

**HEALTH WORKERS ADHERENCE TO THE USE OF
ARTEMETHER-LUMEFANTRINE AS THE FIRST LINE DRUG, IN
THE TREATMENT OF UNCOMPLICATED MALARIA IN
TEMEKE MUNICIPALITY,
DAR-ES-SALAAM.**

By

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(Supervisor)

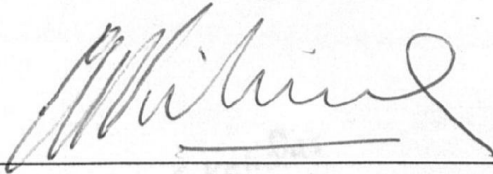
**A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree
of Master of Public Health of the Muhimbili University of Health and Allied
Sciences**

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November, 2007

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance a dissertation entitled **Health workers adherence to the use of Artemether-Lumefantrine as the first line drug, in the treatment of uncomplicated malaria in Temeke municipality, Dar-es-Salaam**, in fulfilment of the requirements for the degree of Master of Public Health of the Muhimbili University of Health and Allied Sciences.



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Date:

2nd November 2007

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I, **Sangini Kalidas**, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Appreciation also goes to Dr D.S. Terimo for his assistance with the literature.

May I also take this opportunity to thank the District Medical Officer of Hala

Signature S. Kalidas for allowing me to use the tool and the District Medical officer of

Tenake Municipality for allowing me to conduct the study in the area together with all

the faculty in charges and administrators, not forgetting Mrs M. Mungu and Mrs J.

Mwaka for their assistance during data collection.

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DEDICATION

This work is dedicated to my spiritual teacher and my guide Sri Sathya Sai Baba.

ABSTRACT

Malaria in Tanzania remains the most common public health problem, being the number one cause of morbidity and mortality especially in children below five years. With the increase in resistance to common antimalarials such as Chloroquine, Sulfadoxine-Pyrimethamine (SP) and Amodiaquine used as a single drug, emphasis is now on the use of drugs which are in combination and more expensive. Tanzania also changed its malaria treatment policy from Chloroquine to Sulfadoxine Pyrimethamine in 2001, with increasing resistance to Sulfadoxine Pyrimethamine, in 2006 the policy changed to the use of Artemether-Lumefantrine (ALu) as the first line drug in the treatment of uncomplicated malaria.

Replacing failing drugs with more efficacious drugs requires that the drugs are prescribed appropriately by health workers according to the guidelines. With the use of Artemisinin-Lumefantrine being relatively new in Tanzania, with little documented information on its usage, the aim of this study was to find out if the new malaria treatment policy was being adhered to by the health workers and to describe their knowledge, perception and practices in relation to this in the treatment of uncomplicated malaria.

A descriptive cross sectional study was carried out in Temeke Municipality in Dar-es-salaam where 160 health workers from 26 health facilities, 13 public and 13 private

(regardless of their affiliation) were interviewed. The dispensing and the prescribing practices of the health workers were confirmed by conducting exit interviews of patients and observation of availability of other materials such as the new national guidelines and the recommended antimalarial drugs.

The findings from the study showed that majority of the health workers (96.9%) were aware of the change in the policy, however only three quarters of those aware knew that the policy had changed less than a year ago. About half of the health workers (45.6%) had received training on the new malaria treatment policy, more than a half (59.4%) being from the government facilities and a significantly greater portion (56.3%) were the clinical staff.

About half of the health workers (44.8%) were highly knowledgeable on the new malaria treatment policy and out of these more than a half (55.8%) came from the government facilities. However, in contrast more than a half of the health workers (52.6%) in the private facilities were having low levels of knowledge. It was also noted that those who had received training were more highly knowledgeable (57.7%) than those who had not received training.

Physical availability of guidelines was seen in only three of the public and two of the private facilities. Availability of ALu was higher in the government facilities than the private facilities. However in some of the public facilities not all the pre packed blisters

were available. About 40.06% of the health workers strongly agreed that ALu should be used as a first line drug and more than a half of the health workers (51.9%) in the government facilities had a positive opinion as regards to the continued use of the drug.

Certification.....

ALu was most frequently prescribed in government facilities (68.8%) followed by SP (12.5%) and Quinine (10.4%) while in private facilities mostly SP (37.7%) was prescribed followed by ALu (24.6%) and AM (14.5%). Majority of the health workers commented on ALu as their first choice of antimalarial and Quinine their alternative choice. ALu was also prescribed correctly by majority of the health workers. However 53.0 % of the exiting patients were not given correct instructions as indicated, on the use of the ALu and more than half (60%) were not given any special instructions to follow when using the drug. Majority (91.6%) were not told of any possible side effects and almost none (97.6%) took their first dose at the facility.

1:0 INTRODUCTION.....

From the findings it can be noted that there is a general acceptance of the new malaria chemotherapy in government facilities while in private facilities availability of ALu at an affordable price hinders effective implementation of the new chemotherapy. More of health workers in the private facilities need to be trained as well as other cadres other than the clinical staff. Availability of ALu should be ensured at affordable price in private facilities. Constant supervision will also ensure that the policy will continue being implemented effectively.

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LIST OF ACRONYMS/ABBREVIATION

1.0 INTRODUCTION

1.1 BACKGROUND

ACO	Assistant Clinical Officer
ACT	Artemisinin Combination Therapy
ALu	Artemether-Lumefantrine
AM	Artemisinin Monotherapy
AMO	Assistant Medical Officer
AS	Artesunate
CO	Clinical Officer
CQ	Chloroquine
DOT	Direct Observed Treatment
HW	Health worker
IEC	Information, Education, Communication
MO	Medical Officer
MOHSW	Ministry of Health and Social welfare
NMCP	National Malaria Control Programme
PI	Principal Investigator
PHN B	Public Health Nurse B
SP	Sulfadoxine -Pyrimethamine
WHO	World Health Organization

CHAPTER ONE

1:0 INTRODUCTION

1:1 BACKGROUND

There are at least 300 million acute cases of malaria each year globally resulting in more than a million deaths. Around 90% of these deaths occur in Africa, south of Sahara mostly in young children. Malaria is a leading cause of under five mortality (20%) and constitutes 10% of the Continent's overall disease burden (WHO, 2006)

In Tanzania it is also the most common public health problem, it is estimated that between 16-18 million cases of malaria occur each year resulting in over 100,000 deaths. 70% of the deaths occur among under- five children. Malaria accounts for 30% of the national disease burden (MOHSW, 2006).

One of the greatest challenges facing Africa in the fight against malaria is the development of drug resistance; it has been among the key factors contributing to malaria morbidity and mortality. Resistance to common antimalarials such as Chloroquine, Sulfadoxine-Pyrimethamine (SP) and Amodiaquine used as single drug is increasing in Africa. As a result of these trends many countries have been forced to change their malaria treatment policies and use drugs which are more expensive, including the use of combinations drugs which can slow resistance (WHO, 2006).

