# ADHERENCE TO NATIONAL MANAGEMENT GUIDELINES FOR MALARIA TREATMENT AT THE KISII TEACHING AND REFERRAL HOSPITAL IN KENYA.

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**A Research Dissertation Submitted in Partial Fulfillment of the Requirements for the Award of the Degree of Master of Pharmacy in Clinical Pharmacy, School of Pharmacy, University of Nairobi**

**2015**

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## DEDICATION

In loving memory of my father, the late Simon. O. Bichanga.

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ACE | Angiotensin converting enzyme |
| ACT | Artemisinin based combination treatment |
| AL | Artemether-lumefantrine |
| CDC | Centre of disease control |
| COPD | Chronic obstructive pulmonary disease |
| DHA-PPQ | Dihydroartemisinin-piperaquine |
| DNA | Deoxyribonucleic acid |
| DOT | Directly observed treatment |
| ERC | Ethics research committee |
| GDP | Gross domestic product |
| HIV | Human immune-deficiency virus |
| IM | Intramuscular |
| IOM | Institute of medicine |
| IPTp | Intermittent preventive treatment of malaria in pregnancy |
| IV | Intravenous |
| KEMRI | Kenya Medical Research Institute |
| KNBS | Kenya National Bureau of Statistics |
| Kg | Kilogram |
| KTRH | Kisii Teaching and Referral Hospital |
| LLIN | Long lasting insecticidal nets |
| MOH | Ministry of Health |
| Mg | milligram |
| Ml | milliliter |
| PAD | Peripheral artery disease |
| PCR | Polymerase Chain Reaction |
| PI | Principal Investigator |
| RBC | Red blood cells |
| RDT | Rapid diagnostic test |
| SP | Sulphadoxine /pyrimethamine |

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## DEFINITION OF OPERATIONAL TERMS

**Anaemia:** A reduction in the quantity of the oxygen-carrying pigment hemoglobin in the blood.

**Artemisinin-based combination therapy (ACT):** A combination of artemisinin or one of its derivatives with an antimalarial or antimalarials of a different class.

**Cerebral malaria**: Severe *P. falciparum* malaria with cerebral manifestations, usually including coma.

**Clinical guidelines**: Statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options

**Cure**: Elimination of the symptoms and asexual stages of the malaria parasite that caused the patient or caregiver to seek treatment.

**Drug resistance**: Defined by the WHO as the ability of a malaria parasite to survive and/or multiply despite the administration and absorption of a medicine given in doses equal to or higher than those usually recommended but within the tolerance of the subject, provided drug exposure at the site of action is adequate.

**Endemic**: Occurring frequently in a particular region or population.

**Immunity**: All those natural processes that prevent infection, re-infection or super-infection, or which assist in destroying parasites or limiting their multiplication, or which reduce the clinical effects of infection.

**Monotherapy**: Antimalarial treatment with a single medicine.

**Parenteral**: The provision of medication into the body by any means other than through the alimentary canal (oral route or rectal).

**Plasmodium**: A genus of protozoan vertebrate blood parasites that include causal agents of malaria. *Plasmodium faciparum, P. malariae, P. ovale* and *P. vivax* cause malaria in humans. Human infection with the monkey malaria parasite, *P. knowlensi* have also been reported from forested regions of South-East Asia.

**Rapid diagnostic test (RDT):** An antigen based stick, cassette or card test for malaria in which a colored line indicates that plasmodial antigens have been detected.

**Severe anaemia**: Hemoglobin concentrations of <5g/100ml (haematocrit <15%).

**Sensitivity:** The ability of a test to correctly identify cases.

**Specificity**: The ability of a test to correctly identify non-cases.

**Uncomplicated malaria**: Symptomatic infection with malaria parasitemia without signs of severity and/or evidence of vital organ dysfunction.

**ABSTRACT**

**Background:** Clinical practice guidelines in healthcare are evidence-based recommendations, strategies or information that assists healthcare workers and patients in making decisions on appropriate healthcare for specific conditions. Practice guidelines for the management of malaria have been developed at international and national levels. Adherence to clinical guidelines improves the quality of care received by the patients and thus improves patient outcomes.

**Objective:** The main objective of this study was to investigate healthcare workers' adherence to malaria treatment guidelines.

**Methodology:** The study was a two-part hospital-based cross-sectional study involving retrospective review of 430 patient files and 20 health care worker interviews. Medical records of malaria patients were selected by stratified random sampling and scrutinized to determine the proportion of the patients who were treated according to the guidelines. Data was collected using pre-tested data collection forms. The data was analyzed using descriptive and inferential statistics. The level of significance was set at <0.05. For the qualitative aspect of the study, healthcare workers were interviewed to identify barriers to adherence to guidelines.

**Results:** Majority of the patients [78.1%] were aged <13 years. The mean age of the sample was 11.2 years [± SD 15.0 years]. The median age was 6 years with a range of 0.1 years to 84 years Out of the 430 cases of suspected malaria, only 65% were tested for parasitemia by either microscopy or RDT. Approximately 35% were not subjected to either confirmatory test. Of those tested, 78.4% tested positive and 25.5% tested negative for malaria. The most common co-morbidity in the patients treated for malaria was anaemia [29.9%] followed by gastroenteritis (9.9%). Patients with co-morbidities were more likely to receive appropriate treatment [p=0.033] compared with those with none. The most commonly used combination of drugs was quinine and AL [44.7%] followed by artesunate and AL (43.3%). The outcomes in these patients were discharge [95.6%], re-admission [2.6%], death [1.4%] and transfer [0.5%]. The healthcare workers interviewed were clinicians [35%], pharmacy staff [30%], nurses [25%] and laboratory technicians [10%]. All the healthcare workers interviewed were aware of the existence of the malaria treatment guidelines. Many were however not aware of the contents of the guidelines. Only 40% had been trained on the guidelines. Those who indicated agreement with the guidelines were 40% with 15% disagreeing with the guidelines and 45% holding no opinion

concerning the guideline recommendations. Overall, 85% of the workers claimed to adhere to guidelines with 15% claiming non-adherence. Lack of adequate resources was indicated as a reason for non-adherence [95%] as well as lack of adequate staff [40%]. Healthcare worker beliefs and attitudes influenced their adherence to the guidelines as some believed in continued efficacy of discontinued drugs [15%] and others had continued confidence in clinical diagnosis in management of malaria cases [5%]. Reasons motivating adherence to guidelines were prevention of antimalarial drug resistance [25%], emphasis on diagnosis and treatment of the right disease [15%] and prevention of inappropriate use of antimalarials [10%]. Health worker adherence to guidelines was not influenced by years of experience, training, cadre or feelings about guidelines.

**Conclusion:** The gap between knowledge of the malaria treatment guidelines and their application by healthcare workers remains wide. The level of knowledge the content of these guideline recommendations by the healthcare workers is also low.

**Recommendations:** For healthcare worker practices to conform to the recommendations, high quality training, follow-up and supervision, external audits and improved staffing and drug supplies are recommended.

# CHAPTER ONE: INTRODUCTION

## 1.1 Background

Clinical guidelines are defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"[1]. They contain systematically developed statements that include recommendations, strategies or information that assists healthcare workers and patients in making decisions on appropriate healthcare for specific conditions [2]. They may present various alternatives in patient care while highlighting the pros and cons of each of them [3]. Clinical guidelines are produced at national or international levels to guide practice in specific areas of healthcare. Reliable and trustworthy guidelines must be based on a systematic review conducted by a panel of experts from different disciplines [2]. These guidelines are a tool for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports. The origin of interest in developing clinical guidelines was the rising healthcare costs and variations in service delivery among providers, hospitals and geographic regions. The presumption that at least some of these variations stem from inappropriate care, and the intrinsic desire of healthcare professionals to offer, and for patients to receive the best care possible also contributed to the development of clinical guidelines [4].

The function of clinical guidelines in healthcare is to describe the appropriate care for a specific condition based on the best available evidence and broad consensus. Evidence-based guidelines clarify which interventions have proved to be of benefit and which interventions are unsupported by science. These guidelines also improve the quality of care given to patients by calling to attention ineffective, dangerous and wasteful activities. Evidence-based guidelines benefit the patient, the healthcare worker, researchers and the healthcare systems. Clinical guidelines benefit the patient by improving the quality of care received thus improving health outcomes and quality of life of the patient. The guidelines simplify clinical decisions and minimize variations in care. Improved consistency of care makes it more likely that all patients will be provided with equivalent quality of care. Patient morbidity and mortality can be reduced significantly by adopting guidelines that promote clinically beneficial interventions and discourage ineffective or

harmful ones. Patients who are aware or informed about clinical guidelines are empowered to make more informed healthcare choices that are beneficial to them [4].

Clinical practice guidelines benefit the healthcare worker in numerous ways. They improve the quality of clinical decisions by giving explicit recommendations for clinicians who are uncertain about how to proceed. This is important in emergency situations as the guidelines simplify clinical decisions and save time and this translates to improved patient outcomes. Evidence based clinical guidelines help to overturn the beliefs of healthcare workers accustomed to outdated practices. They also relieve the practitioner of the burden of reading and evaluating current best evidence in their area of practice by summarizing the information and making recommendations. They improve the consistency of care and provide authoritative recommendations that reassure practitioners about the appropriateness of their treatment policies [4].

For researchers, clinical guidelines highlight shortcomings of existing literature and justify the need for future research. This helps the researchers to justify their need for funding. It also provides a focus for continuing education thus contributing to the evolution of evidence.

For the healthcare system, guidelines improve efficiency by standardization of care thus optimizing value for money. They promote efficient use of resources by giving explicit information on management of conditions.

The use of clinical guidelines may limit personalized medicine as the recommendations may not take into consideration certain peculiarities of the patient or drug interactions. This is because clinical guidelines are disease-centered rather than being patient-centered. If the guideline development had methodological errors or if the evidence was incorrect, it can result in consistently incorrect healthcare [4].

Malaria treatment guidelines have been developed at national and international levels. The first edition of malaria treatment guidelines by the World Health Organization (WHO) was published in 2006. The guidelines covered the diagnosis and treatment of uncomplicated and severe malaria caused by all types of malaria parasites. It also provided information on diagnosis and treatment of malaria in special groups (young children, pregnant women and HIV/AIDS patients), in travelers from non-endemic areas and in epidemics and emergency situations. These global guidelines are applicable widely, even in resource-limited settings. The WHO guidelines

targeted policy makers at national levels and served as a framework for the development of national treatment protocols specific for different countries. These national guidelines are more detailed and tailored to the specific needs and conditions of each country. The global guidelines are reviewed every two years and/or on an ad hoc basis with emergence of new evidence.

The National guidelines for the diagnosis, treatment and prevention of malaria in Kenya were first published by the Ministry of Health (MOH), Division of Malaria Control in 2006 and are updated periodically taking into consideration emergence of new evidence and continuous monitoring and evaluation. The most current guidelines were published in May 2014. These guidelines are aimed at improving malaria case management by all healthcare workers in Kenya and thus harmonizing efforts at reducing morbidity and mortality due to malaria.

Clinical practice guidelines are developed by a panel of experts who review evidence derived from systematic reviews and develop conclusions and recommendations using a formal consensus development process. The question that this panel of experts attempts to answer is whether a specific intervention improves patient outcomes for a specific condition in a specific population. The panel uses a strict evidence-based methodology that follows set standards for development of clinical practice guidelines. The Institute of Medicine (IOM) has developed standards for developing rigorous and trustworthy clinical practice guidelines. Transparency must be established and details about the process of development of the guidelines and funding of the process should be made accessible to the public. Conflict of interest by potential panel experts should be declared or disclosed by the individuals. Members with vested interest in the entities likely to be affected by the guideline recommendation and funders of the process should have no role in the guideline development. It is essential that the composition of the guideline development group is balanced with experts from different disciplines including methodological experts and populations expected to be affected by the recommendations e.g. current or former patients. The quality of evidence and the strength of the recommendation rating should meet set standards and be clearly described.

