%) were treated basing on clinical diagnosis. With the highest being the month of January as it is shown in figure 4 A

Figure 4A: Malaria patients prescribed with antimalaria compared to laboratory confirmed cases in Lindi Region Hospitals, January to December 2011 (n-38014)



Number of patients treated on clinical bases were determine at each hospital involved in the study, Nachingwea in total found to have lower level of clinical diagnosis 54.4% compared to Sokoine hospital, which in 2011 had 79.3% of patients treated depending on clinical diagnosis despite of having laboratory services. It is generally observed that over 50% of patients are managed relying on clinical diagnosis. Laboratory has less support on patient management (Figure 4B)

Figure 4B: Malaria patients prescribed with antimalaria compared to laboratory confirmed cases in Sokoine, Ruangwa and Nachingwea Hospitals Lindi Region, January to December 2011, Analyzed per Health Facility (n-38014)



Factor influencing laboratory malaria diagnosis in Sokoine, Ruangwa and Nachingwea Hospitals lindi Region, October to December 2012

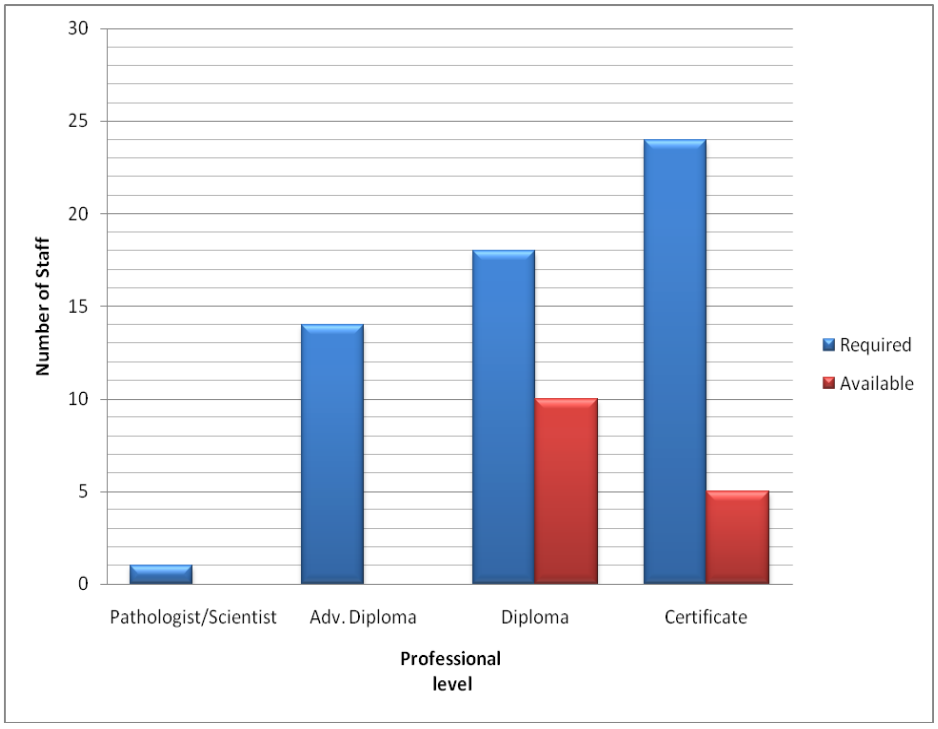
Several factors that influence the outcome of laboratory thick smear microscopy were assessed. Those Laboratory technologists who stained their smears correctly were more likely to have given the correct results (OR 3.1, P value 0.01, CI1.25-7.64) while those who prepared good smear were 1.7 times more likely to have given the correct results, but the association was not statistical significant (OR 1.7, P value 0.76, CI0.42-3.29. Correct smear microscopy was more likely to be reported by that technician who cleaned microscope before use (P value <0.001) OR 13.3 CI 4.1-43.9. Those who air dried blood smear after staining were 14.2 times more likely to have given the correct malaria microscopy results (P value <0.001) as it is shown in table 8.