Tanzania like many other countries changed its policy in 2001 from Chloroquine to SP and over the last four years resistance to SP was found to be on the increase. Studies conducted in the country between 2004 and 2005 indicated a treatment failure rate of 25% for SP and 12% for Amodiaquine, the second line antimalarial. These findings indicated that a change in treatment guidelines was necessary. According to the earlier regulations by the World Health organization (WHO), any drug that reaches an average failure rate of 25% should not be recommended for treatment (Daily News, 25/4/2007).

Thus the ministry of Health and Social welfare reviewed the National guidelines for malaria treatment and diagnosis and introduced the new treatment policy in 2006 according to which Artemisinin-Lumefantrine (ALu) was the first line drug and Quinine was the second in the management of uncomplicated malaria (MOHSW, 2006).

Artemisinin-Lumefantrine (ALu) was made available to all the public facilities countrywide. Prior to the introduction, training of health workers was conducted at all levels to equip them with the relevant knowledge and skills for effective management of malaria using the ACT's (Daily News, 25/4/2007).

Replacing failing drugs with more efficacious drugs with their complexity of costs, long regimens complete therapeutic safety range not known and their deployment poses a challenge. Its success to effectiveness depends on the fact that it is prescribed appropriately by health workers according to evidence based guidelines and

administered correctly to patients at home and in health facilities. As such the existence of an efficacious drug forms only part of a complex process culminating in the reduction of malaria's burden (Zurevac *et al.*, 2004).

1:2. STATEMENT OF THE PROBLEM

Resistance to antimalarials has been one of the greatest challenges of malaria control. One of the contributing factors to this has been poor malaria case management brought about by lack of proper, prompt diagnosis (especially lab diagnosis), inadequate treatment (overdosing and under dosing) poor compliance on the part of the user and the prescribers, in the sense that there is a gap between their knowledge and their practices (Malekela, 2002), and non observance of the treatment guidelines (Font *et al.*, 2001).

Studies in the past have shown that there is a tendency of treatment recommendations for malaria not being followed closely and to the extent that more qualified health workers adhere even less closely to the guidelines (Zurevac *et al.*, 2004).

In the public sector where stock shortages, especially at the month's end is a common scenario, may have also contributed to non adherence of rational standard antimalarial drug management. However in the private sector, the tendency to be driven by demand for profit has contributed to practice of poly pharmacy and use of other alternatives, rather than adhering to the standard guidelines.

Since the use of fixed Artemesinin combination therapy is novel in the country, being recently deployed as a first line drug in the treatment of uncomplicated malaria, there are no documented studies to show how well the drug is being prescribed and dispensed by

the health workers. Also taking into consideration that the health workers have been trained regarding the new change in the treatment guidelines, there is a need to evaluate how effectively these are being followed.

Hence this study aims to show whether the new malaria chemotherapy is being implemented appropriately and adhered to by the health workers.

1.3.1 BROAD OBJECTIVE

1.3 RATIONALE OF THE STUDY

With the introduction of the new treatment policy there is need to find out if the guidelines are being adhered to in the health facilities and thus, what is the current existing scenario.

1. To assess health workers awareness on the change of policy from SP to ALD

The findings will help policymakers, implementers and other stakeholders to see whether there is a need to strengthen or change their strategies and approaches, so that these efficacious drugs are used correctly and appropriately. With the ultimate aim of decreasing the burden of morbidity and mortality due to malaria by appropriate diagnosis and correct treatment.

2. To describe the health workers perception on the new malaria treatment policy

It will also assist in the monitoring and evaluation of these drugs which is a part and parcel of the new policy implementation process.

1:4 RESEARCH QUESTION

Is the new malaria treatment policy being implemented appropriately? Are the standard guidelines for the treatment of uncomplicated malaria being adhered to by the health workers?

1:5 RESEARCH OBJECTIVES

1:5:1 BROAD OBJECTIVE

To assess health workers adherence to the use of Artemether-Lumefantrine as the first line drug in the treatment of uncomplicated malaria in Temeke Municipality, Dar-es-Salaam.

1:5:2 SPECIFIC OBJECTIVES

1. To assess health workers awareness on the change of policy from SP to ALu
2. To determine the proportion of health workers who received training on the new malaria treatment policy.
3. To assess health workers knowledge on the new malaria treatment policy
4. To assess the availability of the new guidelines, 1st line, 2nd line and other antimalarials in the health facilities.
5. To describe the health workers perception on the new malaria treatment policy
6. To describe health workers dispensing and prescribing practices under the new malaria treatment policy

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CHAPTER TWO

2.0 LITERATURE REVIEW

For many years the treatment of malaria in Africa had relied on Chloroquine Sulfadoxine combined with Pyrimethamine, and Quinine, with the latter being used mainly to treat severe cases. Quinine still remains efficacious, but Chloroquine and Sulfadoxine-Pyrimethamine were found to be failing and leading to an increase in mortality from malaria especially in East Africa (Greenwood, 2004).

Among the major contributing factors to drug resistance in many countries has been inappropriate use of antimalarial drugs. The drugs being deployed on a large scale, always as monotherapies, introduced in sequence, and generally poorly managed, in that their use continued despite an unacceptably high levels of resistance (Daily News, 25/4/2007).

Over the past decade, a new group of antimalarials – the Artemisinin compounds, especially Artesunate, Artemether and Dihydroartemisinin – have been deployed on an increasingly large scale. These compounds produce a very rapid therapeutic response, are active against multi drug resistant *Plasmodium falciparum*, are well tolerated by the patients and reduce gametocyte carriage (and thus have the potential to reduce transmission of malaria) to date, no resistance to Artemisinin or Artemisinin derivatives has been reported. If used alone, the Artemisinins will cure falciparum malaria in 7 days,

but studies have shown that in combination with certain synthetic drugs they produce high cure rates in 3 days with higher adherence to treatment. Furthermore, there is some evidence that use of such combinations in areas with low to moderate transmission can retard the development of resistance to the partner drug (WHO, 2006).

As a response to increasing levels of resistance to antimalarial medicines, WHO recommended that all countries experiencing resistance to conventional monotherapies, such as Chloroquine, Amodiaquine or Sulfadoxine–Pyrimethamine, should use combination therapies, preferably those containing artemisinin derivatives (ACTs) for falciparum malaria (WHO, 2006).

Artemisinin based combinations are highly efficacious and have the potential to delay the spread of drug resistance on this basis the combination therapy is recommended (MOHSW, 2006).