An external review should be done by reviewers comprising of all stakeholders and this information should be made available to the public for input. Analysis of the evidence by the external review team minimizes the influence of conflict of interest of the members on the recommendations. The clinical guideline publication date and proposed date for future review

should be clearly documented and the guidelines should be updated and/or modified with emergence of new evidence. Essentially, guidelines need to be updated regularly whether or not significant new evidence is available [2].

## 1.2 Problem Statement

Malaria is among Africa's leading causes of mortality for children under the age of 5 years and it contributes to 10% of the continent's overall disease burden. It accounts for 40% of public health expenditure, 30-50% of in-patient admissions and up to 50% of out-patient visits in areas of high malaria transmission. Of all malaria deaths in the world today, 90% occur in Sub-Saharan Africa [5].

According to the Kenya Medical Research Institute (KEMRI), malaria is the leading cause of morbidity and mortality in Kenya. Out of a population of 34 million Kenyans, 25 million are at risk of malaria [6]. Malaria accounts for 30-50% of all outpatient attendance and 20% of all admissions to health facilities. It is estimated to cause 20% of all deaths in children under the age of five years (MOH 2006). The most vulnerable group to malaria infections are pregnant women and children under 5 years of age. An estimated 170 million working days are lost to the disease each year (MOH 2001).

This level of morbidity and mortality is high despite the fact that malaria is an easily preventable and treatable disease and that treatments are available. This burden impairs economic and social development at the individual, family, community and national levels [7]. One of the reasons for the current state of affairs could be poor patient management from diagnosis to treatment and follow-up, arising from non-adherence to national treatment guidelines [8]. The improper use of antimalarial medicines and the resultant development of resistance is another possible undesirable consequence of non-adherence to national treatment guidelines [9].

Healthcare workers' management of malaria cases may differ from national guidelines. Resistance to antimalarial medicines has been documented in all classes of antimalarials including artemisinin derivatives and this is a major threat to malaria control. The widespread and indiscriminate use of antimalarials exerts a strong selective pressure on malaria parasites to

develop high levels of resistance [10]. Resistance can be prevented, or its onset slowed considerably by ensuring very high cure rates through full adherence to the treatment guidelines.

## 1.3 Justification of the study

The impact of clinical guidelines in practice is currently not optimal and there is much room for improvement. Studies have shown that patients with similar conditions are managed differently and given conflicting care depending on the practitioner. Healthcare workers manage cases of malaria differently from what is recommended in the national guidelines and this may contribute to the observed high morbidity and mortality.

Malaria continues to be one of the most severe public health problems worldwide despite global efforts to control it. Guideline adherent management is an important factor in preventing and treating malaria. Studies on the prevalence of guideline-adherent management of malaria patients in Kenya are lacking. This study addressed this gap as it sought to determine the prevalence of guideline-concordant management of malaria cases as well as to investigate the reasons for non-concordant management of these cases.

Practice patterns can be monitored to rank compliance with guidelines as an index of the quality of care offered to patients with suspected malaria. To achieve the long-term goal of malaria eradication, there is need to invest in the monitoring and use of evidence based guidelines. This study is useful for performance improvement purposes in terms of adherence to guidelines. The results may be useful in modifying and improving practices by healthcare workers in public health facilities in Kenya. The findings may help with developing strategies to improve adherence to malaria treatment guidelines and target the factors that impede malaria treatment guideline adherence. The study could also form a foundation for further studies which will assist in improving patient care. The recommendations will be forwarded to the division of malaria control as well as the hospital in which this study was carried out.

## 1.4 Research question

What proportion of patients managed for malaria were diagnosed and treated in accordance with the national treatment guidelines and what were the reasons for non-adherence to guidelines by healthcare workers?

## 1.5 Objectives

### 1.5.1 General objective

To evaluate the adherence to national guidelines for management of malaria by healthcare workers at the Kisii teaching and referral hospital in for the period between June and December 2014 .

### 1.5.2 Specific objectives

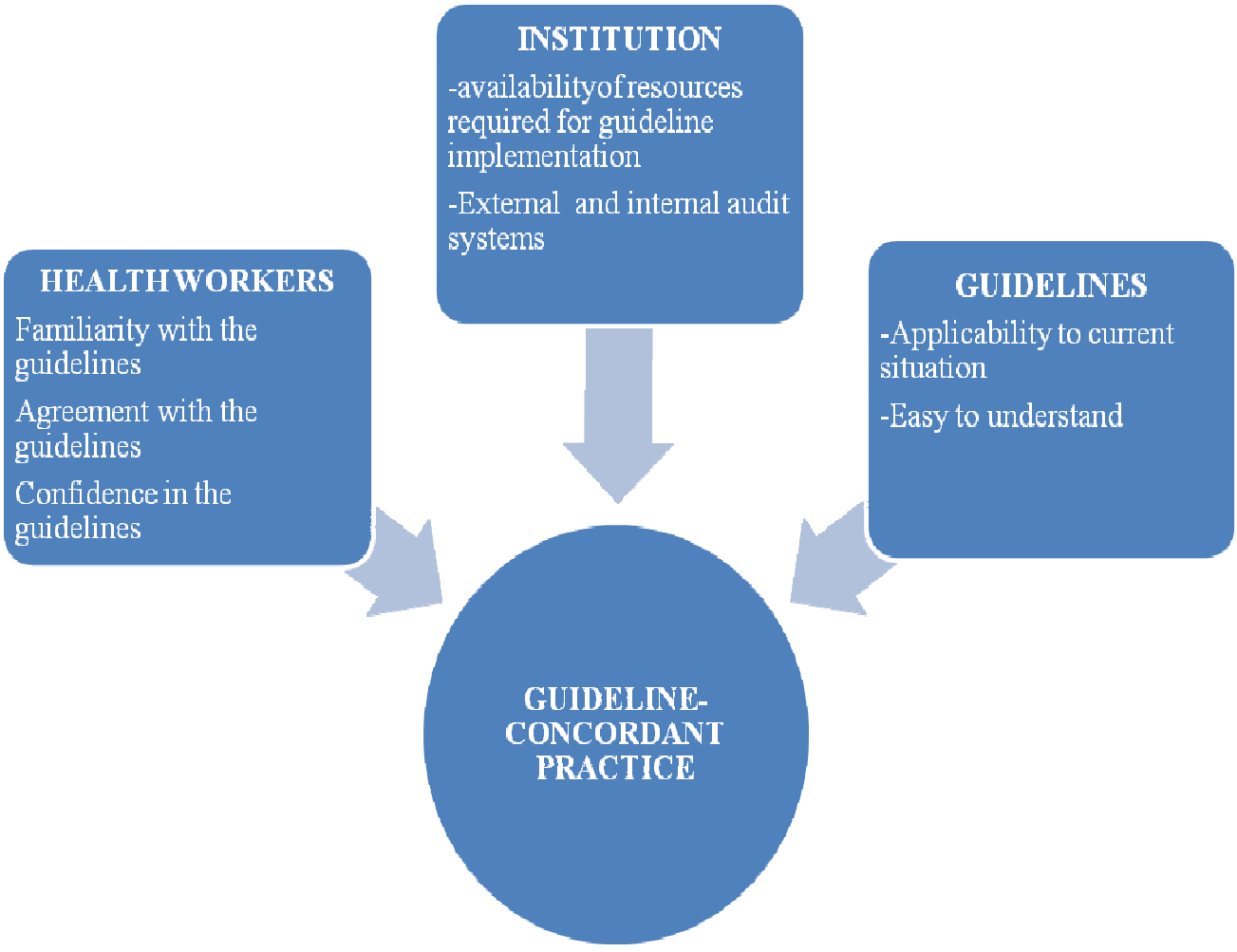
1. To determine the proportion of malaria cases diagnosed and managed in accordance with national treatment guidelines.
2. To describe the types of deviations from the national malaria treatment guidelines.
3. To examine the outcomes of malaria treatment and explore possible association between treatment outcomes and attendant co-morbidities.
4. To identify health worker related factors associated with non-adherence to the national malaria management guidelines.

## 1.6 Conceptual framework

Several factors contribute to less than optimal adherence to malaria treatment guidelines by healthcare workers. These factors together determine the level of guideline-concordant practice that is rendered to patients. There are factors related to healthcare workers' knowledge and attitudes towards the guidelines, institutional factors and factors relating to the nature of the guidelines themselves (figure 1). Healthcare workers' familiarity with the guidelines and attitudes towards the guidelines influences guideline adherence. Wide dissemination of the guidelines and frequent training of healthcare workers improves knowledge and understanding of the guidelines. Understanding of the guidelines in turn influences attitudes towards the guidelines. Healthcare workers who have a positive attitude towards the guidelines and those with more than a casual awareness of the guidelines are more likely to implement them. Those

who disagree with the guidelines are more likely to fail to implement them in their practice. Guidelines that are written in a clear and straightforward language that is easily understood by the practitioners are easier to follow. Guidelines containing ambiguous or conflicting information evoke negative attitudes towards them. The guidelines should also be applicable to the target setting by taking into consideration the availability of the resources necessary for implementation of the recommendations. If the resources required for guideline implementation are available, external audit systems will ensure accountability and thus influence guideline adherence. These factors interact to influence the general level of adherence to the recommended guidelines by healthcare workers.

**Figure 1: Conceptual Framework**



# CHAPTER TWO: LITERATURE REVIEW

## 2.1 Introduction

This chapter analyses relevant studies that have been carried out with respect to the prevalence of guideline adherent treatment of different conditions, factors associated with non-adherence and associated barriers to adherence. It also compares the outcomes of guideline-concordant and non-concordant patient management.

## 2.2 Utility of clinical practice guidelines

Guidelines are directions or principles presenting current or future rules of policy for assisting healthcare practitioners in patient care decisions regarding diagnosis, therapy or related clinical circumstances. Their aim is to reduce inappropriate variations in practice and to promote delivery of evidence based healthcare. Guidelines may be developed by government agencies at different levels including institutional level, professional societies, governing boards or by convening of panels of experts. These guidelines serve as an evaluation of all aspects of healthcare delivery [2].

There is evidence that guideline-driven care is effective in changing the process and outcome of care provided by professionals [11]. Successful implementation of the clinical practice guidelines has been associated with improved quality of care [3]. Guidelines make it possible for professional roles to be substituted effectively in certain circumstances for example in health care facilities that do not have doctors and are run by nurses. A systematic review comparing performance of nurses operating in accordance with set clinical guidelines with "standard care" provided by physicians found no significant difference between the two. A systematic review compared introduction of clinical guidelines with a no guidelines control. Seven out of nine of the studies yielded results indicative of improved patient outcomes with the intervention (introduction of guidelines) compared to the control (no guidelines). The two studies that yielded results of no difference were compromised by small sample size or unit of analysis errors and were thus unreliable [11]. In another study, adherent care demonstrated improvement in patient outcomes and a reduction in cost of treatment in management of patients with lower back pain. Adherence to guidelines resulted in lower pain and disability ratings for the patient as well as fewer hospital visits which translated to lower costs [12].

Another study of patients with Peripheral Artery Disease (PAD) showed that guideline adherent treatment was associated with significant reduction in morbidity and mortality. The guideline recommended that the patients with PAD stop smoking cigarettes and be treated with aspirin, statins and Angiotensin Converting Enzyme (ACE) inhibitors. Patients treated according to the guidelines had a reduced three year risk of major adverse cardiovascular or cerebrovascular events (MACE;Myocardial infarction, stroke and death) and major adverse limb effects (MALE; major amputations, thrombolysis or surgical bypass). Adherence to all four recommended guidelines resulted in a 36% reduction in MACE, 45% reduction in MALE and 44% reduction in death within 3 years of original angiography. The study also revealed a dose-response relationship between the number of guideline recommended therapies implemented and the patient outcomes. There was a reduction of 33%, 30% , 28% and 26% on three year complication rates for patients on 1, 2, 3 and 4 of the guideline recommended therapies respectively [13].