Table 8: Laboratory practices influencing results in Sokoine, Ruangwa and Nachingwea Hospitals Lindi Region, October to December 2012 (n-479)

Factors		Correct Results		OR	95%CI	p Value
		Yes	No			
Good Stained blood Smear						
	Yes	11	130	3.1	1.25-7.64	0.01
	No	9	329			
Well prepared thick blood Smear						
	Yes	15	330	1.17	0.42-3.29	0.76
	No	5	129			
Well dried smear before staining						
	Yes	19	456	0.12	0.01-1.26	0.04
	No	1	3			
Drying of Smear after staining						
	Yes	9	25	14.2	5.3-37.42	<0.001
	No	11	434			
Cleaning of Microscope after every examination						
	Yes	5	11	13.3	4.1-43.9	<0.001
	No	15	448			

Based on the MoHSW Tanzania staff establishment, the three hospitals under study was supposed to have a total of 57 on the contrary, 17 (29.8%) including 2 non laboratory personnel who also perform smear microscopy were available at the studied hospitals. General laboratory technicians contributing to the large proportion 10 (58.8%) of the existing staff, as displayed in figure 5

Figure 5: Availability of qualified staff in Sokoine, Ruangwa and Nachingwea Hospitals Lindi Region, October to December 2012



CHAPTER FIVE

5.1 DISCUSSION

Timely and appropriate malaria diagnosis could be achieved by having adequate facilities, trained laboratory personnel and clinicians to provide standard services. Inefficient diagnostic practices are important obstacles in the management of the deadly disease; Malaria as it was also noted by study conducted in Zambia [43]

This study has shown that laboratory personnel (52%) was lacking continued training on malaria laboratory diagnosis and some were lacking professional qualifications, lack of training timetable is the evident. Most of the influencing factors for poor laboratory performance was also been reported in a study conducted in Tanzania **[44]**

Diagnosis of malaria using clinical presentation was evident in the current study. The practice is highly sensitive but with very low specificity leading to irrational use of antimalarial as it was also noted by the study conducted in Zambia and Tanzania **[45, 46, 47]** The evidenced malaria over diagnosis and hence irrational medication might lead to malaria drug resistance. as it was also reported by Ishengoma [48]

Quality control of laboratory test plays an important role in determining the outcome of the laboratory results. Studies and literatures have shown that quality control should appropriately recognize and accredit good performance **[49]**. In the current study, it was observed that, 7 (41.2%) of laboratory personnel perform regular laboratory quality check in their daily routine work. This is way below the required standard; lack of quality control system may result in inaccurate and untimely management of patient having results with a direct impact on the treatment given to a patient; lives lost, create unnecessary cost by presumptive treatment and delayed treatment, reducing personal productivity

Our study revealed that, of the samples that were examined, 16% could not meet the required TAT. This could be due to the ratio between laboratory personnel to patients or some of the laboratory technicians not adhering to standard operating procedure. The practice could

compromise the quality and accuracy of test results produced. Delay in the treatment of malaria cases as a result of delayed laboratory result may result in high case fatality [49]

This study has revealed that, good laboratory practices including use of clean microscope slides, smear preparation and proper staining influence correct laboratory results, in regards to malaria diagnosis. Poor smear preparation, use of unclean microscope can lead to false positive results, artifacts and other encountered debris in the stain can be easily confused

Tanzania and Lindi in particular is inadequately maintaining good laboratory diagnosis and hence leading to patient management relying on clinical diagnosis. In the current study the laboratory results were compared with that of reference laboratory and revealed that; Laboratory performance PPV was 33.3% and NPV was 94% with 70% and 92% sensitivity and specificity respectively. This means that most of the patients reported to have malaria parasites did not actually have the parasites. The reported relatively high malaria slide positivity rate coupled with the observed presumptive diagnosis practices indicates high level of malaria misdiagnosis in the study health facilities. Malaria control program under the MoHSW target to achieve a reduction of malaria from 25% in 2007 to 80% by 2013, however, without clear diagnosis and quality results from the laboratory the achievement will be met with difficulties

In the current study, only 8.8% among patients diagnosed to have malaria using clinical features were detected to have malaria parasites by smear microscopy. Likewise, only thirty two (11.6%) of the patient with fever had malaria positive by laboratory test, thus managing malaria depending on fever increases rate of over diagnosis and hence over reporting. This study revealed fall of malaria prevalence in the study area

Lack of criteria for requesting malaria test allow unnecessary request and hence overloading the inadequate number of available laboratory personnel leading to poor result provision. This study revealed acute shortage of skilled staff in the study area, only 17 (26.3%) of the required laboratory Technologist available. A study conducted in Tanzania[50] revealed that high workload, too few staff and infrequent or unequal opportunities for training is the stamping block towards quality of laboratory results