2:1 Antimalarial drug policy change process

Until recently, first-line drugs for malaria were inexpensive, easy to give, safe and, at least initially, highly efficacious. While there was some concern over adherence, as demonstrated by a few studies looking at this phenomenon, there was little effort or incentive to devise strategies to improve the way that such antimalarials were deployed. A review article by Bloland *et al.*, (2003) on the trends in antimalarial drug deployment in sub-Saharan Africa showed that this indifference had changed only recently. The

situation of comparatively high drug cost, complex regimens, uncertain safety poor diagnosis and heightened concern over resistance argues strongly in favor of a fundamental change in the way that antimalarial drugs are deployed and used. Such fundamental changes require a new vision of malaria treatment policy and practice (Bloland *et al.*, 2003).

3.2 Purpose of antimalarial drug policy and national guidelines

The decision to change the policy is a very sensitive issue considering the financial implications of the change, both to the government and to the users of the drugs, the lack of expertise to manage the change and the uncertainty of treatment outcomes in the use of the new drug (Mubyazi *et al.*, 2005).

The National consultative process of policy change was initiated in mid 2003 by the Ministry of Health and Social welfare. They had a task of choosing an alternative from the ones recommended by WHO which included Artesunate-SP, Artesunate-Amodiaquine and Artemether-Lumefantrine. The first option being unsuitable due to increased resistance of SP, the other two were tested for their therapeutic efficacy and found to be equivalent in terms of their adequate clinical and parasitological response. In the case of Amodiaquine other issues of some degree of resistance, concerns on possible cross resistance with Chloroquine and concerns regarding the safety profile, risk of potential side effects and negative perception of the drug among users were considered. Thus Artemether-Lumefantrine was recommended as the drug of choice for treatment of uncomplicated malaria in Tanzania Mainland (Daily News, 25/4/2007).

Further to introduction of the new treatment policy, The Ministry of Health and social welfare also reviewed the National guidelines for Malaria Diagnosis and Treatment. The primary objective of these national guidelines was to provide standard management reference for the care of patients with malaria (Daily News, 25/4/2007).

2:2 Purpose of antimalarial drug policy and national guidelines

The guiding principal of antimalarial drug policy is to promote safe, effective, good quality, affordable, accessible and acceptable malaria treatment in achieving effective case management of malaria. At the same time to promote rational drug use in order to minimize the development of drug resistance (MOHSW, 2006).

The primary objective of the national guidelines for malaria diagnosis and treatment is to provide standard management reference for the care of patients with malaria. The recommendations represent the minimum level of care that patients should expect at different levels of health care in the public and private sectors (MOHSW, 2006).

The goal of appropriate malaria diagnosis and treatment is to reduce morbidity, mortality and the socio-economic loss attributed to the disease and the use of national Guidelines for Diagnosis and Treatment of Malaria is the key to achieving this goal (MOHSW, 2006).

2:3 Treatment of uncomplicated malaria according to the national guidelines

According to the guidelines the objectives of treatment of uncomplicated malaria are:

1. To provide rapid and long lasting clinical and parasitological cure
2. To reduce morbidity including malaria related anaemia
3. To halt the progression of simple disease into severe and potentially fatal disease.

In order to achieve these objectives, uncomplicated malaria must be diagnosed early and the correct treatment administered without delay. The treatment of uncomplicated malaria using combination therapy has been recommended. The aim of combination therapy is to improve treatment efficacy and also delay the development of drug resistance. The drug indicated as the first line drug is the use of Artemether-Lumefantrine. The second line drug is Quinine to be given for 7-10 days at a dose of 10mg/kg every 8hours which is recommended if the treatment with ALu is contraindicated or failed; it is also the drug of choice in first trimester of pregnancy, in lactating mothers with children below 5kg and in children under weighing below 5kg (MOHSW, 2006).

2.4 Artemether- Lumefantrine (ALu)

An oral fixed combination of 20mg Artemether- a derivative of Artemisinin and 120mg Lumefantrine combining the benefits of the fast onset of action of Artemether with the long duration of action and high cure rates of Lumefantrine. The dose being, twice a day for three days. Though for practical purposes to improve compliance it is recommended

that the first dose be given as DOT at the health facility, the second dose strictly after eight hours and the subsequent doses to be given twice daily in the second and third day of treatment until completion of six doses. It is recommended in all age groups except in children below 5kg body weight, in the first trimester of pregnancy and in lactating mothers with child below 5kg of body weight.

Overall incidence of side effects of ALu is low (MOHSW, 2006). In a study done on integrated assessment of the clinical safety of ALu, the most commonly reported possible side effects were of the gastro intestinal kind such as abdominal pain, anorexia, nausea, vomiting, diarrhoea and central nervous systems such as headache and dizziness. Pruritus and rash was reported in a very minor number of patients, all patients with QT prolongation remained asymptomatic and no clinical cardiac events were reported. Majority of the side effects were rated as mild to moderate in intensity (Bakshi *et al.*, 2000). It is generally well tolerated and has minimal side effects (Daily News, 25/4/2007).

It is recommended that ALu be taken with fatty meals to enhance its absorption (MOHSW, 2006) especially with the Lumefantrine component whose absorption is greatly enhanced by co administration of fats. A study done on how much fat was required to optimize Lumefantrine oral bioavailability showed that a relatively small amount of fat such as soya milk was required to ensure maximum absorption of Lumefantrine (Ashley *et al.*, 2007).

2:5 Training and supervision

Prior to introduction of the new treatment in Tanzania MOHSW conducted training to all health service providers at all levels as well as the journalists were also trained to ensure that the public was well informed regarding this new treatment (Daily News, 25/4/2007). Such kind of training can equip the health care providers with the relevant knowledge and skills for effective management of malaria. A study done in Sudan on dispensing and prescribing practices supports this concept. After the introduction of the new protocol which was the use of Artemisinin based combination therapy, it was seen that out of 20 workers only half of the workers knew the recommended first line, although, 90% were aware of the new protocol but only one tenth had been trained on it, hence there was a gap in the understanding and adherence to the new protocol (Abbas, 2006).

Such programmatic interventions such as in service training, constant supervision provision of guidelines and wall charts, may or may not improve the quality of treatment. Some studies have shown strong associations while others have shown that these kinds of interventions were not fruitful. A study done by Zurevac et al in Kenya showed commonly used interventions such as in-service training, possession of the NMCP guideline, treatment wall charts, and supervision for improving HW practices were significantly associated with prescribing the recommended treatment (Zurevac *et al.*, 2004).

A study done on Adherence to Antimalarial combination therapy with SP and Artesunate in rural Tanzania also highlighted that with the introduction of interventions such as health worker training, simple aid jobs, patient counseling, directly observed therapy with SP plus AS brought about reasonable levels of adherence right from the first weeks of the introduction of the combination drug (Kachur *et al.*, 2004). However a study done in Zambia during the period of drug transition to Artemether-Lumefantrine showed that provision of programmatic interventions such as in service training and job aids did not seem to influence ALu use (Zurevac *et al.*, 2005).