## 2.3 Adherence to clinical practice guidelines

Clinical research studies on impact of guideline adherent treatment on patient clinical outcomes have demonstrated a strong association between guideline adherent treatment and improved patient survival [3]. Adherence to treatment guidelines has been associated with improved patient outcomes. In a study investigating adherence to treatment guidelines in management of patients with breast cancer, it was found that patients who were treated according to the clinical guidelines had better overall survival rates and better disease-free survival compared to those not treated according to the guidelines. Guideline violations were associated with significant impairments in survival parameters. The study showed that the rate of violation of the guidelines resulted in proportionally worse outcomes [14].

Among Dutch physicians, 97% believed that guidelines were useful and 94% believed that guidelines were based on sound evidence. In spite of this, their implementation of these guidelines was not optimal. This was attributed to patient factors, external factors and physician’s attitudes and behaviors. Lack of applicability of the guidelines to particular patients and patient preferences were cited as barriers. Of the physicians interviewed, 35% had a problem with changing their routines and habits to adhere to guidelines while 14% lacked the knowledge and skills required to implement the guidelines [15].

A study evaluating the attitudes and perceptions of Spanish physicians towards clinical guidelines identified two constructs that impacted most on the physician's attitudes. One was knowledge which referred to the theoretical meaning of the guidelines and the other was usefulness which indicated a pragmatic approach to the guidelines. The tension between the theoretical and pragmatic constructs determined the extent of the use of the guidelines by the physicians as well as their attitudes towards the guidelines. These constructs were intercalated through a series of categories including confidence, usability, accessibility, dissemination and formats of the guidelines [16].

Studies have been done to identify barriers to health care workers adherence to clinical practice guidelines. In a study that aimed to explore and synthesize qualitative research on General Practitioners' (GPs') attitudes to and experience with clinical practice guidelines, 6 themes were identified as presented in Table 1 below; questioning the guidelines, General practitioner's experience, preserving the doctor-patient relationship, professional responsibility, practical issues and guideline format [17].

**Table 1: Themes representing General Practitioners' attitudes to and experience with clinical practice guidelines.**

| THEME | EXAMPLE |
|---|---|
| **Questioning the guidelines** | The GPs argued that population based trials were not applicable to individual patients.<br>Some disagreed with the guidelines as they conflicted with their beliefs/experience. |
| **GPs experience** | Some were reluctant to change practice for concern for the patient e.g. patient resource limitations.<br>Some resisted discontinuation of the current practice.<br>Some had negative experiences with guidelines e.g. patient non-compliance |
| **Preserving the doctor-patient relationship** | If clinical guidelines implied rationing of services to the patient which would jeopardize the doctor-patient relationship. |
| **Professional responsibility** | Risk aversion leading to defensive practice. This is fueled by a fear of litigation and the emotional burden of missing a diagnosis. |
| **Practical issues** | Lack of time to read and assess the guidelines.<br>Lack of skills required for new procedures.<br>Lack of resources required for new procedures. |
| **Guideline format** | Guidelines that are difficult to read and understand.<br>Guidelines that are too complex to explain to patients. |

Comparative analysis and synthesis revealed that the GP's reasons for not following guidelines differed according to whether the guidelines in question were prescriptive i.e. encourages a certain type of behavior or treatment or proscriptive i.e. discourages certain behaviors or treatments. For thematic patterning, 5 prescriptive studies, 5 proscriptive studies and 2 mixed studies were compared. Themes identified exclusively in proscriptive studies were two; preserving the doctor-patient relationship and professional responsibility, each featuring in 4 out of 5 of the studies. The main theme identified in prescriptive studies was practical issues which appeared in all prescriptive studies but in only 3 proscriptive studies [17].

A study on barriers to adherence to clinical guidelines in the management of chronic obstructive pulmonary disease (COPD) found that only one in four clinicians adhered to the recommended guidelines. The sub-optimal adherence was attributed to certain barriers to adherence. Guideline familiarity was one of the factors that contributed to non-adherence as less than a third of the clinicians cited high familiarity with the guidelines. There was disparity in the level of confidence in the guidelines by the clinicians. Some reported high confidence in the guidelines while others did not. Their attitudes towards the guidelines influenced their behavior in implementing the guidelines. External barriers to guideline implementation e.g. resource availability was a factor that contributed to poor adherence to the guidelines. Lack of equipment e.g. spirometers limited the capacity of the clinicians to adhere to the guidelines [18].

Although many healthcare workers cited awareness of clinical practice guidelines, very few cited knowledge and understanding of these guidelines. Many were unaware of the specific contents of the guidelines [19]. In a study analyzing knowledge of Artemisinin based Combination Treatments (ACTs) and malaria treatment practices in Malawi, 95.7% of the participants reported knowledge of at least one ACT with the most commonly mentioned ACT being AL (94.6%). However, only 31.5% of the respondents had received training on management of malaria using ACTs [20]. This supports other studies that reveal that few healthcare professionals receive training after changes in treatment policies.

Several factors have been shown to influence correct treatment of patients with confirmed malaria. According to a study carried out in publicly-funded health facilities in Malawi, patient level symptoms and cadre of the healthcare worker influenced correct patient treatment. Patients with confirmed malaria who complained of fever were 72% more likely to receive correct

treatment. Those with confirmed malaria who complained of chills were 30% more likely to receive correct treatment while those who complained of cough were 27% less likely to receive correct treatment. Type of healthcare worker attending to the patients was significantly associated with correct malaria treatment. Medical assistants, a cadre with 2 years of medical training were 54% more likely to offer correct treatment for confirmed malaria compared to medical officers and clinical officers. Previous training of the healthcare workers did not significantly influence malaria case management [21] [22]. There were factors that were related to overtreatment of patients without malaria. Symptoms of the patients and cadre of the healthcare workers significantly influenced overtreatment. The patients who complained of fever and chills were more likely to be over-treated while those who complained of fatigue were less likely to be over-treated. Those seen by medical assistants or nurses were more than 3 times more likely to be over-treated compared to those seen by medical officers or clinical officers. Overall, only 66.7% of patients with parasitologically confirmed malaria received correct management. Nearly 33.3% of patients without confirmed malaria received malaria treatment resulting in 31% of all outpatients being incorrectly treated for malaria [21].

A retrospective evaluation of malaria care management at some health facilities in Zambia revealed that malaria management was characterized by poor adherence to the guidelines. Out of 4,891 cases of suspected malaria, only 67% were tested for parasitemia by either microscopy or Rapid Diagnostic Test (RDT). Approximately 25% were not subjected to either of the confirmatory tests for malaria. Out of 2,247 reported cases of malaria, 71% were parasitologically confirmed while 29% were clinically diagnosed. When it came to treatment, 56% of the reported cases were treated with AL while 35% were treated with SP. Those treated with quinine were 8% while 1% did not receive any treatment for malaria. Approximately 30% of those who tested negative for malaria were still treated with an antimalarial [23].

The extent of adherence to clinical guidelines by health care workers can be assessed using voluntary inspection systems or external inspection systems. The purpose of these systems is to promote quality improvements in healthcare organizations' behavior, healthcare workers' behavior and patient outcomes. In a study comparing the effectiveness of external inspection systems to no intervention (no external inspection) on compliance with accredited standards in healthcare facilities, it was found that there was improved healthcare worker's behavior and

patient outcomes in the intervention group. Externally authorized and driven inspection processes are therefore superior in promoting adherence to treatment guidelines [24]. External inspection systems are likely to provide more reliable results compared to self-reporting as they are less susceptible to bias.

Self-reporting bias is likely to overestimate the impact of guidelines compared to monitoring of actual practice [25]. The self reports provide information on clinician's knowledge of guideline recommendation rather than the measure of guideline adherence. Self-reports should therefore not be used as the sole measure of guideline adherence [26].

Monitoring and evaluation of uptake and adherence to clinical guidelines is important as it highlights processes of care that are weak or sub-par and thus provide a reference for quality improvement. The degree of adherence to clinical guidelines can also be used as a measure of the quality of care received by patients [27] . Methods that can be used to measure the degree of adherence to clinical guidelines include prescription or dispensing data, clinician survey data and review of patient records [27]. Methods that measure adherence essentially relate clinicians' adherence to guidelines to favorable patient outcomes. All these methods however suffer methodological limitations as there is a lack of well validated adherence measuring methods. Measures of adherence are usually a specific guideline recommendation. The most common method used to study clinicians' adherence to clinical practice guidelines is the use of clinician self-report questionnaire.

The advantages of this method are the efficiency and ease of distribution while the main disadvantage is the possibility of poor response rates [27]. Some studies measure the degree of adherence before and after the implementation of an intervention designed to promote guideline adherence. These studies could compare adherence to guidelines before and after dissemination of the guidelines [28]. In a survey of hypertension guideline implementation in Finnish health centers, questionnaires were administered by trained interviewers over the telephone. The main problem encountered was poor response rates and dropouts as clinicians cited difficulty in finding time for the interviews. Unwillingness to participate and recall bias also compromised the quality of the results [29]. Comparison of the prescription patterns and dispensing patterns with the specific guideline can also be used to measure adherence to the guidelines. After diagnosis of the patient through structured clinical interviews, prescriptions were assessed for

medication and dosage. They were then classified as concordant with the guidelines for the specific condition or non- concordant with the treatment guidelines. The main limitation of this method was the small sample size that compromised validity of the results [30]. Medication utilization information can be obtained from pharmacy files that include all prescriptions with details of the dispensing date, the drug name and the quantity dispensed [31].

# CHAPTER THREE: METHODOLOGY

## 3.1 Introduction

This chapter details the methods of data collection, analysis and presentation that were used in this study. It focuses on the methodology and steps that were taken to enhance validity and reliability of the data.

## 3.2 Study design

This study used both quantitative and qualitative techniques as outlined below.

### 3.2.1 Quantitative techniques

A retrospective cross-sectional survey of patient files was used to assess current practice at the hospital and to compare the practice with the national treatment guidelines for management of patients with malaria. The patient records for the period from June 2014 to December 2014 were analyzed to determine the proportion of patients treated according to the guidelines and to identify the nature of deviations from the national guidelines. This study period enabled evaluation of adherence to the latest national guidelines which were published in May 2014. Because malaria is endemic throughout the year in this region, the study period was not expected to affect the sample population.

### 3.2.2 Qualitative techniques

A cross-sectional survey of healthcare workers that assessed knowledge, attitudes and practice was carried out using interviewer-administered questionnaires. The questionnaires contained both open-ended and closed-ended questions and were formulated guided by the 2014 MOH guidelines for malaria management.

## 3.3 Location of the study

The study site was the Kisii teaching and referral hospital in Kenya. It serves as a referral facility for the Kisii county and the greater Gusii region, including nine neighboring sub-county hospitals. It has a catchment of 3 million people and a staff establishment of 500 workers and 13 specialists. It receives an average of 400 out-patients daily and has a capacity of 500 beds and 20 cots. According to the 2012 population estimates, Kisii town has a population of 200,000 and it

is the second most populous urban centre in Nyanza after Kisumu. Kisii is a malaria endemic zone and transmission of malaria is intense throughout the year.

## 3.4 Target population

For the quantitative component of the study, the study population were patients with suspected malaria who presented to the health facility between the months of June and December 2014. Because malaria in this region is endemic throughout the year, there is no association between the study period and the outcomes of interest. This study period was also sufficient for acquisition of the desired sample size. The selected study period allowed for assessment of the latest guidelines published in May 2014.

For the qualitative component, the study population was healthcare workers in the facility who are directly involved in diagnosis and management of suspected cases of malaria. They are the clinicians (doctors and clinical officers), the lab technicians, pharmacists and pharmaceutical technologists and the nurses.

### 3.4.1 Inclusion criteria

1. Records of patients of all ages treated for malaria at the Kisii teaching and referral hospital between the months of June 2014 and December 2014. This consisted only of in-patient records as out-patient records were not accessible.