As we strive to achieve MDG and reducing malaria prevalence from 25% to 80% reduction, clinicians and laboratory technologist who are involved in diagnosing malaria cases should work as a team. It is noted in this study that; clinicians less often rely on laboratory results in malaria patient management despite of availability of laboratory facilities in the study areas, the findings concede with another study conducted in Tanzania [45, 48, 50]. Impact of clinical criteria for handling patients includes missed other febrile illnesses with similar presentations, lost person time seeking medical care and increase burden to health workers for the repeated seeking medical attention. The findings obtained might conclude the negative perception of clinicians towards the available methods of malaria diagnosis. The findings concede with other studies conducted in Zambia and Health laboratories in Tanga region of Tanzania [45, 48] which concluded that "perceptions and practice remains one of the major barriers to effective laboratory use" This means that most of patients suspected, treated and reported to have malaria, were actual having other missed febrile illnesses rather than malaria

5.2. CONCLUSION

This study shows that, the laboratories in the study site have inadequate capacities for malaria diagnosis and the quality of malaria diagnostic services is more likely to be compromised by inadequate trained and over-worked laboratory personnel. Though more than 50% of clinicians mentioned to trust laboratory results, but clinicians infrequently used test results for management of patients. The scenario is also confirmed by laboratory personnel who mentioned other health workers not trusting laboratory results. Clinicians do not trust laboratory malaria results obtained, and hence managing patients with febrile illness based on clinical diagnosis. The mistrust of the laboratory results lead into misdiagnosed other febrile illnesses (Viral and bacterial). Mismanagement of patients is evident. Laboratory practices and inadequate staffing in terms of number and qualification is identified to be the stamping block towards quality laboratory malaria results in the study area

5.3. RECOMMENDATION

Laboratory remains as the golden standard test for quality health service provision. To maintain quality, trained staff is of ultimate important. Recruitment of staff according to staff establishment, conduct regular on job training, provision of quality laboratory supplies and supervising laboratory personnel to practice according to level of qualification and or competence.

Training of all stakeholders when new method is introduced in the malaria management system could minimize mistrust of diagnostic methods. Policies governing rational prescription of antimalarial drugs should be strengthened. Malaria laboratory knowledge is an important tool in this location aiming at setting epidemiological study and hence management of the disease strategies.

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APPENDICES

Appendix Ia. Consent Form for Laboratorian

Title: To determine factors influencing laboratory diagnosis of malaria in lindi region hospitals

Foreword

My name is Theophil Malibiche. I am a researcher from Muhimbili University of Health and Allied Sciences. I am conducting a study on laboratory diagnosis of malaria in lindi hospitals

How to participate in this study

You are asked to participate in this study because you are one among Laboratory personnel routinely doing malaria microscopy. If you are willing to participate in this study, you will be interviewed several questions to aid in this study and you will be requested to examine and report stained blood smears taken from patients attending this laboratory. Put your results in a reporting sheet provided

Purpose of the study

The study will help to inform both health staff and policy maker to identify gaps and put strategies to improve malaria diagnosis and case management

Confidentiality

Any information will be treated confidentially and anonymously as no person links will be documented.

Risks

There is no risk will happen to you as a result of participating in the study

Taking part in this study is completely of your choice. You have the right to participate or decide otherwise without giving any reason for your decision. Once you have decided to participate you are also free to terminate your participation at any time.

Who to contact

If you have any questions about this study you are free to contact, the principal investigator, Mr. Theophil Malibiche [0754-623082].

If you have any questions concerning your rights as a participant you may contact Prof M. Aboud, Chairman of MUHAS Research and Publications Committee. P.O.BOX 65001 Dar es Salaam. Tel 2150302-6

If you agree to this interview, please sign this consent form.

I …… have read and understood the contents of this consent form and my questions have been sufficiently answered. I therefore consent for the participation in this study.

Signature of the interviewee …… Date ……

Signature of the interviewer ……..…… Date ……

KIAMBATANISHO IA: KISWAHILI

FOMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI YA MTAALAMU WA MAABARA

Kichwa cha utafiti
Uchunguzi wa upimaji wa malaria katika maabara za hospitali za mkoa wa Lindi

Utangulizi

Jina langu ni Theophil Malibiche mtafiti kutoka chuo Kikuu cha mafunzo ya afya cha Muhimbili. Ninafanya uchunguzi wa *upimaji wa malaria katika maabara za hospitali za mkoa wa Lindi*

Jinsi ya kushiriki katika utafiti huu

Unaombwa kushiriki katika utafiti huu kwa sababu wewe ni mmoja kati ya wataalamu wa maabara wanaochunguza vimelea vya malaria. Ukikubali kushiriki, utaulizwa maswali machache kuhusu ujuzi na uzoefu wako katika upimaji wa vimelea vya malaria na utapewa kipimo cha damu toka kwa wagonjwa wanaohudhuria hapa katika maabara yako. Majibu utakayopata utajaza katika fomu maalumu utakayopewa.