2:6 Availability of Artemether-lumefantrine.

In Tanzania ALu can be accessed at both public and private health facilities including pharmacies. ALu available in public facilities is highly subsidized by the Government and has a different packaging while in the private are sold at different market prices (Daily News, 25/4/2007).

Considering the main challenge in deployment of these drugs is the cost and these being ten times more expensive than the conventional drugs used as monotherapies (Daily News, 25/4/2007), availability of these drugs in private facilities where these drugs are not available at subsidized prices becomes questionable. A study done in Sudan supports this hypothesis as though according to the new protocol Artemisinin based combination therapy was recommended as the first line drug, most frequently found antimalarial drug was CQ followed by SP and then Quinine, Artesunate+ SP was found in minority of the

dispensaries while non had Coartem in stock. The reason being that for these dispensaries their main route of supply was the private market which was through loans to be paid back on monthly basis hence many had a tendency to provide cheaper drugs that patients could afford and avoid drugs such as Artemisinin based combination therapies (Abbas, 2006).

On the other end constant availability of recommended antimalarials may also help to ensure effective implementation and usage of these. A repeat cross sectional study done in Zambia showed that facilities where Artemether-Lumefantrine was in stock, the proportions of children weighing 10 kg or more, who should have received this drug, increased from 22% in 2004 to 59% in 2006 (Zurevac *et al.*, 2007). However availability on its own may not favour the effective use of the recommended drug as interestingly seen in the same study done in 2004 in Zambia when the policy was in its transition state from CQ to ALu in children weighing 10kg and above and SP for children below 10 kg, despite the availability of ALu in the facilities it was rarely prescribed (22%) for children above 10kg and most prescribers opted for the familiar SP (68%) in this weight group (Zurevac *et al.*, 2005).

2:7 Health workers adherence to the standard recommended treatment.

Prescribers' adherence to the treatment guidelines remains critical to the success of any new drug policy however studies have shown that this is not the case. According to a study conducted in Kenya by Zurevac *et al.*, (2004), showed that clinical officers and

nurses were much less likely than nursing aides to adhere to guidelines. The results even suggested that clinical officers were less adherent than nurses, who were less adherent than nursing aides (Zurevac *et al.*, 2004).

Though Changing and implementing new drug policies can be difficult especially when the regimen is complex and expensive, comparatively deciding on the change can be an easy part of the complex process of policy, rather, the greatest challenge remains in changing the clinical practices. A study done to describe treatment practices in Zambian children during the transition from Chloroquine to Artemether-Lumefantrine and to Sulfadoxine-Pyrimethamine and examine the factors influencing the prescribing of Artemether-Lumefantrine showed out of 394 children with uncomplicated malaria, among the children weighing 10 kg or more, Sulfadoxine-Pyrimethamine was commonly prescribed 266/394 (68%), whereas recommended Artemether-Lumefantrine was prescribed for only 42/394 (11%) children. The study showed that the change of drug policy towards Artemether-Lumefantrine did not necessarily translate into adequate use of this drug at the point of care in Zambian facilities (Zurevac *et al.*, 2005).

A cross-sectional study to assess the impact of the national protocol for malaria treatment was conducted in a town in Gezira state, Central Sudan, the adherence to the protocol was checked by asking the health workers what regimens they used for the treatment of simple malaria and complicated malaria and compared to the standard regimens recommended by the Malaria Administration at the Ministry of Health.

Despite the relatively high rate of awareness, just over half of the interviewed health workers (57.5%) showed no adherence to the protocol, with a significant difference between the different categories of the health workers. When asked about reasons for not adhering to the protocol guidelines, one-third of health workers mentioned lack of awareness of them. Among the senior hospital staff, however, it was due to negative attitudes towards the protocol, since 72.0% of consultants and 100% of registrars claimed that the protocol was ineffective. Some health workers (11.5%) said that they did not adhere to the guidelines in order to satisfy patients (Ahmed *et al.*, 2004).

Health workers perception regarding the recommended malaria treatment may also contribute to poor adherence to the standard guidelines and can hinder the effective use of the required drugs. A study done in holoendemic Kibaha district in Tanzania to see how SP was perceived after phasing out of CQ showed that not only did the public not have confidence in the drug but also some of health workers also expressed fear and negative perceptions towards the drug (Nsimba, 2006).

A study done in Songea on health workers adherence to the new malaria treatment showed that even after the policy change to the use of SP, CQ was still prescribed as it was still perceived to be the potent one (Tarimo *et al.*, 2007). Such findings would imply that even after the new policy of ALu would be in place health workers would continue advising patients to continue using the monotherapies. Many health workers also felt that SP was not well known and had a lot of side effects (Tarimo *et al.*, 2007).

One side effect being, hypersensitivity to the sulfonamide component ie. Sulfadoxine with the potential of causing Steven- Johnson syndrome (Warell, 1993), which can be fatal especially in the background of the human immunodeficiency virus acquired immunodeficiency syndrome (HIV//AIDS) (Raviglione *et al.*,1988). Hence not trusted. Such side effects could potentially induce negative perceptions to the new drug hence the need to document and report any adverse events (Tarimo *et al.*, 2007).

Long term familiarity and perceived efficacy may also influence the preference of prescribing the drug. In the same study done in Songea it was seen that even before the policy change Quinine was perceived as an alternative to CQ, thus despite SP being the second line drug the former was preferred to the latter (Malekela, 2002).

Effectiveness of the drug alone is not sufficient especially in the reign of highly efficacious but costly drugs. Correct diagnostic and prescribing practices are the essence of creating substantial evidence of clinical effects. Prescriber's practices can be improved by an increase in programmatic such as a variety of in service training, availability of the standard national guidelines and supervisory visits. A repeat cross sectional study done in Zambia in 2006 after the initial survey done in 2004, showed that when the correctness of prescribed ALu was assessed according to the weight specific criteria, it was found to be very high (81% to 96%) in all weight groups. Even the number of children who had ALu dispensed to them at the facility rose from 44% in 2004 to 58% in 2006. Majority of the caretakers were also given advise on the dosing

schedule (98%) and the advise to take ALu after a meal rose from 31% in 2004 to 71% in 2006 (Zurevac *et al.*, 2007).