2. For the qualitative component, all healthcare workers involved in management of suspected malaria cases from diagnosis, testing, treatment and follow-up.

### 3.4.2 Exclusion criteria

1. Records that were incomplete.

2. Healthcare workers who declined to give consent.

## 3.5 Sample size

The sample size for the number of patient files to be reviewed was calculated using the Fisher's formula [32] .

$$n = \frac{z^2 p\,(1-p)}{d^2}$$

where:

n= the desired sample size (for a target population is greater than 10,000)

z=the standard normal deviate at 95% confidence interval (1.96).

p= the proportion of the target population estimated to be non-adherent to the treatment guidelines (estimated at 50% due to lack of available literature).

d=the level of statistical significance set (0.05)

$$n = \frac{(1.96)^2 (0.5)(0.5)}{(0.5)^2}$$

$$= 384$$

For this study, 384 files were to be

sampled.

A 10% addition to the sample size to allow for adjustment of factors such as incomplete records was done. The final adjusted target sample size was 425. A minimum of 425 files was sufficient for the purposes of this study.

The sample size of health care workers in the qualitative component was arrived at through the progressive evaluation for theme saturation, with the minimum sample size set at 20 as per the recommendations for qualitative analysis [33]. The sampling procedure and determination of theoretical saturation is detailed in section 3.6 below. Theme saturation was observed and occurred with the minimum of 20 interviews, and additional recruitment was not necessary.

## 3.6 Sampling techniques

Patient files dated June 2014 to December 2014 were scrutinized to identify those containing malaria cases. A total of 1,392 files of the patients treated for malaria within the study period were identified for sampling. The sampling method was systematic random sampling. The sampling frame was created and the corresponding sampling interval, n, calculated by dividing

the total number of files (1,392) by the target sample size of 425. The files were then arranged in chronological order, and every 3rd (n=3) file was then selected for inclusion in the study population. If the selected 3rd file contained incomplete records, it was skipped and the immediate next file in the sequence was selected.

Purposive sampling combined with theme saturation was used to select the healthcare workers who would participate in the study. The basis of the purposive sampling was selection of healthcare workers relevant to the research. The healthcare workers were selected based on their direct and indirect involvement in diagnosis and management of cases of suspected malaria at the hospital. The cadres from which these healthcare workers were selected were clinicians, laboratory technologists, nurses and pharmacists. These are the healthcare workers involved in testing for malaria, prescribing, dispensing and administration of antimalarials. Consent by the healthcare workers was sought before enrolment into the study. Representatives from each of the cadres were selected and interviewed by the principal investigator (PI). The method focused more on clinicians as they are responsible for making most decisions concerning patients with suspected malaria. There were 7 clinicians, 6 pharmacy staff, 5 nurses and 2 laboratory technicians. Themes were identified from each interview and reviewed after every interview until the point of theme saturation was reached. This was the point in data collection where no new or relevant themes emerged, and the identified themes were considered fully developed. The decision that theme saturation had been reached was made by constant analysis of the interviews for new themes. Three interviews with no new or relevant information were considered indicative of theme saturation. Theme saturation was sought within-cadre for each of the groups.

## 3.7 Data collection techniques

The data collection instruments that were used were an interviewer-administered questionnaire for the qualitative component and a data collection form for the quantitative component.

The data collection forms (Appendix III) were used in the quantitative component of the study to collect data that was then used to determine the proportion of malaria patients treated according to the national treatment guidelines. This data collection forms were used to record data on the treatment of the selected malaria patients at the facility, their demographical features and the outcomes of the patients' management. Data was collected by the Principal Investigator between 8am and 5pm on Mondays, Tuesdays and Thursdays during the data collection period. Since this

retrospective patient file review survey did not include any intervention, it was considered a minimal risk study.

For the healthcare workers' recruitment, the PI introduced herself to the potential participants and provided a brief summary of the research, its purpose, benefits of participation in the study, any potential risks of participation and the PI's contact information. Since this health care worker interview did not include any intervention, this was considered a minimal risk study. Written consent by the potential participant was then sought for their inclusion in the study. Those who consented in writing were then enrolled into the study. The participants were made aware of their right to decline to answer any questions, to stop the interview and to ask any questions concerning the subject. An Informed Consent Form was used for this purpose (Appendix 1).

A pre-tested interviewer-administered questionnaire was used to collect information from the healthcare workers (Appendix II). The questionnaire collected information on barriers to guideline adherence and factors that contribute to non-adherence to guidelines by healthcare workers. The healthcare workers were interviewed face to face and their responses were entered into the questionnaire. The interviews were conducted on Wednesdays, Fridays and Sundays over the data collection period. The interview period spanned over a period of three weeks. This covered the entire shift cycle and ensured that the healthcare workers selected were representative of their specific cadres.

## 3.8 Data quality control

Before the study, pre- testing of the questionnaire was done at the Kenyatta National Hospital by interviewing healthcare workers of different cadres at the hospital and post-graduate students at the College of Health Sciences, University of Nairobi. Two representatives of each involved cadre were randomly selected and interviewed in the pre-testing of the questionnaire. The findings were then used to adjust the questionnaire accordingly.

The data was checked for accuracy and completeness and any errors and omissions were rectified.

## 3.9 Data security

Data entry into the computer was done on the day that it was collected. The computer was secured by a password accessible only by the investigator. The data was backed up daily and

stored under lock and key. The back -up was in the form of secured external hard disks which were stored at a location separate from the personal computer. Filled questionnaires were also kept under lock and key by the investigator.

## 3.10 Data analysis

For the purpose of data analysis, the following definitions were applied. A diagnosis of malaria was considered only if malaria parasites were found in peripheral blood or the RDT detected the plasmodial antigen. The malaria diagnosis was further classified into uncomplicated malaria or severe malaria. The basis for the classification was the presence or absence of the documented features of severe malaria as defined by the WHO (9) Age classification was as follows; ages 0-5 years were classified as young children, ages 6-13 were classified as older children and all patients above the age of 13 were classified as adults.

A database of the collected data was created in Microsoft Excel 2010 spreadsheet and exported to SPSS version 22. Descriptive and inferential statistics were then calculated. The level of significance was set at 0.05. The data was summarized and presented in the form of tables, pie-charts and bar charts.

Content analysis of the qualitative data was carried out by the researcher. The interview scripts were scrutinized and the identified themes were then coded, compiled and presented in tabular and narrative form.

## 3.11 Ethical considerations

This study began after approval by the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee (study reference number ***P715/12/2014***).

Permission was sought from the research committee of the Kisii Teaching and Referral Hospital before commencement of the study.

Informed consent was sought from the participants and only consenting participants took part in the study. Confidentiality of the participants was assured and maintained and no participant identifiers were recorded. The findings from the study would be shared with the participating institution and the individual participants.

# CHAPTER FOUR: RESULTS

## 4.1 Introduction

This chapter focuses on the findings of this research. The data is summarized into tables of frequencies, percentages and p-values. The results are organized according to the demographic characteristics of the study participants, proportion of guideline adherence, outcomes of patient, knowledge and attitudes of healthcare workers and availability of resources necessary for guideline-concordant practice.

## 4.2 Patient Characteristics

### 4.2.1 Demographic characteristics of the Patients

A total of 430 patients from the Kisii Teaching and Referral Hospital had their demographic characteristics analyzed. The mean age of the sample was 11.2 years [± SD 15.0 years]. The median age was 6 years with a range of 0.1 years to 84 years. Majority of the patients [78.1%] were between the ages of 0 and 13 years with only 94 [21.9%] being older 13 years. Majority of the patients were male 243 [56.5%] while 187 [43.5%] were female. This is presented in table 2 below.

**Table 2: Demographic characteristics of Patients**

| Characteristics | Frequency | Percentage |
|---|---|---|
| **Age (years)** | **n** | **%** |
| 0-5 | 212 | 49.3 |
| 6-13 | 124 | 28.8 |
| > 13 | 94 | 21.9 |
| **Gender** | | |
| Male | 243 | 56.5 |
| Female | 187 | 43.5 |

### 4.2.2 Co-morbidities in Patients Treated for Malaria

Of the study participants, 156 [36.3%] had no co-morbidities while 269 [63.7%] had either one co-morbidity or a combination of co-morbidities (table 3). Anaemia was the most prevalent co-morbidity with 127 [29.5%] of the patients having the condition followed by gastroenteritis in 42 [9.8%] patients. Pneumonia and meningitis each occurred in 22 [5.1%] patients while peptic

ulcer disease (PUD) was diagnosed in 17 [4.0%] patients. Malnutrition was diagnosed in 10 [2.3%] patients while 7 [1.6%] patients had a urinary tract infection (UTI). The rest of the co-morbidities accounted for less than 1.5% of the total (table 3).

**Table 3: Co-morbidities associated with malaria in Kisii teaching and referral hospital**

| Co-morbidity | n | % |
|---|---|---|
| Anaemia | 127 | 29.5 |
| Gastroenteritis | 42 | 9.8 |
| Pneumonia | 22 | 5.1 |
| Meningitis | 22 | 5.1 |
| Peptic Ulcer Disease | 17 | 4.0 |
| Malnutrition | 10 | 2.3 |
| Urinary Tract Infection | 7 | 1.6 |
| Anaemia + Gastroenteritis | 7 | 1.6 |
| Psychiatric | 5 | 1.2 |
| Epilepsy | 5 | 1.2 |
| Anaemia + Malnutrition | 5 | 1.2 |
| Anaemia + Pneumonia | 4 | 0.2 |
| Anaemia + peptic ulcer disease | 1 | 0.9 |
| None | 156 | 36.3 |

## 4.3 Guideline concordance with management of malaria

### 4.3.1 Adherence to guidelines in the diagnosis of malaria

The number of patients who underwent a confirmatory laboratory test for malaria was 278 [65%] as presented in table 4 below. Most of the patients were diagnosed using microscopy [98.2%] with only 5 patients diagnosed using the RDT [1.8%]. The other 150 [35%] patients did not undergo any laboratory tests for diagnosis of malaria and were managed on clinical suspicion. Clinical diagnosis, which is the traditional method based on the patient's signs and symptoms is discouraged. This recommendation is applicable to all age-groups of patients and in all epidemiologic settings. This therefore constitutes a deviation from recommendations of diagnosis based treatment which is recommended for all patients with suspected malaria. Of the

147 [34.6%] patients who were not tested for malaria, 125 [83.9%] were treated as cases of severe malaria.

Among the patients who underwent a confirmatory test for malaria, 208 [74.8%] tested positive for malaria while 70 [25.5%] tested negative. All those who tested negative were still treated for malaria. This is a deviation from guidelines recommendations which indicate that only those patients who test positive should be treated for malaria. Of the ones who tested positive 109 [25.3%] were classified as uncomplicated cases while 101 [23.5%] were classified as severe cases according to the WHO classification of malaria.

**Table 4: Proportion of patients tested for malaria**

| **Variable** | | **n** | **%** | **P value** |
|---|---|---|---|---|
| **Lab test done** | Yes | 278 | 65 | <0.001 |
| | No | 150 | 35 | |
| **Type of test** | Microscopy | 274 | 98.2 | |
| | RDT | 5 | 1.8 | |
| **Result of test** | Positive | 208 | 74.8 | |
| | Negative | 70 | 25.2 | |
| **Type of malaria** | Uncomplicated | 109 | 25.3 | |
| | Severe | 101 | 23.5 | |

These results reveal that there exists a significant deviation from the guidelines at the level of diagnosis [p <0.001]. This shows that the lack of testing was statistically significant and warrants an intervention.

A bivariate analysis found no association between testing and age or testing and gender. The p values were 0.455 and 0.207 showing no statistically significant probability of either variables affecting likelihood of testing of the patient.