Dhumuni la utafiti

Utafiti huu utasaidia kugundua njia bora ya kufanya uchunguzi kwa usahii, taarifa itakayopatikana itasaidia watunga sera na watumishi wa afya kugundua na kutibu kwa uhakika ugonjwa huu wa malaria.

Usiri

Taarifa na utakazotoa, na mengineyo yote yatabakia kuwa siri na kutumika kwa ajili ya utafiti tu. Timu inayohusika na utafiti itatumia majibu yote kuandaa taarifa inayoonyesha hali halisi ya upimaji

Madhara

Sitarajii madhara yoyote kutokea kwako iwapo utashiriki katika utafiti huu

Haki ya kushiriki

Ushiriki wako katika utafiti huu si lazima. Una hiyari ya kukubali au kukataa bila kutoa sababu zozote za kufanya hivyo. Na ukikubali, unaweza kubadili uamuzi wako wakati wowote. Ukiwa na maswali yoyote kuhusu utafiti huu, uwe huru kuwasiliana nami, mtafiti mkuu, Theophil Malibiche [0754-623082]

Kama utakuwa na maswali kuhusu haki zako kama mshiriki, unaweza kumpigia Prof M. Aboud, ,Mwenyekiti wa kamati ya utafiti. Simu namba 2150302-6

Kama umekubali kuhojiwa, tafadhali saini hapa:

Mimi……., nimesoma na kuelewa kilichoelezwa kwenye fomu hii na maswali yangu yamejibiwa kiufasaha. Hivyo ninakubali kuhojiwa kwa ajili ya utafiti huu.

Sahihi ya mhojiwa …… Tarehe ……..

Sahihi ya mhojaji…… Tarehe……

Appendix IB. Consent Form for Clinicians

Title: To determine factors influencing laboratory diagnosis of malaria in lindi region hospitals

Foreword

My name is Theophil Malibiche. I am a researcher from Muhimbili University of Health and Allied Sciences. I am conducting a study on laboratory diagnosis of malaria in lindi hospitals

You are asked to participate in this study because you are one among clinicians diagnosing and managing malaria in this Hospital. If you are willing to participate in this study, you will be interviewed several questions to aid in this study. Your response will be put in a prepared data collection sheet.

Purpose of the study

The study will help to inform both health staff and policy maker to identify gaps and put strategies to improve malaria diagnosis and case management

Confidentiality

Any information will be treated confidentially and anonymously as no person links will be documented.

Risks

There is no risk will happen to you as a result of participating in the study

Taking part in this study is completely of your choice. You have the right to participate or decide otherwise without giving any reason for your decision. Once you have decided to participate you are also free to terminate your participation at any time.

Who to contact

If you have any questions about this study you are free to contact, the principal investigator, Mr. Theophil Malibiche [0754-623082].

If you have any questions concerning your rights as a participant you may contact Prof M. Aboud, Chairman of MUHAS Research and Publications Committee. P.O.BOX 65001 Dar es Salaam. Tel 2150302-6

If you agree to this interview, please sign this consent form.

I …… have read and understood the contents of this consent form and my questions have been sufficiently answered. I therefore consent for the interview for this study.

Signature of the interviewee……..... Date ……

Signature of the interviewer.....…….. Date ……

KIAMBATANISHO IB: KISWAHILI

FOMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI YA TABIBU

Kichwa cha utafiti;

Uchunguzi wa upimaji wa malaria katika maabara za hospitali za mkoa wa Lindi

Utangulizi

Jina langu ni Theophil Malibiche mtafiti kutoka chuo Kikuu cha mafunzo ya afya cha Muhimbili. Ninafanya uchunguzi wa *upimaji wa malaria katika maabara za hospitali za mkoa wa Lindi*

Jinsi ya kushiriki katika utafiti huu

Unaombwa kushiriki katika utafiti huu kwa sababu wewe ni mmoja kati ya madaktari/matabibu wanaowatibu wagonjwa wa malaria. Ukikubali kushiriki, utaulizwa maswali machache kuhusu ujuzi na uzoefu wako katika kutibu wagonjwa. Taarifa zako zitatunzwa katika fomu maalumu ya kukusanyia taarifa.

Dhumuni la utafiti

Utafiti huu utasaidia kugundua njia bora ya kufanya uchunguzi kwa usahii, taarifa itakayopatikana itasaidia watunga sera na watumishi wa afya kugundua na kutibu kwa uhakika ugonjwa huu wa malaria.