Giving clear detailed explanations on how to take the drug can be effective in bringing about high levels of adherence to ALu in patients, as was shown by a study done in Uganda on adherence to the six dose regimen of ALu for the treatment of uncomplicated malaria, however patient's level of education may have an effect on the understanding of the instructions hence a need to put an extra emphasis on the appropriateness of the health education messages to promote adherence to the use of the drug (Fogg *et al.*,2004)

CHAPTER THREE

3:0 METHODOLOGY

3:1 Study area

The study was conducted in Dar-es-Salaam region, the largest city in Tanzania according to the 2002 population National Census; it has a total population of 2,497,940. Dar-es-salaam has three municipalities Ilala, Temeke and Kinondoni. Out of which Temeke district was chosen as the study area, as it was thought to be more reflective of an urban/ rural mix population because of an influx of patients in that area from the coast region.

Temeke district is the southernmost of the three districts in Dar es Salaam. It is bounded by the Indian Ocean in the East, Mkuranga district (coast region) in the south, Ilala Municipal/district in the north and the west. It has an area of 656sq.km and is the largest among the three municipalities of Dar-es-salaam region. The municipal has an estimated population of 813,725 as per the 2002 census. The natives are the Wazaramo and Wandengereko but due to urbanization many people of different ethnicity have immigrated. For administrative purposes the municipality is divided into 3 divisions (Chang'ombe, Mbagala and Kigamboni), 24 wards and 165 streets (*mitaa*).

About 90% of the population lives within five kilometers from a health facility. The municipality has 104 operating health facilities out of which 3 are hospitals, 1

government and 2 privately owned, 1 mini hospital Vijibweni, government owned, 5 Health Centres, 1 government and 4 privately owned, and 95 dispensaries out of which 25 are publicly owned and the rest private. Most of the private facilities are concentrated in urban area.

Health services provided are rehabilitative, promotive, preventive and curative. Based on routinely collected data the commonest out patient conditions are Malaria, Acute respiratory infection, Pneumonia, Anaemia, Urinary tract infection, Tuberculosis, Aids, Hypertension, Malnutrition and Skin infection. Malaria remains the leading cause of morbidity and mortality in the municipality.

3:2 Study design

A descriptive, cross sectional study was conducted from June to mid July 2007. Quantitative technique using a structured questionnaire having both open and closed ended questions was used together with an observation checklist for the available inventory in the facilities.

3:3 Study population

The study population comprised of the health care providers. These included Prescribers (MO, AMO, CO, ACO) and Dispensers which included Pharmacists, Pharmaceutical technician, pharmaceutical assistants and Nursing staff which included nursing officers to the nursing assistants.

3:4 Sample size

a) Number of health workers

The minimum sample size for the study was obtained from the formula:

$$n = \frac{z^2 P (100-P)}{E^2}$$

Where P = Expected proportion of the health workers adhering to the National

Malaria Guidelines, since not known then p assumed to be 50%

E= 8%, margin of error

z = 1.96, standard deviation

$$n = \frac{1.96^2 \times 50(100-50)}{8^2} = 150.06$$

The calculated minimum sample size was equal to 150.

b) Number of health facilities

For studies based on health facilities, (Kielman,1995) recommended a sample which should include 25-30 percent of all health facilities. So out of 104 operating facilities in the municipality 26 facilities were selected to cater for the required sample size.

c) Number of exiting patients

A corresponding number of 150 exiting patients treated for uncomplicated malaria in these facilities were estimated to study the dispensing and prescribing practices of the health workers.

3:5 Sampling procedures

a) Selection of health facilities

The health facilities were stratified into public and private facilities regardless of their affiliation (whether private for profit or faith based). For each of these strata, facilities at all levels (hospital, health centre and dispensary) were considered. An equal number of private and public facilities were selected from each of these levels. The municipality has 2 public (1 mini hospital) and 2 private hospitals, thus all the hospitals were conveniently studied. For the health centres, the municipality has 1 public and 4 private health centres out of which the 1 for public was taken and from the 4 private, 1 was selected conveniently. The remaining number of 20 facilities (10 private and 10 public) were chosen conveniently from the level of dispensary.

b) Selection of Health Workers

An allowance of 20 health workers from the various hospitals, 5 from the health centres and 3 from each dispensaries was made to cater for the required sample size. The health workers available during the period of study were interviewed, the ones included were, in the prescribing section (all from the out patient department and other departments) and the ones in the dispensing section.

c) Selection of exiting patients

Exiting patients treated for uncomplicated malaria on the day of the study at the facility where the health workers were interviewed were considered. An equal number of exiting patients corresponding to the number of health workers were taken.

3:6 Data collection

a) Recruitment and training

Three research assistants especially with a medical background and a research experience were recruited and given orientation to the study. Logistic arrangements were also made.

b) Data collection tool and technique

i) A structured questionnaire with both open and close ended questions was used to interview the eligible and available health workers at the selected facilities. Both Swahili and English versions of the questionnaire were prepared, however mostly the Kiswahili version was used.

ii) Exit interview of patients leaving the dispensing section after being treated for uncomplicated malaria was conducted using the Swahili version of the questionnaire having both open and closed ended questions to check for the appropriate dispensing practices of the health workers. The treatment cards/ records were also checked to confirm for the appropriate prescribing practices.

iii) An inventory checklist was used to determine the availability of various antimalarials, and guidelines related to the malaria case management.

c) Data collection procedure

The data was collected by the help of the three research assistants. Each one who participated in the study was first explained as to what the study was all about and what was the aim. Thereafter each one of the participants was asked for his/her consent before

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being interviewed. The responses were then recorded on the questionnaire by the PI or the research assistants.

d) Pre testing

Prior to commencing the study the questionnaire was pre tested in a public health facility in Ilala municipality to check if the questionnaire was well understood, if the sequence of the questions were logical and if there was a need for any modification in terms of structuring or rephrasing the questions. This was done and amendments were made where necessary. The questionnaire was then used for final data collection.

3:7 Study variables

Cadre, type of training, type of facility were the independent variables while dependent variables included awareness, training, level of knowledge, availability of guidelines availability of 1st line, 2nd line and other antimalarials, perception on the 1st line drug, dispensing and prescribing practices in relation to the new malaria treatment policy.

3:8 Definitions of terms

Health Worker

For the purpose of this study a health worker consisted of anyone who diagnosed, prescribed and dispensed the appropriate treatment for uncomplicated malaria. These included clinicians, nursing staff and pharmaceutical personnel.

Uncomplicated malaria

This refers to when the patient is infected with *Plasmodium falciparum* and presents with clinical features such as fever, headache, joint pain, malaise, vomiting, diarrhoea, body ache, poor appetite and weakness. With appropriate medication mostly oral antimalarials, the patient recovers and does not need to be hospitalised.

The new malaria treatment policy

In the context of this study this refers to the use of combination therapy Artemether-Lumefantrine as the first line drug for the treatment of uncomplicated malaria and Quinine as the second line drug in the event of non response to ALu or where ALu contraindicated.