**Table 5: Association between age and gender and testing for malaria**

| | | Lab test done | | | | |
|---|---|---|---|---|---|---|
| | | Yes | | No | | |
| **Variable** | | **n** | **%** | **n** | **%** | **P value** |
| | Male | 164 | 67.5 | 79 | 32.5 | |
| **Gender** | Female | 114 | 61.6 | 71 | 38.4 | 0.207 |
| | Children | 220 | 65.9 | 114 | 34.1 | |
| **Age group** | Adults | 58 | 61.7 | 36 | 38.3 | 0.455 |

### 4.3.2 Guideline adherence in management of patients diagnosed with malaria

Out of the 278 patients who underwent laboratory confirmation of malaria, 208 [74.8%] tested positive while 70 [25.2%] tested negative. Treatment with antimalarials was given to 99% of the patients who tested positive, 95.8% of those who tested negative and 100% of the untested patients. Of those who tested positive, 109 [25.3] were classified as uncomplicated malaria and 101 [23.5%] were classified as severe malaria (table 6). This classification was based on the WHO clinical features of uncomplicated and severe malaria [10]. Only one case of uncomplicated malaria was treated as such with the other 107 [99.1%] cases being managed contrary to the guideline recommendations by being treated with drugs for severe malaria which are parenteral artesunate or Quinine. Of the cases fitting the classification of severe malaria, 95 [95%] received guideline concordant management with parenteral artesunate or quinine followed by oral AL and 5 [5%] received non-concordant management by receiving drugs other than parenteral artesunate or quinine followed by oral AL.

**Table 6: Treatment of patients with confirmed malaria**

| Guideline-adherent treatment | Frequency | Percentage |
|---|---|---|
| **Uncomplicated malaria** | **N** | **%** |
| **Yes** | 1 | 0.9 |
| **No** | 107 | 99.1 |
| **Severe malaria** | | |
| **Yes** | 95 | 95 |
| **No** | 5 | 5 |

### 4.3.3 Drug combinations used to treat malaria

The recommended treatment for uncomplicated malaria is artemether-lumefantrine (AL) co-formulated tablet. In the event of confirmed treatment failure, therapy with the second line ACT dihydroartemisinin-piperaquine (DP) is initiated. DP is also the recommended second line treatment for uncomplicated malaria in Kenya. Parenteral artesunate is the recommended first line treatment for severe malaria. Artemether or parenteral Quinine may be used in the absence of artesunate. As soon as the patient is able to tolerate oral medication, a complete course of AL is given. For the purposes of this discussion, the first drug refers to the initial drug given to the patient and the second drug refers to the follow-up drug given either after the first drug or in combination with the first drug.

The most common combination of antimalarials used was Quinine and AL 190 [44.7%] followed by Artesunate and AL 184 [43.3%]. Five patients [1.2%] were treated with both quinine and artesunate. This constitutes inappropriate management as these drugs should be used singly and not in combination. The remaining 15 [2.6%] were treated with DP as a second drug after quinine or artesunate (table 7). This treatment is inappropriate and thus a deviation from the guidelines as DP is a second line drug that should only be used when there is confirmed treatment failure after treatment with AL. The 3 [0.7%] patients who were treated with a combination of artesunate and proguanil had a diagnosis of sickle-cell anaemia and were on proguanil prophylaxis as recommended in the guidelines.

**Table 7: Combinations of antimalarial drugs used**

| First drug | Second drug | Frequency | Percentage |
|---|---|---|---|
| Quinine | AL | 190 | 44.7 |
| Artesunate | AL | 184 | 43.3 |
| AL | None | 24 | 5.6 |
| Quinine | D-P | 13 | 3.1 |
| Artesunate | Quinine | 5 | 1.2 |
| Quinine | Artesunate | 3 | 0.7 |
| Artesunate | Proguanil | 3 | 0.7 |
| Artesunate | D-P | 2 | 0.5 |
| Quinine | None | 1 | 0.2 |

## 4.4 Outcomes of the patients treated for malaria

There were four main outcomes. These were: discharge, death, re-admission and transfer. Discharge refers to release of the patient from the hospital by the responsible clinician. This could be after improvement of the state of health of the patient or release of the patient at their own insistence against medical advice. Death refers to loss of life of the patient. Re-admission refers to return of the patient to the hospital within 14 days of discharge after treatment for malaria and transfer indicated movement of the patient from the hospital to another facility.

The patients who were treated and discharged were 410 [95.6%] of the cohort. Those re-admitted were 11 [2.6%], those who died were 6 [1.4%] while those who were transferred were 2 [0.5%] (Table 8).

**Table 8: Outcomes of malaria treatment at the Kisii teaching and referral hospital**

| Outcome | Frequency | Percentage |
|---|---|---|
| Discharge | 410 | 95.6 |
| Death | 6 | 1.4 |
| Re-admission | 11 | 2.6 |
| Transfer | 2 | 0.5 |

A comparison of the outcomes of the patients treated in accordance with the guidelines with those treated contrary to the guidelines is summarized in table 9 below. Of the patients who were diagnosed as per the guidelines, 96.4% were discharged, 1.1% died, 2.2% were re-admitted and 0.4% were transferred. The patients not diagnosed as per the guideline had the following outcomes: discharge [94%], death [2%], re-admission [3.4%] and transfer [0.7%]. There was no statistically significant association between testing for malaria and patient outcomes [p= 0.705]. The outcomes of the patients treated as per the guideline had the outcomes of discharge [95.8%], death [2.1%], re-admission [1%] and transfer [1%]. The patients not treated as per the guideline had the following outcomes: discharge [95.5%], death [1.2%], re-admission [3%] and transfer [0.3%]. There was no statistically significant association between testing for malaria and patient outcomes [p= 0.491].

**Table 9: Associations between adherent management and patient outcomes**

| | | Outcome | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Discharge | | Death | | Re-admission | | Transfer | | |
| **Adherence** | | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **P value** |
| | **No** | 140 | 94.0 | 3 | 2 | 5 | 3.4 | 1 | 0.7 | |
| **Testing** | **Yes** | 268 | 96.4 | 3 | 1.1 | 6 | 2.2 | 1 | 0.4 | 0.705 |
| | **No** | 318 | 95.5 | 4 | 1.2 | 10 | 3.0 | 1 | 0.3 | |
| **Treatment** | **Yes** | 92 | 95.8 | 2 | 2.1 | 1 | 1.0 | 1 | 1.0 | 0.491 |

Patients treated for malaria who had no co-morbidities were 151 [35.5%] while those with co-morbidities were 259 [60.9%]. Of these patients, 151 were discharged, one died, two were re-admitted within 14 days of discharge and one was transferred to another facility. Analysis of the data found no statistically significant associations between the co-morbidities and the patient outcomes (table 10).

**Table 10: Association between co-morbidities and outcomes**

| **Outcomes** | | **Co-morbidity present** | | **Co-morbidity absent** | | |
|---|---|---|---|---|---|---|
| | | **n** | **%** | **n** | **%** | **P value** |
| **Discharge** | No | 15 | 5.5 | 5 | 3.2 | 0.283 |
| | Yes | 259 | 94.5 | 151 | 96.8 | |
| **Death** | No | 269 | 98.2 | 155 | 99.4 | 0.314 |
| | Yes | 5 | 1.8 | 1 | 0.6 | |
| **Re-admission** | No | 265 | 96.7 | 154 | 98.7 | 0.206 |
| | Yes | 9 | 3.3 | 2 | 1.3 | |
| **Transfer** | No | 273 | 99.6 | 155 | 99.4 | 0.686 |
| | Yes | 1 | 0.4 | 1 | 0.6 | |

The most prevalent co-morbidity was anaemia which occurred in 29.9% of the study population. Although analysis revealed no statistically significant association between co-morbidities and outcomes [p=0.428], it is worth noting that anaemia accounted for 5 out the total 6 deaths [83.3%] and almost half of all re-admissions [46.2%]. Gastroenteritis was the second most prevalent co-morbidity occurring in 42 [9.9%] of the patients treated for malaria. All the patients with gastroenteritis were treated and discharged. Pneumonia and meningitis each occurred in 22 [5.1%] of the patients. Peptic ulcer disease occurred in 17 [4%] patients, out of whom two were re-admitted. Malnutrition occurred in 12 [2.8%] of the patients. Of these patients, two were readmitted. The other co-morbidities occurred in less than 2% of the patients and they were not associated with any deaths, readmissions or transfers.

**Figure 2: Co-morbidities associated with death**

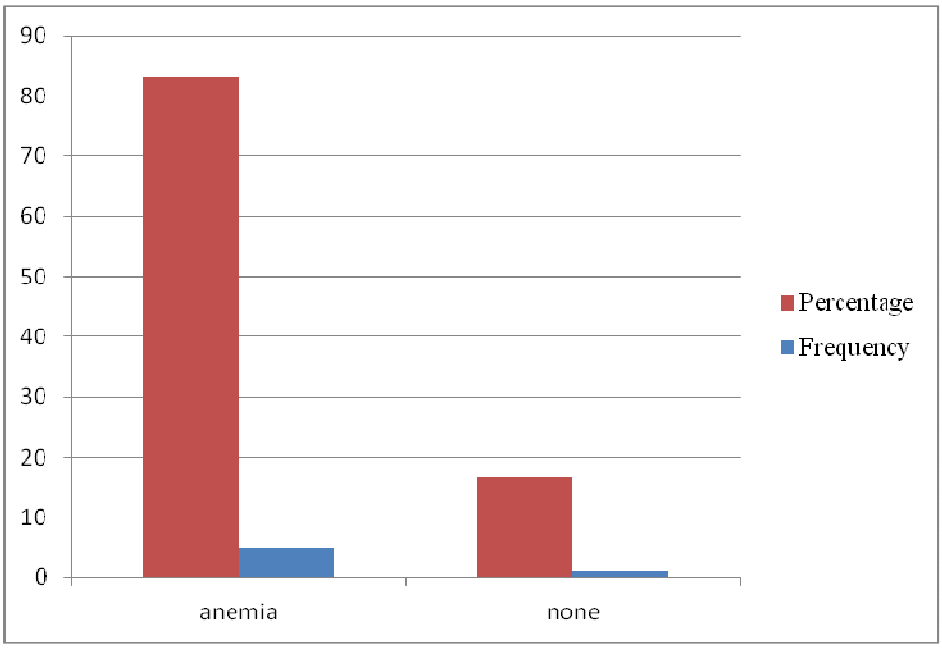
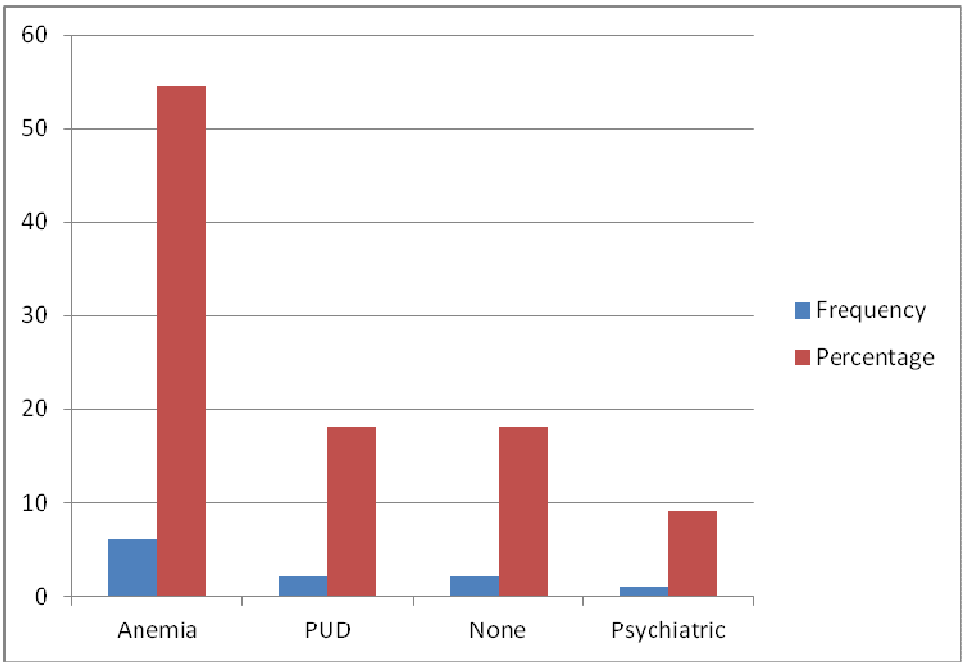



**Figure 3**: **Co-morbidities associated with re-admission**



There was a statistically significant association between the presence of a co-morbidity and appropriate or inappropriate patient management. Patients with co-morbidities were more likely to receive appropriate management [p=0.003] as presented in table 11 below.