Usiri

Taarifa na utakazotoa, na mengineyo yote yatabakia kuwa siri na kutumika kwa ajili ya utafiti tu. Timu inayohusika na utafiti itatumia majibu yote kuandaa taarifa inayoonyesha hali halisi ya upimaji

Madhara

Sitarajii madhara yoyote kutokea kwako iwapo utashiriki katika utafiti huu

Haki ya kushiriki

Ushiriki wako katika utafiti huu si lazima. Una hiyari ya kukubali au kukataa bila kutoa sababu zozote za kufanya hivyo. Na ukikubali, unaweza kubadili uamuzi wako wakati wowote. Ukiwa na maswali yoyote kuhusu utafiti huu, uwe huru kuwasiliana nami, mtafiti mkuu, Theophil Malibiche [0754-623082]

Kama utakuwa na maswali kuhusu haki zako kama mshiriki, unaweza kumpigia Prof M. Aboud, ,Mwenyekiti wa kamati ya utafiti. Simu namba 2150302-6

Kama umekubali kuhojiwa, tafadhali saini hapa:

Mimi……., nimesoma na kuelewa kilichoelezwa kwenye fomu hii na maswali yangu yamejibiwa kiufasaha. Hivyo ninakubali kuhojiwa kwa ajili ya utafiti huu.

Sahihi ya mhojiwa …… Tarehe ……

Sahihi ya mhojaji…… Tarehe……

Appendix IC. Consent Form for Cases

Title: To determine factors influencing laboratory diagnosis of malaria in lindi region hospitals

Foreword

My name is Theophil Malibiche. I am a researcher from Muhimbili University of Health and Allied Sciences. I am conducting a study on laboratory diagnosis of malaria in lindi hospitals

You are asked to participate in this study because you are one/your child is among patients suspected to have malaria. If you are willing to participate in this study, you will be interviewed several questions to aid in this study and 2 more blood slides will be collected and examined by other method or sites.

Purpose of the study

The study will help to inform both health staff and policy maker to identify gaps and put strategies to improve malaria diagnosis and case management

Confidentiality

Any information will be treated confidentially and anonymously as no person links [name, patient Ids number] will be documented.

Risks

There is no risk will happen to you as a result of participating in the study

Taking part in this study is completely of your choice. You have the right to participate or decide otherwise without giving any reason for your decision. Once you have decided to participate you are also free to terminate your participation at any time.

Who to contact

If you have any questions about this study you are free to contact, the principal investigator, Mr. Theophil Malibiche [0754-623082].

If you have any questions concerning your rights as a participant you may contact Prof M. Aboud, Chairman of MUHAS Research and Publications Committee. P.O.BOX 65001 Dar es Salaam. Tel 2150302-6

If you agree to this interview, please sign this consent form.

I …… have read and understood the contents of this consent form and my questions have been sufficiently answered. I therefore consent for the interview for this study.

Signature of the interviewee …….……..... Date ……

Signature of the interviewer……...……. Date ……

KIAMBATANISHO IC: KISWAHILI

FOMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI YA MGONJWA

Kichwa cha utafiti: Uchunguzi wa upimaji wa malaria katika maabara za hospitali za mkoa wa Lindi

Utangulizi

Jina langu ni Theophil Malibiche mtafiti kutoka chuo Kikuu cha mafunzo ya afya cha Muhimbili. Ninafanya uchunguzi wa *upimaji wa malaria katika maabara za hospitali za mkoa wa Lindi*

Jinsi ya kushiriki katika utafiti huu

Unaombwa kushiriki katika utafiti huu kwa sababu wewe ni mmoja kati ya wagonjwa wanohitaji vipimo vya kuchunguza vimelea vya malaria. Ukikubali kushiriki, utaulizwa maswali machache yatakayosaidia katika utafiti huu. Pia, kipimo cha damu kitachukuliwa katika vioo 2 vya ziada kwa ajili ya kupima kwa njia na mahala pengine zaidi ya hapa.

Dhumuni la utafiti

Utafiti huu utasaidia kugundua njia bora ya kufanya uchunguzi kwa usahii, taarifa itakayopatikana itasaidia watunga sera na watumishi wa afya kugundua na kutibu kwa uhakika ugonjwa huu wa malaria.