Knowledge

Knowledge is defined as what is known by a person in a particular field, the total facts and information regarding the subject or theoretical and practical understanding of a subject.

Perception

The individual's feelings/ notions concerning the subject matter which an individual is knowledgeable about and has experienced. It usually influences the individual's decision and actions.

Correctness in prescribing of Artemether- Lumefantrine

This was when the correct number of tablets were prescribed for the patients according to their age/weight and the appropriate timing of dosage was indicated, that is the first dose stat, the second after eight hours and then the subsequent doses twice daily for the following two days of treatment.

Correctness in dispensing of Artemether- Lumefantrine

This was when the patient could correctly recall the amount of drug he had to take, at the appropriate time he/she was supposed to take the dose and the duration of the therapy.

3:9 Data management and analysis

Data was collected for a period of one and a half month from June to mid July under the supervision of the PI. The questionnaires and the checklist were collected every three days to monitor the trend of sample size and to avoid bias of manipulation of data. Manual data cleaning was done to check for accuracy and completeness of the questionnaires before entering them into the computer. Open ended questions were coded and categorised. Data entry was done using EPI DATA, and the data was cleaned, validated and analysed using the EPI INFO 6 VERSION. It involved both Univariate and Bivariate Analysis.

Frequency tables and cross tabulations were computed where appropriate and statistical associations were made for the independent and the dependent variables using the chi square test and the significance level set at $p < 0.05$.

Knowledge on the new malaria chemotherapy was measured by responses from 6 questions for knowledge. The questions asked were whether the respondent knew the first line, the second line drug, criteria used to give the first line drug, in which patients the first line drug was not recommended, possible side effects, and how the drug was to be given in terms of the timings.

A knowledge scale was then constructed whereby scores were given for each of these questions answered. A wrong response meant zero while a right question meant either one or two points depending on the question. Scores correctly answered were then added for each respondent. The maximum score was ten while the lowest score was zero. Frequency distribution was then obtained. The highest score was eight while the lowest score was three. Based on this, participant getting five points and below were categorised as having low knowledge while participants having six points were considered to be moderately knowledgeable and seven points and above highly knowledgeable.

3:9 Ethical issues

Ethical approval was obtained from the Research and Publication Committee of the MUHIMBILI UNIVERSITY COLLEGE OF HEALTH SCIENCES. The permission to

conduct the study in the study area was obtained from the district medical officer of Temeke municipality and for pretesting from the Ilala municipality. All the administrators of the facilities and in charges were also asked for their permissions to conduct the study in their facilities. The health workers and the exiting patients were also asked for their consent and told the purpose of the study before asking them to participate in the required study. They were also assured that in no way their names would be used and that the information provided by them would only assist to improve the implementation of the new malaria chemotherapy. Those not wishing to participate were allowed to withdraw from the study.

3:10 Study limitations

Non willingness of some of the health workers and the exiting patients especially in the private facilities to participate in the study. The presence of the researcher, during the exit interviews and interviews with the health workers which may have influenced the responses from the participants leading to bias.

CHAPTER FOUR

4:0 RESULTS:

4:1 Socio-demographic characteristics of the study population

A total of 160 health care providers from 26 facilities (13 public and 13 private) were interviewed. The studied facilities included 3 hospitals (2 private and 1 public), 1 mini hospital (public), 2 health centers (1 private and 1 public) and 20 dispensaries (10 private and 10 public). Out of the 160 health care providers interviewed 54 (33.8%) were from the private facilities and 106 (66.3%) were from public facilities. A total of 165 exiting patients treated for uncomplicated malaria exiting at the dispensing section were also interviewed and their treatment cards were reviewed.

Table 1: Distribution of health workers by cadre and type of health facility

Cadre	Government		Private		Total	
	Freq	%	Freq	%	Freq	%
Clinical staff	49	46.2	31	57.4	80	50.0
Nursing staff	48	45.3	14	25.9	62	38.8
Pharmacy staff	9	8.5	9	16.7	18	11.3
Total	106	66.3	54	33.8	160	100

In this study 80/160 (50%) of the respondents were clinical staff (medical officers, assistant medical officer, clinical officers and assistant clinical officers) while the nursing staff (nursing officers, nurse midwives, PHN B, and nursing assistants) and the pharmacy staff (pharmacist, pharmaceutical technician and pharmaceutical assistant) comprised of about 62/160 (38.8 %) and 18/160 (11.3 %) respectively.

About 106/160 (66.3%) were from the government facilities and the rest from the private facilities (private for profit and non profit). Majority of the respondents, 49/106 (46.2%) in the government facilities comprised the clinical staff and the nursing staff 48/106 (45.3%) while in the private, majority of the respondents were the clinical staff 31/54 (57.4 %).

Table 2: Distribution of health workers by cadre and the level of health facility

Cadre	Hospitals		Health Centres		Dispensaries		Total	
	Freq	%	Freq	%	Freq	%	Freq	%
Clinical staff	27	65.9	5	6.3	48	43.6	80	50
Nursing staff	4	9.8	2	22.2	56	50.9	62	38.8
Pharmacy staff	10	5.5	2	22.2	6	24.4	18	11.3
Total	41	25.6	9	5.6	110	68.8	160	100.1

Majority of the respondents 110/160 (68.8 %) came from the dispensaries while 41/160 (25.6 %) and 9/160 (5.6 %) came from the hospital and the health centre respectively. From the dispensaries the nursing staff comprised about half of the respondents 56/110 (50.9%) while from the hospitals about 27/41 (65.9 %) of the respondents were the clinical staff.

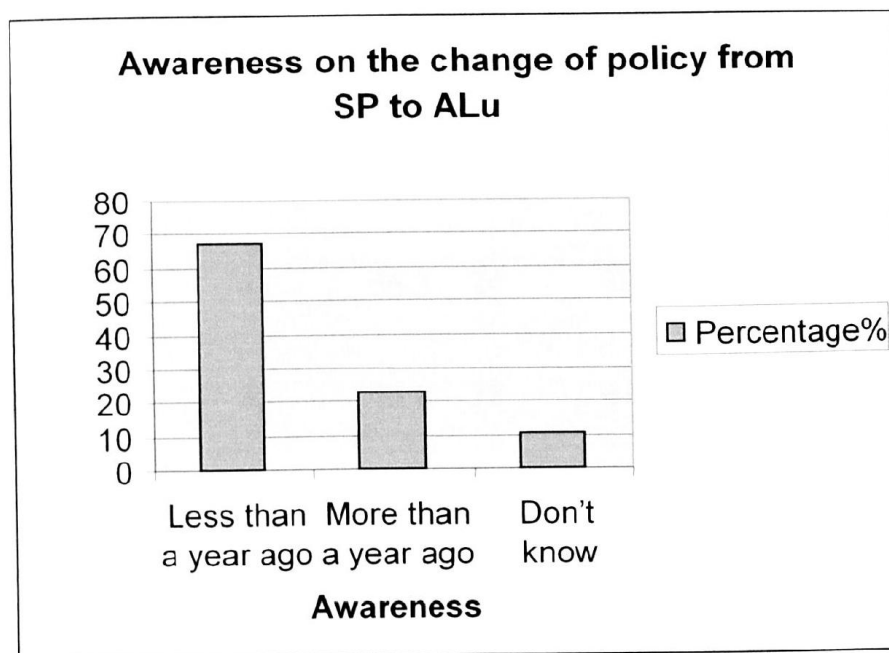
Table 3: Distribution of the health workers by the type of specialization (N=160)