**Table 11: Association between presence of co-morbidities and adherent management**

| | **Patient management** | | | | |
|---|---|---|---|---|---|
| | **Adherent** | | **Non- adherent** | | |
| | n | % | n | % | P value |
| Co-morbidity Present | 70 | 25.5 | 204 | 74.5 | |
| Co-morbidity Absent | 26 | 16.7 | 130 | 83.3 | 0.033 |

## 4.5 Knowledge and Utilization of Malaria Treatment Guidelines by Healthcare Workers

### 4.5.1 Demographic characteristics of healthcare workers

As presented in table 12 below, there was equal distribution of both genders of healthcare workers with half being male and half being female. Clinicians represented by the medical officers and clinical officers interviewed were 7, making up 35% of the total population participating in the study. Pharmacists and pharmaceutical technologists were 6 and accounted for 30% of the healthcare workers interviewed. The number of participating nurses was 5 [25%] and that of laboratory technicians was 2 [10%].

**Table 12: Demographic characteristics of health workers**

| **Characteristics** | **Frequency** | **Percentage** |
|---|---|---|
| **Gender** | **N** | **%** |
| Male | 10 | 50.0 |
| Female | 10 | 50.0 |
| **Designation** | | |
| Pharmacist/Pharmacist intern | 5 | 25.0 |
| Nursing officer | 5 | 25.0 |
| Medical officer (MO)/ Intern | 4 | 20.0 |
| Clinical officer/Intern | 3 | 15.0 |
| Laboratory technologist | 2 | 10.0 |
| Pharmacist technologist | 1 | 5.0 |

In terms of years of experience of the participants measured by duration of practice, majority of healthcare workers had practised for 1-3 years [55%], [30%] had practiced for 4-10 years while [15%] had practiced for 12-37 years as presented in table 13. The duration of practice did not influence adherence [p=0.403]. The designation of the participants also did not influence adherence to guidelines [p=0.186] as presented in table 14.

**Table 13: Years of Practice of the Health Workers**

| Designation | Duration of Practice (Years) | | |
|---|---|---|---|
| | **1-3** | **4-10** | **12-37** |
| Pharmacist/Pharmacist intern | 3 | 2 | 0 |
| Nursing officer | 3 | 1 | 1 |
| Medical officer (MO)/ Intern | 3 | 1 | 0 |
| Clinical officer/Intern | 2 | 1 | 0 |
| Laboratory technologist | 0 | 1 | 1 |
| Pharmacist technologist | 0 | 0 | 1 |

**Table 14: relationship between cadre and adherence to guidelines**

| Designation | Adherent | | Non-adherent | | |
|---|---|---|---|---|---|
| | **n** | **%** | **n** | **%** | **P value** |
| Clinical officers | 3 | 100 | 0 | 0 | 0.186 |
| Lab technicians | 2 | 100 | 0 | 0 | |
| Medical officers | 4 | 100 | 0 | 0 | |
| Nursing officers | 4 | 80 | 1 | 20 | |
| Pharmaceutical technician. | 1 | 100 | 0 | 0 | |
| Pharmacists | 2 | 40 | 3 | 60 | |

### 4.5.2 Awareness and Training on Malaria Treatment Guidelines

All the healthcare workers interviewed were aware of the existence of national treatment guidelines for malaria in Kenya. Only 8 [40%] who were aware of the existence of the guidelines had attended at least one training on the current national guidelines for management of malaria as presented in table 15.

**Table 15: Healthcare workers awareness of guidelines and training**

| Characteristic | Frequency (n) | Percentage (%) |
|---|---|---|
| **Aware** | | |
| **Yes** | 20 | 100 |
| **No** | 0 | 0 |
| **Trained** | | |
| **Yes** | 8 | 40 |
| **No** | 12 | 60 |

Analysis for possible associations between training of health workers and adherence to malaria treatment guidelines revealed no statistically significant association [p=0.369]. Feeling of the health workers towards the guidelines also did not influence their adherence to guidelines [p=0.637] neither did the number of years of experience [p=0.403] as presented in table 16.

**Table 16: Factors affecting adherence to guidelines by health workers**

| | | Adherence to guidelines | | | | |
|---|---|---|---|---|---|---|
| | | Yes | | No | | |
| **Variable** | | **n** | **%** | **n** | **%** | **P value** |
| **Trained** | Yes | 8 | 88.9 | 1 | 11.1 | |
| | No | 8 | 72.7 | 3 | 27.3 | 0.369 |
| **Feelings** | Agreement | 8 | 88.9 | 1 | 11.1 | |
| | Disagreement | 2 | 66.7 | 1 | 33.3 | 0.637 |
| | Neutral | 6 | 75.0 | 2 | 25.0 | |

When asked about their knowledge of types of laboratory tests for confirmation of malaria, 5 [25%] of the participants had knowledge of both microscopy and RDTs as methods of testing. Those who knew at least one of the methods (microscopy or RDT) were 7 [35%] while 8 [40%] did not have knowledge of either of the tests as presented in figure 2 below.

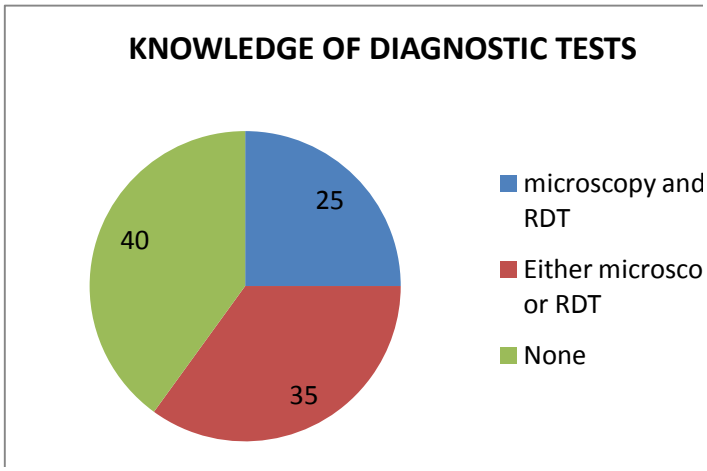



**Figure 4: Knowledge of laboratory tests for malaria**

Respondents were asked to rate their feelings concerning the malaria treatment guidelines on a 5-point scale. Out of those interviewed, 8 [40%] indicated agreement with the guidelines, 9 [45%] indicated neutrality in their feelings, and 3 [15%] disagreed with the guidelines. Agreement indicated confidence that the guidelines were based on solid evidence and that they were reliable in patient management. Neutrality of feelings indicated neither agreement nor disagreement i.e. lack of opinion on the guideline recommendations. Disagreement indicated lack of confidence that the guidelines were based on solid evidence and that they were applicable to their setting.

Some healthcare workers who disagreed with the guideline held the opinion that other antimalarials not recommended in the guidelines were superior to the recommended ones:

"*Some patients respond better to some drugs that are no longer recommended e.g. METAKELFIN, MALARIAQUIN and CHLOROQUINE as compared to ACTs. I don't understand why they were removed from the recommendations*"

### 4.5.3 Perceived usefulness of malaria treatment guidelines

Healthcare workers who participated in the study had a positive opinion about usefulness of the malaria treatment guidelines. Only two [10%] of the respondents indicated that they did not find the guidelines useful in their practice. Of those who found the guidelines useful, three [15%] indicated that the guidelines helped to reduce waste of drugs. These healthcare workers were concerned about wasteful use of antimalarials:

*"Treatment of unconfirmed cases of malaria puts an unnecessary burden on the pharmacy as there are limited resources allocated to drug procurement"*.

Two [10%] of the respondents indicated that the guidelines simplified clinical decisions as it allowed them to know how to manage the patient and when to refer the patient to another facility. By simplifying clinical decisions, the guidelines allow paramedical personnel to manage cases of malaria in resource-limited settings such as dispensaries which are run by nurses. One of the health workers specifically indicated this as a reason she found the guidelines useful:

*"When I was working at a dispensary and was the only healthcare provider, I was able to know when to refer patients with severe malaria by referring to the guidelines"*.

### 4.5.4 Impact of adherence to guidelines on patient outcomes

Most respondents i.e. 14 [70%] believed that adherence to malaria treatment guidelines would lead to improvement of patient outcomes while one [5%] believed that they would not as presented in table 17 below. The remaining 5 [25%] had no opinion on the matter.

**Table 17: Opinion of respondents on effect of guideline adherence on patient outcomes**

| **Characteristics** | **Frequency** | **Percentage** |
|---|---|---|
| Adherence improves outcomes | N | % |
| Yes | 14 | 70.0 |
| No | 1 | 5.0 |
| No opinion | 25 | 25.0 |

### 4.5.5 Availability of resources necessary for malaria management

The healthcare workers interviewed indicated that there were some considerable external barriers to obtaining of a confirmatory diagnosis of malaria. Although nearly all of them, 18 [90%] thought that there was availability of the necessary laboratory reagents and equipment for malaria diagnosis, only 7 [35%] thought that the laboratory was adequately staffed with qualified personnel. Staffing issues were seen as a particular concern:

*"There are very many patients who come to the hospital every day and most of them require testing for malaria. We however have very few laboratory technicians who work long hours and this may compromise the quality of their work. The reagents and equipment are available but the technicians are few".*

In matters of treatment of malaria cases, 19 [95%] of the healthcare workers interviewed indicated that the hospital lacked sufficient quantities of antimalarials in the right doses. Only one [5%] was of the opinion that the hospital had enough resources in terms of antimalarials (Table 18).

**Table 18: Responses on Resource Availability for Malaria management**

| Characteristics | Frequency | Percentage |
|---|---|---|
| **Availability of equipment & reagents for diagnosis** | | |
| Yes | 18 | 90.0 |
| No | 2 | 10.0 |
| **Adequately staffed with qualified personnel** | | |
| Yes | 7 | 35.0 |
| No | 13 | 65.0 |
| **Adequate supplies of antimalarial in right doses** | | |
| Yes | 1 | 5.0 |
| No | 19 | 95.0 |
| **Safe drinking water at pharmacy** | | |
| Yes | 1 | 5.0 |
| No | 19 | 95.0 |
| **Safe drinking water at ward** | | |
| Yes | 1 | 5.0 |
| No | 19 | 95.0 |

### 4.5.6 Barriers to implementation of Directly Observed Therapy

When interviewed concerning whether or not the healthcare workers observed DOT in the outpatient setting, it was noted that none of them did. They indicated several reasons for not doing DOT for the first dose of AL. The most common reason which was given by 6 [30%] of the participants was unawareness of this recommendation in the guideline. High patient load was the second reason with 2 [10%] respondents and one [5%] respondent disagreed with this guideline as they believed that patients were capable of understanding and following instructions making DOT unnecessary. One [5%] respondent indicated lack of safe drinking water at the pharmacy as the primary reason for non-implementation of DOT.

### 4.5.7 Utilization of guidelines by healthcare workers

Of the 20 participants interviewed, 17 [85%] claimed that they follow the guideline recommendation in their diagnosis and management of malaria. Only 3 [15%] responded in the contrary (table 19). When asked why they do not follow the guidelines, the 3 [15%] indicated their past experience in practice as the reason. They believed that drugs other than those recommended in the guideline were more efficacious in treatment of malaria and that they produced better outcomes.