Usiri

Taarifa na utakazotoa, na mengineyo yote yatabakia kuwa siri na kutumika kwa ajili ya utafiti tu. Timu inayohusika na utafiti itatumia majibu yote kuandaa taarifa inayoonyesha hali halisi ya upimaji

Madhara

Sitarajii madhara yoyote kutokea kwako iwapo utashiriki katika utafiti huu

Haki ya kushiriki

Ushiriki wako katika utafiti huu si lazima. Una hiyari ya kukubali au kukataa bila kutoa sababu zozote za kufanya hivyo. Na ukikubali, unaweza kubadili uamuzi wako wakati wowote. Ukiwa na maswali yoyote kuhusu utafiti huu, uwe huru kuwasiliana nami, mtafiti mkuu, Theophil Malibiche [0754-623082]

Kama utakuwa na maswali kuhusu haki zako kama mshiriki, unaweza kumpigia Prof M. Aboud, ,Mwenyekiti wa kamati ya utafiti. Simu namba 2150302-6

Kama umekubali kuhojiwa, tafadhali saini hapa:

Mimi……., nimesoma na kuelewa kilichoelezwa kwenye fomu hii na maswali yangu yamejibiwa kiufasaha. Hivyo ninakubali kuhojiwa kwa ajili ya utafiti huu.

Sahihi ya mhojiwa …… Tarehe ……..

Sahihi ya mhojaji…… Tarehe……

Appendix II: Individual patient data collection sheet

1. Study number _____
2. Name of the facility_____ Date_____
3. Demographics:

   Time in_____Time out_____

   Age_____Gender_____Location_____Occupation_____Education_____

   Mobile_____

4. **Reasons for requesting a test:** Fever □ Vomiting□ Diarrhoea □ Skin rash □

Medical examination □ Coughing □ Loss of appetite Patient request □ No reason given□

Joint pain□ G/body malaise □

Others □ specify. .....

5. **Treatment outcome (**Interviewer to verify the drug prescribed before blood smear)

5.1 Have you been prescribed with anti -malarial drug? 1 = Yes 2 = No ☐

5.2 Have you screened for malaria? 1 = Yes 2 = No ☐

5.3 If yes, what method was used 1= B/S, 2= RDT ☐

5.4 Blood smear local results 1: Positive 2: Negative ☐

(To be obtained at the drug dispensing point)

5.5 Anti Malaria prescribed post lab results 1 = Yes 2 = No ☐

5.6 Other drugs prescribed: Antibiotic □ Antipyretic □ Antihypertensive □ None □

5.7 Blood smear results from a reference laboratory 1: Positive 2: Negative ☐

Quality control of Laboratory examination

6.0 Pre-analytic Phase

6.1. How was the blood slide labelled? 1= Well labelled, 2= Not well labelled, Not labelled at all ☐

6.2. How was the blood smear dried? 1= Air dry, 2= Direct sun light, 3= oven, 4= others; Specify..... ☐

6.3. How is the quality of smear 1= Well prepared 2= Not Well prepared ☐

7.0. Analytical Phase

7.1. How is the blood smear quality of staining 1= Well stained, 2= Not well stained ☐

7.2. How was the blood smear dried after staining 1= Air dry, 2= Direct sun light, 3= oven, 4= others; Specify..... ☐

7.3. Is the microscope cleaned before examining blood smears? 1= Yes, 2= No ☐

Appendix III: Malaria Laboratory quality assessment questionnaire based on WHO checklist;

Facility Name_____Facility level _____Date__/___/____

Quality System Element		Yes	No	Investigators comments
Organization	Is there a quality manual present and accessible?			
	Does the site have a designated quality officer			
	Is the site manager aware of all quality system components?			
	Is there malaria continuing education schedule			
Personnel	Has the staff been oriented to the patient/client or samples flow at the laboratory?			
	Evidence of routine malaria training available			
	Is competence assessment testing practiced			
	Is the lab has adequate number of skilled			**Regional level**; 1

	staff as per staff establishment?			Pathologist, 5 Technologist, 8 Technicians, 8 Lab Assistant **District level;** 3 Technologist, 5 Technicians, 8 Lab assistants,
Documents and records	Are SOPs for all aspects of the testing process written, up-to-date, and accessible to staff?			
	Well documented patient results			
	Performing internal QC, records kept			
	Patient results verified by 2nd person?			
Equipments and Reagents	Standard reagent used			**Region;** Giemsa, MRDT. **District**; Giemsa, MRDT
	Giemsa stain available			
	Does Giemsa stain used?			