Type of specialization	Frequency	Percentage (%)
Medical officer and assistant medical officer	25	15.6
Clinical and assistant clinical officer	54	33.8
Nurse	66	41.3
Pharmaceutical personnel	15	9.4

Majority of the respondents studied were specialized as nurses 41.3% and Clinical Officers 33.8%.

4.2 Awareness on the change of policy from SP to ALu.

Figure 1: Distribution of health workers by awareness on the change of policy from SP to ALu (N=160)



Of the health workers interviewed, 155/160 (96.9%) were aware of the change in the policy from SP to ALu and of those who were aware 104/160 (67.1%) knew that the policy had changed less than a year ago.

4.3 Training on the new malaria treatment policy

Table 4: Distribution of health workers who received training on the new malaria treatment policy by cadre

Training	Clinical staff		Nursing staff		Pharmacy staff		Total	
	Freq	%	Freq	%	Freq	%	Freq	%
Received training	45	56.3	24	38.7	4	22.2	73	45.6
Not received training	35	43.8	38	61.3	14	77.8	87	54.4
Total	80	50	62	38.8	18	11.3	160	100

Out of 160 health workers interviewed about 73/160 (45.6 %) had received training on the new malaria treatment policy, a significantly greater proportion of clinical staff 45/80 (56.3%) had undergone training on the new malaria treatment policy compared to the nursing staff 24/62 (38.7%) and pharmacy staff 4/18 (22.2%); ($P < 0.05$).

Table 5: Distribution of health workers who received training on the new malaria treatment policy by type of health facility

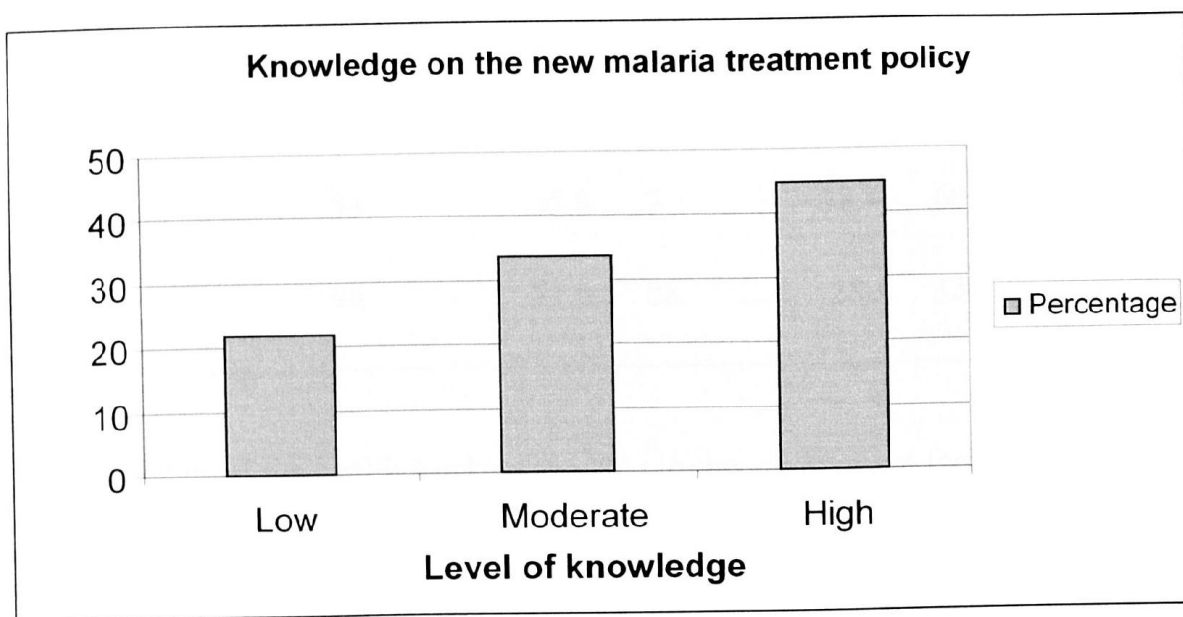
Training	Government		Private		Total	
	Freq	%	Freq	%	Freq	%
Received training	63	59.4	10	18.5	73	45.6
Not received training	43	40.6	44	81.5	87	54.4
Total	106	66.3	54	33.8	160	100

A significant proportion of health workers from the government facilities 63/106 (59.4%) who were interviewed had received training compared to the ones in the private facilities (18.5%); ($P < 0.05$).

Of the health workers who had undergone training about 64/73 (87.6%) had received training outside the health facilities, majority of them being seminars organised by the MOHSW, while the rest 9/73 (12.3%) had received training within the health facilities.

4.4 Knowledge on the new malaria treatment policy

Figure 2: Distribution of the health workers' knowledge on the new malaria treatment policy (N=134)



Almost a half of the health workers (44.8%) were highly knowledgeable on the new malaria chemotherapy while 33.6% and 21.6% were having moderate and low level of knowledge respectively.

When the health workers were asked regarding their knowledge about possible side effects, more than a half (54%) reported knowing only one side effect, while 39% reported knowing only two side effects and a very few (6.8%) knew more than two side effects.

Table 6: Distribution of the health workers' knowledge on the new malaria treatment policy by type of health facility.

Level of knowledge	Government		Private		Total	
	Freq	%	Freq	%	Freq	%
Low	9	9.5	20	52.6	29	21.6
Moderate	34	35.8	11	28.9	45	33.6
High	53	55.8	7	18.4	60	44.8
Total	96	71.6	38	28.4	134	100

More than a half of the health workers (55.8%) in the government facilities were highly knowledgeable on the new malaria treatment policy, while 35.8% were moderately knowledgeable and a very few had a low level of knowledge (9.5%).

In contrast more than a half of the health workers (52.6%) in the private facilities were having low levels of knowledge on the new malaria treatment policy while 28.9% were moderately knowledgeable and a very few had a high level of knowledge (18.4%).

Table 7: Distribution of health worker's knowledge on the new malaria treatment policy by training.