**"***In our setting, quinine is superior to artesunate. I have had numerous experiences where patients do not get well until they receive parenteral quinine"*

*"Cholroquine still works in Kisii"*

One respondent believed in the adequacy of clinical suspicion in diagnosis of malaria while 3 [15%] felt that the guidelines were not applicable in their setting. One health worker suggests that a clinician with extensive experience can correctly diagnose malaria on clinical suspicion:

*"With experienced clinicians, clinical symptoms are sufficient to make a diagnosis of malaria. Even if a patient tests negative but has these symptoms, an antimalarial should be issued".*

Prevention of emergence of resistance to antimalarials was the major motivating factor for guideline adherence by five [25%] of the respondents. Making the right diagnosis and treating the right condition was the reason given by 3 [15%] of the respondents who followed the guidelines. Another two [10%] indicated that they followed guidelines to reduce the unnecessary use of antimalarials which strains the hospital's resources.

**Table 19: Reasons for adherence and non-adherence to guidelines**

| **Reason for adherence** | **Frequency** | **Percentage** |
|---|---|---|
| Prevention of drug resistance | 5 | 25 |
| Treatment of the right disease | 3 | 15 |
| Avoiding wastefulness of antimalarials | 2 | 10 |
| **Reason for non-adherence** | **Frequency** | **Percentage** |
| Belief in efficacy of discontinued or alternative drugs | 3 | 15 |
| Inapplicability of guidelines to their setting | 3 | 15 |
| Belief in adequacy of clinical diagnosis | 1 | 5 |

## 4.6 Summary of results

The proportion of patients treated in accordance with the guidelines was 22.5%. The deviations from guideline recommendation occurred at diagnosis and treatment of the patients. Out of the 430 cases of suspected malaria, only 65.4% were tested for parasitemia by either microscopy or RDT. Approximately 34.6% were not subjected to either confirmatory test and were clinically diagnosed. Of those tested, 78.4% tested positive and 25.5% tested negative for malaria. All the patients whether tested or untested, negative or positive were prescribed antimalarials.

Of the 208 patients who tested positive, 109 were classified as uncomplicated malaria while 101 were classified as severe malaria. Of the 100 cases of severe malaria, 95% received guideline-adherent management with only 5% receiving non-adherent management. There were no associations between age or gender and testing for malaria.

The most common co-morbidity in the patients treated for malaria was anaemia [29.9%] followed by gastroenteritis [9.9%]. Patients with co-morbidities were more likely to receive appropriate management [p=0.003]**.** The most commonly used combination of drugs was quinine and AL [44.7%] followed by artesunate and AL [43.3%]. Other combinations were quinine and DP [3.1%], artesunate and DP [0.5%], artesunate and quinine [1.9%] and artesunate and proguanil [0.7%].

The outcomes in these patients were discharge [95.6%], re-admission [2.6%], death [1.4%] and transfer [0.5%]. There was no association between adherent treatment and outcomes of the patients.

The healthcare workers interviewed were clinicians [35%], pharmacy staff [30%], nurses [25%] and laboratory technicians [10%)]. All the healthcare workers interviewed were aware of the existence of the malaria treatment guidelines. Many were however not aware of the contents of the guidelines. Only 40% had been trained on the guidelines. Those who indicated agreement with the guidelines were 40% with 15% disagreeing with the guidelines and 45% holding no opinion concerning the guideline recommendations. Most of the healthcare workers believed that adherence to guidelines improved patient outcomes [70%] with 25% holding no opinion on the matter and only 5% indicating disagreement with this fact. Overall, 85% of the workers claimed to adhere to guidelines with 15% claiming non-adherence. Lack of adequate resources was indicated as a reason for non-adherence [95%] as well as lack of adequate staff [40%]. Healthcare worker beliefs and attitudes influenced their adherence to the guidelines as some believed in continued efficacy of discontinued drugs [15%] and others had continued confidence in clinical diagnosis in management of malaria cases [5%]. Reasons motivating adherence to guidelines were prevention of antimalarial drug resistance [25%], emphasis on diagnosis and treatment of the right disease [15%] and prevention of inappropriate use of antimalarials [10%]. Analysis for possible associations between training of health workers, cadre, years of practice, feelings and adherence to malaria treatment guidelines revealed no statistically significant associations.

# CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

## 5.1 Introduction

In this chapter, study findings are discussed and conclusions are drawn from the findings. Recommendations have been made based on the study findings and conclusions.

## 5.2 Discussion

Almost half of the patients treated for malaria at the facility were aged 0-5 years [49.3%]. A total of 78.1% of the surveyed patients were children between the ages of 0-13 years. The adult child ratio in other studies conducted in Kenya was 66.7% which is less than what was observed [34]. This is consistent with evidence that shows that in Kenya as in the rest of Sub-Saharan Africa, children under the age of 5 years are the most vulnerable group to malaria infection [6]. Of those who died, 66.7% were children under the age of 13 years. This shows the severity and high mortality due to malaria in children and suggests the possibility that adults in these endemic areas have developed some degree of natural immunity towards the disease [34]. Development of acquired immunity to malaria occurs in childhood and thus the disease is severe and has rapid progression in children who have not yet developed this immunity.

For this study, adherence was measured in terms of parasitological diagnosis of malaria and treatment with the correct drug. Non-adherent treatment was defined in terms of inconsistency in confirmatory diagnosis of malaria, prescribing of antimalarials which are not recommended and prescribing antimalarials to cases testing negative. Malaria case management was characterized by sub-optimal adherence to the treatment guidelines.

Of the 425 patients surveyed, 65% underwent a confirmatory test for malaria (microscopy or RDT) while 35% were diagnosed clinically. Parasitological confirmation is essential as the result informs the clinician's decision on whether or not to prescribe an antimalarial. As in other studies conducted in Africa, co-morbidities were present in 36% of the patients. This is comparable to a study conducted in Gabon in which 22% of the study population had co-morbidities [35]. In children, it is essential to differentiate malaria from Upper Respiratory Tract Infection and Gastroenteritis. In this study 6.7% of the patients had an Upper Respiratory Tract Infection as a co-morbidity and 9.8% had Gastroenteritis. The inability to correctly diagnose and

treat non-malarial fevers contributes to the decision to treat all or most fevers as malaria. Studies have indicated that the concordance rate between “presumptive” and “actual” parasitological malaria ranges between 10% and 60% [36]. This shows that presumptive treatment for malaria leads to many other febrile illnesses being treated as malaria and this endangers the patient’s life and contributes to waste of resources. The 34.6% diagnosed clinically and treated for malaria should therefore be considered to have been inappropriately managed as only parasitologically confirmed cases should be prescribed antimalarials. Presumptive treatment of malaria was recommended by WHO for a long time. This method is however no longer recommended as it has very poor specificity. One study in Malawi showed that algorithms for malaria that are based solely on clinical symptoms do not perform well as they are non-specific and overlap with other potential causes of fever [21]. The symptoms of malaria have a significant overlap with conditions like pneumonia [21] which was present in 5.1% of the patients in this study. Clinical diagnosis of malaria without attendant parasitological confirmation makes it impossible to correctly estimate the disease burden in the region. This in turn limits efficient planning and implementation of strategies to control and manage the disease. Laboratory confirmation of malaria would lead to a significant decrease wasteful use of antimalarials. Introduction of RDTs in public health facilities in Malawi resulted in a decrease in consumption of ACTs [21]. In a study evaluating the effect of increased use of RDTs on management of patients with malaria in Tanzania, it was established that correct treatment of malaria was significantly higher in the post-RDT implementation areas [85.9%] compared to the pre-RDT recommendation areas [58.3%]. Overtreatment was lower in the post-RDT [20.9%] areas compared to the pre-RDT areas [45.8%] [37]. Implementation of confirmatory diagnostic procedures has thus been proven to improve management of patients with suspected malaria.

Of the 278 patients who were tested, 74.8% had a positive result while 25.2% tested negative. Almost all who tested negative were still treated with antimalarials [95.8%], contrary to the guidelines which prescribe that patients with negative parasitological results are not prescribed antimalarials. These patients are therefore classified as receiving inappropriate treatment. This number is far higher than that in other studies across Africa that found that approximately 30% [23] and 33% [21] of patients who tested negative at the participating facilities were still treated with antimalarials. The large proportion may be due to the fact that the patients in this study were all in-patients and many had attendant co-morbidities which may influence overtreatment.

In a study conducted in Tanzania, Ghana and Zambia, 50% of negative results were treated with an antimalarial [36]. This number is still unacceptably high and interventions are necessary to bring it down. In another study conducted in Tanzania, of the 168 patients presenting for treatment at the public health facility, only 63% were tested for malaria. Of those tested, 30% were positive and 70% were negative. Antimalarials were then issued to all the positive results, 14% of the negative results and 28% of those not tested [38]. The prevalence of positive results was higher in this study compared to that in Tanzania [38]. However, overtreatment was more prevalent in this study as 95.8% of negative results and 100% of untested patients received antimalarials.

The patients surveyed were treated as cases of uncomplicated malaria or severe malaria. Almost all patients with symptoms of uncomplicated malaria received treatment for severe malaria [99%]. Of the patients with symptoms of severe malaria, 95% received guideline-adherent management while only 5% received treatment that was contrary to the guidelines. Overtreatment of confirmed and unconfirmed cases of malaria was rampant. This may be due to perceived severity of the illness in the presence of co-morbidities. Anaemia was the most prevalent co-morbidity followed by gastroenteritis, pneumonia, meningitis, PUD, malnutrition, UTI, epilepsy and psychiatric illness. This is consistent with other studies that showed that patients who were considered “more ill”, e.g. those with higher fevers were treated more aggressively with more potent antimalarials [39]. We found no significant association between age of the patient and guideline adherent treatment. This is unlike a study in Uganda which revealed that children <6 months were less likely to be prescribed an antimalarial after a negative test result compared to children >6 months of age [40].

Patient co-morbidities influenced correct management. Patients who had attendant co-morbidities were more likely to receive appropriate treatment compared to those who had no co-morbidities. A possible explanation for this would be that patient-level symptoms influenced testing and treatment. Patients perceived to be more ill are more likely to be tested more thoroughly and treated more aggressively than less ill patients. This is consistent with another study that showed that children who tested negative for malaria but had symptoms suggestive of severe malaria were more likely to receive proper treatment as well as overtreatment[40]

Though we did not find statistically significant associations between adherent treatment and patient outcomes, this does not infer that adherence had no influence on outcomes. In comparison of outcomes of patients, 66.7% of deaths occurred in patients who received inappropriate management. Of the 11 readmissions, 90.1% occurred in patients managed contrary to the guidelines. This is consistent with other studies that have shown associations between non-adherent treatment and poor patient outcomes [14] [13] [12]. Studies have shown higher mortality in children treated for malaria without confirmatory diagnosis compared to those who had a positive blood smear [41].

The most common combination of antimalarials used was Quinine and AL 190 [44.7%] followed by Artesunate and AL 184 [43.3%].This was perhaps due to the greater availability of quinine compared to artesunate at the facility. The choice of drug is usually determined by availability and licensing. In general, artesunate is preferred to quinine as research has shown that it decreases mortality in both adults and children with severe malaria compared to quinine [42] [43]. Artesunate is also easier and safer to administer compared to quinine which has a narrow therapeutic index and requires cautious administration with glycaemic state and cardiac rhythm monitoring. This finding is consistent with a study in Uganda which revealed that IV Quinine was prescribed more frequently than IV artesunate to in-patient children being managed for malaria [40].

Overall, the interviewed health care workers showed a positive attitude towards malaria treatment guidelines. Almost all indicated that the guidelines are a useful source of information on how to manage patients. This is consistent with other studies done elsewhere [15] [44]. However, there are a number of factors that cause a gap between the positive attitude and the practical use of the guidelines. These factors include limited knowledge of the guidelines, perceived usefulness of the guidelines, disagreement with guideline recommendations, inadequacy of staff and other resources, lack of training and supervision and inertia of previous practice.