	Buffer pH 7.2 available			
	Is the reagent used kept in appropriate container [Judge according to type]			
	Is the laboratory involved in the procurement of reagents			
	Is there budget set aside for reagent procurement			
	Reagents well labeled			
	Schedule for maintenance available and followed			
	Is the working Microscope available for malaria? [verify]			
Process control [Specimen Management]	Is there a written procedure for collecting, processing and storing specimens?			
	Are specimens appropriately labeled [Cross check with their respective request forms]			
Quality control	Are internal quality control samples analyzed?			
	Are internal quality control results			

	reviewed and recorded?			
	Are external quality control samples analyzed?			
	Are external quality control results recorded and reviewed?			
	Is there evidence of reagent quality control available?			
	Is there evidence of regular meeting to discuss on quality issues?			
Occurrence management	Is there a written policy for investigating errors?			
	Is there communication mechanism with affected customers?			
	Are all errors, with any corrective action and communication, recorded?			
Assessment	Is there any laboratory performance assessment conducted?			
	If Yes, How often? Once/yr, twice/yr, No specific schedule			
	Have corrective actions been taken for previously identified problems?			
Total				

Appendix IVA. Laboratory Staff competence assessment questionnaire;

1.0 Demographic information

1.1 How old are you _____Yrs

1.2 For how long have you worked in this lab_____Yrs/Months

1.3When was your last malaria microscopy training_____[Mention Year, Month]

1.4 What is your level of education 1= STD VII, 2= Form IV, 3=Form VI ☐

1.5 What is your level of professional education 1= None, 2= Certificate, 3= Diploma 4= Adv Diploma 5= Degree ☐

2.0 Competence assessment

2.1 How often do you work at malaria diagnosis unit 1= always, 2= Once per week 3= Once per month ☐

2.2 Do you know quality control [Justify] 1= Yes 2= No ☐

2.3 Do you practice quality control in Malaria 1= Yes ☐ = No [Yes if observe/documented]

2.4 At what stage the quality control used? 1= Pre-analytical 2= Analytical, 3= Post analytical, 4=All stages (Observe practices) ☐

2.5 What type of microscope slide routinely used? 1= Always new, 2= Reusable 3= Both ☐

2.6 How do you count and report malaria (Compare with study SOP given) 1= correct 2= Wrong ☐

2.7 When did you get training on malaria microscopy 1=≤ 1Yr, 2= >1Yr-<2Yrs, 3= >2Yrs 4=No training ☐

2.8 Examine given slides and report your findings as in routine reporting style

3.0 Availability of supplies

3.1 Do you know where reagents for malaria are ordered from 1= Yes 2= No ☐

3.2 Are you comfortable with stock of reagent used to diagnose malaria in your laboratory? 1= Yes 2= No ☐

3.3 If **NO** in question 3.2 above what type of reagents you could prefer 1= Field stain, 2= Giemsa, 3= Acridine orange, 4= Others, mention ☐

3.4 In your view; Do you think Health workers respect laboratory results 1= Yes 2= No 3= I don't know ☐

3.5 Do you think your lab produce accurate, reliable reproducible blood smear results? 1= Yes 2= No 3= I don't know (Compare with Results from reference lab) ☐

3.6 What are possible factors causing poor blood smear results in your laboratory? _____

3.7 Have you used RDT 1 = Yes 2 = No ☐

3.8 How do you rank rapid Diagnostic Test in comparison with smear microscopy? 1= Best 2=No difference 3 = Poor ☐

3.9 Give reason for your response in 3.8

_____

_____

Kiambatanisho IVB: Kiswahili

Dododoso la kuhakiki ujuzi wa watoa huduma za Maabara;

1.0 Taarifa binafsi

1.1Una umri gani _____Miaka

1.2 Kwa muda gani umefanya kazi katika maabara hii_____Miaka/Miezi

1.3 Ulipata lini kwa mara ya mwisho mafunzo ya kupima malaria_____(Taja miaka/miezi)

1.4 Taja kiwango chako cha elimu 1= Darasa la saba, 2= Kidato cha nne, 3=Kidato cha sita ☐

1.5 Una ujuzi wa maabara wa kiwango gani 1= Hakuna, 2= Cheti, 3= Stashaada 4= Stashaada ya juu, 5= Shahada ☐

2.0 Uhakiki wa ujuzi

2.1 Ni kwa muda gani unafanya kazi katika kitengo hiki cha kupima malaria? 1= Kila siku ya kazi, 2= Mara moja kwa wiki, 3= Kila mwezi mara moja ☐

2.2 Unajua ubora wa vipimo (thibitisha) 1= Ndio 2= Hapana ☐

2.3 Wewe unafanya njia za kuhakikisha ubora wa vipimo vya malaria? 1= Ndio 2= Hapana ☐ (**Ndio kama taarifa zipo**)

2.4 Ni wakati gani unafanya njia za kuhakikisha ubora wa vipimo?? 1= wakati wa kukusanya sampuli 2= Wakati wa kupima sampuli, 3= Baada ya kupima sampuli ☐