As in other studies, healthcare workers were generally aware of the existence of the malaria treatment guidelines [45]. It was however evident that awareness of the existence of guidelines did not translate into guideline familiarity or the ability to correctly implement them [45]. In this study, only 25% indicated knowledge of both microscopy and RDT as laboratory tests for

malaria diagnosis. On the recommended DOT for the first dose of AL, 30% of the respondents indicated unawareness of this guideline as a barrier to its implementation. The ever expanding and evolving body of knowledge in medicine has made it so that there are a lot of recommendations which healthcare workers are not able to keep up with. Interventions to improve the healthcare workers knowledge of guideline content include trainings, job aids, support supervisions and external audits. Our study found no significant association between previous training of health workers and adherence to malaria treatment guidelines. This should not be construed to mean that training and supervision do not lead to better adherence to treatment guidelines by health workers. Studies on the efficacy of training as a method to improve guideline adherence have however yielded conflicting results. Some studies show improvement [46] [36] while other show minimum or no improvement on healthcare workers practice [23] [21]. As the overall effect of training would be to translate guideline knowledge into practice, it remains an important intervention to improve healthcare workers adherence to guidelines.

In this study, 70% of respondents believed that adherence to malaria treatment guidelines would improve patient outcomes. However, as in other studies, inertia of previous practice was a major contributor to non-concordant patient management. The percentage of respondents indicating this as a barrier was 15%. They indicated unwillingness to abandon previous practice in preference to new recommendations as was demonstrated in other studies. They specifically had belief in continued efficacy of non-recommended drugs and confidence in non-parasitological diagnosis of malaria as the main factors influencing their unwillingness to abandon previous practice [44] [15].

The cadre of healthcare worker attending to the patient had no significance on the care the patient received. This is unlike in other studies that reported differences in type of health worker and guideline adherent management of patients. A study in Malawi showed that health worker type was significantly associated with correct malaria treatment. the study revealed that lower cadre health workers were more likely to adhere to malaria treatment guidelines [21].

There were considerable external barriers to guideline implementation in terms of obtaining laboratory confirmation and treatment of malaria. Nearly 65% of the respondents indicated that the laboratory was inadequately staffed and 95% indicated that there were insufficient supplies

of the medicines required in malaria treatment. Shortage of staff leads to increased workload and this affects the quality of care offered to the patients. This is a common problem in public health facilities as evidenced by other studies [39]. A further 5% of the respondents indicated absolute lack of safe drinking water as the main barrier to implementation of DOT.

## 5.3 Strengths and Limitations of the study

This study was conducted at only one public health facility in Kenya. The reason for selection of only one facility was limitation of resources, specifically time and money. The results obtained may therefore not be generalisable to all other public health facilities in Kenya or to private health facilities in Kenya. However, majority of patients seek treatment at public health facilities. The study site serves as a primary care facility as well as a referral facility and thus serves as an adequate catchment area for a generalisable survey.

The retrospective nature of data collection from patient records suffered challenges arising from incomplete records or poorly documented records. This was minimized by excluding all incomplete records from the study.

Exclusion of incomplete records required the perusal of more files so as to achieve the required sample size. The target sample size had been adjusted upwards to cater for this, and the final sample size was not compromised.

The adherence was measured by healthcare workers' self-reporting. This information was not corroborated by any external audits and thus its reliability is limited. The healthcare workers' ability to accurately self-assess may have been limited thus resulting in collection of biased data. This is an inherent limitation of the use of self-reporting to assess aspects of adherence, and it was minimized by using well formulated, pre-tested interviewer-administered questionnaires. In addition, no subject identifiers were recorded from the respondents.

## 5.4 Conclusions

Malaria management was characterized by poor adherence to diagnosis and treatment guidelines. This is despite widespread belief that adherence to the guidelines leads to improved patient outcomes and deters emergence of resistance to antimalarials.

Antimalarial prescription in patients who test negative and those who are untested is still practiced in Kenya as in other countries. Strategies need to be put in place to curb this culture of overtreatment.

There is need for better management of febrile illnesses especially in children to avoid the high mortality in this population due to misdiagnosis or treatment of unconfirmed malaria cases.

Although all the interviewees were aware of the existence of these guidelines, few were knowledgeable on the content of the guidelines. This resulted partially from lack of training of the health workers on the guidelines. Several barriers to guideline adherence were identified. Although there is evidence suggesting inefficacy of discontinued antimalarials, some participants believed that these drugs were still efficacious. Many indicated lack of resources necessary for management of malaria as barriers to adherence.

## 5.5 Recommendations

Healthcare workers should be reminded about the potential for co-morbidities in patients presenting with symptoms of malaria. They should also be encouraged to perform confirmatory diagnostic tests on all febrile patients. An emphasis should be made on the recommendation of not treating patients who test negative for malaria with antimalarials but instead investigating for other causes of the symptoms.

Wider dissemination of the guidelines and extensive training of healthcare workers on the same is recommended. Continuous medical education on the guidelines should be done to augment the trainings and update healthcare workers on any changes in the recommendations. Other recommended interventions that would likely improve guideline adherence are; enhanced supportive supervision, job aids, internal and external audits and feedback sessions. Further

exploration of the factors related to non-adherence and development of strategies to address the same is also recommended.

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# CHAPTER SIX: APPENDICES

## 6.1 APPENDIX I: CONSENT FORM FOR HEALTHCARE WORKERS

To be read by the participant.

**Title of the study: Assessment of adherence to national management guidelines for malaria at the Kisii Teaching and Referral Hospital in Kenya.**

**Institution**

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**Investigator**

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**Supervisors**

Dr. P. N. Karimi M.pharm, M.Sc, MBA

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**Ethical Approval**

Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee, P.O BOX 20723-00202, Nairobi. Tel 2726300/2716450 Ext 44102

**Introduction**

In this study I, Dr. Philet Kerubo Bichanga, a student of Master of Pharmacy in Clinical Pharmacy at the University of Nairobi, will be assessing the adherence to national management guidelines for malaria at the Kisii Teaching and Referral Hospital.

**Purpose of the study**

To find out the proportion of patients with suspected malaria in this facility who are treated according to the national treatment guidelines and to assess the reasons for non-adherence to these guidelines by healthcare workers.

Permission is requested from you to enroll you in this research study. The following general principles which apply to all participants in a medical research:

i. Your agreement to participate in this study is voluntary.

ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal without any consequences to you.

iii. After you have read the explanation please feel free to ask any questions that will enable you to better understand the nature of the study.

**Procedure to be followed**

With your permission, I will ask you some questions about your knowledge of and attitudes towards the national malaria treatment guidelines. All information will be handled with confidentiality and will only be used for the purpose of this study.

**Benefits and rewards**

I will inform you of the latest guidelines for malaria management as well as the benefits of guideline adherence to the patient, to the healthcare worker and to the government. There is no no reward for your participation in the study.

**Discomfort and Risks**

Some questions that you will be asked will be of a personal nature and may make you uncomfortable. You are free to decline to answer these questions if you so wish. You may also stop the interview at any time. Participation will require 15-20 minutes of your time and may slow service provision by yourself at the hospital.

**Assurance of confidentiality**

All information obtained from you will be kept confidential. At no point will you or your name be mentioned or used during data handling or in any resulting publications. Serial numbers will be used instead to maintain confidentiality.

**Contacts**

If you need to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study please feel free to do so using the contact information provided above.

**Informed consent**

I, the undersigned, willingly agree to participate in this study, the nature and purpose of which I clearly understand. I understand that the information gathered will be used for the purposes of this study only and maximum confidentiality will be maintained.

Respondent _____

Sign _____ Date _____

Witness (Investigator) _____

Sign _____ Date _____

**Investigator's statement**

I, the undersigned, have explained to the participant the procedures to be followed in the study and the risks and benefits involved.

Investigator _____

Sign _____ Date _____

## 6.2 APPENDIX II: QUESTIONNAIRE

To be administered to the respondent by the principal investigator.

Title: Assessment of adherence to national management guidelines for malaria at the Kisii Teaching and Referral Hospital in Kenya. Please answer the following questions as accurately as you can. The information given will be handled as confidential.

Questionnaire number ……

1. Gender of the respondent
   - □ Male
   - □ Female
2. Designation of the respondent
   - □ Medical officer (MO)/ MO intern
   - □ Clinical officer (CO)/ CO intern
   - □ Laboratory technologist
   - □ Pharmacist/Pharmacist intern
   - □ Pharmaceutical technologist
   - □ Nursing officer
   - □ Other. Please specify……
3. How long have you practiced as a Healthcare worker?

   ……years.
4. Are you aware of the existence of national treatment guidelines for malaria in Kenya?
   - □ No
   - □ Yes
5. Have you ever been trained on the national guidelines for management of malaria ?
   - □ No
   - □ Yes
6. If you answered yes to question 5 above, how many times have you been trained on the national guidelines for management of malaria in Kenya?
   - □ Once
   - □ Twice
   - □ Three times

□ More than three times

7. Have you read a current copy on the national guidelines for management of malaria in Kenya?

   □ Yes

   □ No

8. If you answered yes to question 7 above, do you clearly understand the national guidelines for management of malaria in Kenya?

   □ Yes

   □ No

9. Please circle the number that describes your feelings about the recommended national guidelines for malaria management in Kenya. The numbers represent the following responses:

   1= Strongly agree

   2= Agree

   3= Neutral

   4= Disagree

   5= Strongly disagree

   Elaborate on your response

   ……
   ……
   ……..

10. Do you find the recommended guidelines helpful in your practice, specifically in management of cases of suspected malaria?

    1= Strongly agree

    2= Agree

    3= Neutral

    4= Disagree

    5= Strongly disagree

……
……..

11. Do you think adherence to the national guidelines for management of malaria would make a difference in patient outcomes?

    □ Yes

    □ No

    □ Other (elaborate)

……
……
…….....

12. When a case of suspected malaria comes to your facility, what is the first thing that is done?

…….
…….
…….

13. If a patient with suspected malaria says that they have no money to pay for a lab test, what do you do at your facility?

……
……
……

14. Does your laboratory have the equipment and reagents necessary for diagnosis of malaria?

    □ Yes

    □ No

15. Is your hospital laboratory adequately staffed with qualified personnel for carrying out the malaria lab test?

    □ Yes

    □ No

16. What lab tests do you know that detect malaria and what exactly do each of the tests detect?

……
……
……

17. In your opinion, should you always issue antimalarials for suspected cases of malaria?

    □ Yes

    □ No

    □ Other (elaborate)

    ……
    ……
    ……..

18. Do you have adequate supplies of antimalarials in the right doses?

    □ Yes

    □ No

19. Do you always have safe drinking water at the pharmacy?

    □ Yes
    □ No

20. Do you always have safe drinking water at the wards?

    □ Yes

    □ No

21. Are you conversant with the dosing schedule of AL?

    □ Yes

    □ No

22. Do you do directly observed therapy (DOT) for the first dose of AL?

    □ Yes

    □ No

    □ Other (specify)……

## 6.3 APPENDIX III: DATA COLLECTION FORM

1. Inpatient/ outpatient number…….
2. Age documented……
3. Gender of the patient
   - □ Male
   - □ Female
4. Lab test done?
   - □ Yes
   - □ No
5. Type of malaria lab test done
   - □ Microscopy
   - □ RDT
   - □ Other
6. Result of patient's lab test for malaria
   - □ Positive
   - □ Negative
   - □ Inconclusive
7. Antimalarial drug issued to the patient for positive lab result?
   - □ Yes
   - □ No
8. Antimalarial issued to the patient for negative result?
   - □ Yes
   - □ No
9. Antimalarial issued to the patient for inconclusive result
   - □ Yes
   - □ No

10. Antimalarial issued to the patient and dose of the drug issued

……
……
……

11. Other treatments issued to the patient, specify?

……
……
……

12. Patient's other co-morbidities, if any?

……
……
……

13. Outcome of patient treated for malaria

□ Discharge

□ Death

□ Readmission