2.5 Kwa kawaida unatumia vioo gani vya hadubini? 1= Kila wakati vipya, 2= Vinavyosafishika/vilivyotumika ☐

2.6 Unahesabu vipi wadudu wa malaria? [Hakiki usahii]

1= Sahii 2= si sahii

2.7 Ulipata lini mafunzo ya upimaji wa malaria

1= ≤ mwaka1, 2= > mwaka 1-< Miaka 2, 3= ≥ Miaka 2

2.8 Pima damu [A na B] hii katika slide na utoe majibu kama unavyotoa kwa wagonjwa.

3.0 Upatikanaji wa vitendea kazi

3.1 Unafahamu ni wapi vitendanishi vya kupimia malaria vinapatikana?1=Ndio 2= Sijui

3.2 Vifaa/vitendanishi unavyotumia kupimia malaria vinakutosheleza? 1= Ndio 2= Hapana

3.3 Kama jibu ni hapana katika swali la 3.2, vitendanishi aina gani ungependa vitumike? 1= rangi yaField, 2= rangi ya Giemsa, 3= rangi ya Acridine orange, 4= Nyinginezo (Taja) _____

3.4 Kwa mawazo yako; unafikiri wafanyakazi wengine wa afya wanathamini na kujali majibu ya malaria toka maabara 1= Ndio 2= Hapana 3= Sijui

3.5 Unafikiri maabara yako inatoa majibu sahii ya kipimo cha malaria?

1= Ndio 2= HApana 3= Sijui

3.6 Sababu zipi zinapelekea kutoa majibu yasiyo sahii katika maabara yako? _____

3.7 Umewahi kutumia kipimo cha RDT 1= Ndio 2= HApana

3.8 Unalinganishaje kipimo cha RDT na Kile cha Hadubini? 1 = Bora sana 2 = hakuna tofauti kwa ubora 3 = hakina ubora

3.9 Toa sababu ya jibu lako katika swali la3.8_____

Appendix V: SOP for Blood Collection and Staining by Giemsa

Patient's finger is cleaned with 70% Methylated spirit and allowed to dry. The fingertip is pricked with a sharp sterile lancet one drop of blood is put on one glass slide and thick smear will be made from it, stained and examined under routine technique. Onto the second glass slide, two drops of blood are placed on two different points [1mm apart] on a glass slide. One drop is smeared in a circular motion with the edge of the slide to obtain thick blood smear and thin smear made using an edge of another slide, and air dried. Thin smear should be fixed for 2 minutes using Methanol.

At reference laboratory, the smear will be stained with diluted Giemsa [1: 20 vol/vol] for 20 min, and washed by placing the film in 7.2pH buffered water for 3 min. The slide is then allowed to air-dry in a vertical position and examined under a light microscope

Appendix: VI a. Proficiency testing Clinicians

QUESTIONNAIRE ON MALARIA MANAGEMENT

1. Demography

1.1. Study Number _____

1.2. Level of education 1= STD VII, 2= Form IV, 3 = Form VI ☐

1.3. Level of professional 1= Specialist, 2= MD, 3 = AMO, 4 = Cl. Officer, 5 = Cl. Ass ☐

1.4. For how long have you worked in this field _____

1.5. In average, how many cases of malaria do you attend in a day _____

2. Case management

2.1. When did you graduate _____Year.

2.2. When did you receive malaria management training 1= Less than 1Yr, 2=1-2Yrs 3 = 3-5 Yrs, 4= More than 5 Yrs ☐

2.3. Did you get training on IMCI 1=Yes, 2 = No ☐

2.4. What are typical signs and symptoms of malaria which can lead you to prescribing ant malaria? _____

2.5. When did you train IMCI _____

2.6. Which way do you prefer in malaria diagnosis; 1= Clinical 2 =Laboratory ☐

2.7. Are you happy with blood smear results from your laboratory? 1=Yes, 2 = No ☐

2.8. If the answer in 2.7 is No, what do you think is the problem?

_____

_____

2.9. What can be done to solve the problem you mentioned in 2.8.

_____

_____

2.10. Ever you heard of Rapid Diagnosis Test for malaria 1=Yes, 2 = No ☐

2.11. How do you rank rapid Diagnostic Test in comparison with smear microscopy? 1= Best 2=No difference 3 = Poor ☐

2.12. Give reason for your response in 2.11

_____

_____