Level of knowledge	Received training		Not received training		Total	
	Freq	%	Freq	%	Freq	%
Low	7	8.8	22	47.8	29	21.6
Moderate	26	33.3	9	19.6	45	33.6
High	45	57.7	15	32.6	60	44.8
Total	78	58.2	46	34.3	134	100

There was a statistically significant difference between the health workers who had received training and those who had not received training in terms of their level of knowledge. More than half of the respondents who had received training (57.7%) were highly knowledgeable while almost a half of the respondents (47.8%) who had not received training were having a low level of knowledge ($P < 0.05$).

4.5.1 Availability of guidelines in the health facilities

Table 8: Distribution of reported availability of the new malaria guidelines by type of health facility.

Guidelines	Government		Private		Total	
	Freq	%	Freq	%	Freq	%
Reported availability	96	90.6	9	8.6	105	65.6
Reported non availability	5	12.5	35	87.5	40	25
Not sure of availability	5	4.7	10	18.5	15	9.4
Total	106	66.3	54	33.8	160	100

Reported availability of guidelines was significantly higher in government facilities (90.6%) than in private facilities (8.6%); ($P < 0.05$). However when availability of these guidelines in the health facilities were observed it was found that out of 13 government health facilities visited, in only 3 facilities and in private in only 2 facilities they were seen physically.

When the health workers were asked as to how many had access to the guidelines 62.5% commented they had access and when asked how often they referred to it 19% commented always, 13% most times, 40% sometimes and 28% never.

4.5.2 Availability of 1st line, 2nd line and other antimalarials.

Table 9: Distribution of reported availability of antimalarials by type of health

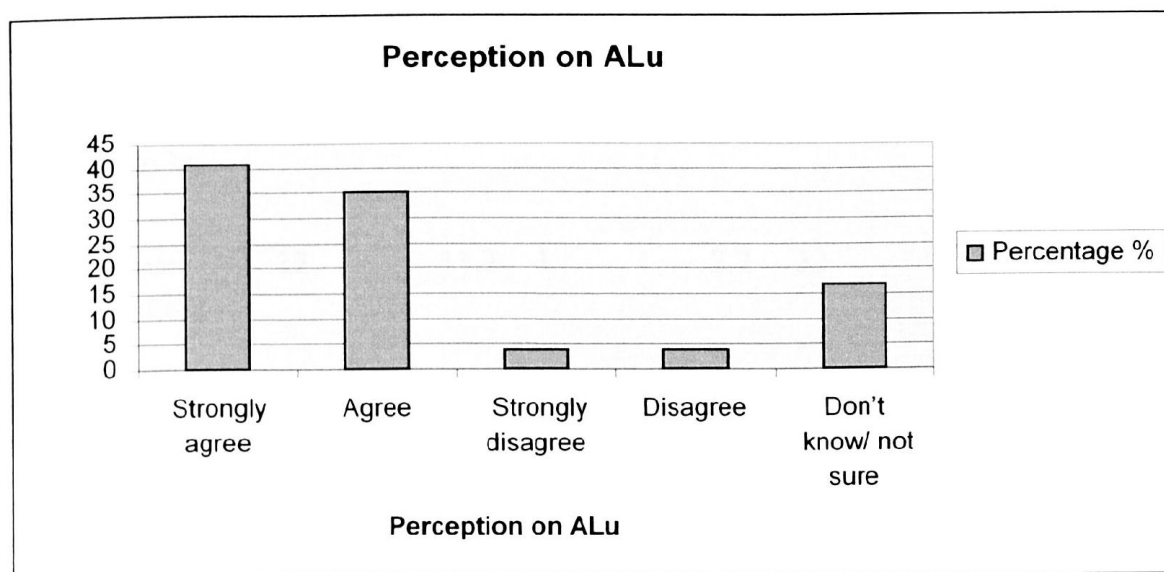
Reported availability of antimalarials	of	Government		Private		Total	
		Freq	%	Freq	%	Freq	%
ALu		103	76.9	31	23.1	134	100
Quinine		95	64.6	52	35.4	147	100
Amodiaquine		59	65.6	31	34.4	90	100
SP (Fansidar)		82	62.1	50	37.9	132	100
AM		0	0.0	45	100	45	100
Metakelfin		0	0.0	11	100	11	100

In a multiple response analysis of reported availability of antimalarials (N=503) it was noted that the availability of ALu, the first line drug was significantly more available in government facilities (76.9%) compared to the private facilities (23.1%); ($P < 0.05$). There was no significant difference in availability of quinine the second line drug in the type of health facilities ($P > 0.05$). Reported availability of SP (62.1%) was higher in government facilities while AM (100%) were reported to be available only in private facilities.

When the same antimalarials were observed physically in these facilities it was seen that in majority of the government facilities the drug ALu was available, though in six facilities (30%) all the prepacked (weight based) blisters were available while in seven facilities (35%) not all the required pre packed (weight based) blisters were available. In the private only seven facilities (35%) had ALu, in a twenty four blister pack.

4.6 Perception on the new malaria treatment policy

Figure 3: Distribution of health worker's perception on the use of ALu as the first line drug, as recommended by the guidelines. (N=160)



Less than a half (40.6%) of the health workers strongly agreed that ALu should be used as the first line drug as recommended by the guidelines while only about 4% disagreed.

Table 10: Distribution of health worker's opinion on ALu by type of health facility

Opinion on ALu	Government		Private		Total	
	Freq	%	Freq	%	Freq	%
Many tablets, Compliance difficult	26	24.5	3	6.5	29	19.1
More education on the drug to be imparted to the public	6	5.7	6	13.1	12	7.9
More research to be done on the drug	5	4.7	0	0.0	5	3.3
Good medication should be continued to be used	55	51.9	19	41.3	74	48.7
Poor response, patients coming back	12	11.3	1	2.2	13	8.5
Expensive in private, price to be subsidized in private	2	1.9	17	36.9	19	12.5
Total	106	69.7	46	30.3	152	100

More than half (51.9%) of the health workers in the government facilities felt that ALu was a good medication and its use should be continued while in the private facilities 41.3 % felt the same, however 36.9% in private facilities commented that the medication is expensive in private and that the price should be subsidised in private so that many

patients can have access to it. About 24.5% in the government facilities also commented that the tablets were many per dose for the patients to partake and that compliance is difficult.

4.7 Dispensing and Prescribing practices of the health workers

Table 11: Distribution of health worker's dispensing practices in relation to the 1st line drug (No. of exit interviews=83)

Variable	Frequency	Percentage %
Not given correct instructions as indicated, on the usage	44	53
Not given special instructions required, when taking the drug	50	60.2
Not told of any possible side effects	76	91.6
Not taken the first dose at the facility	81	97.6

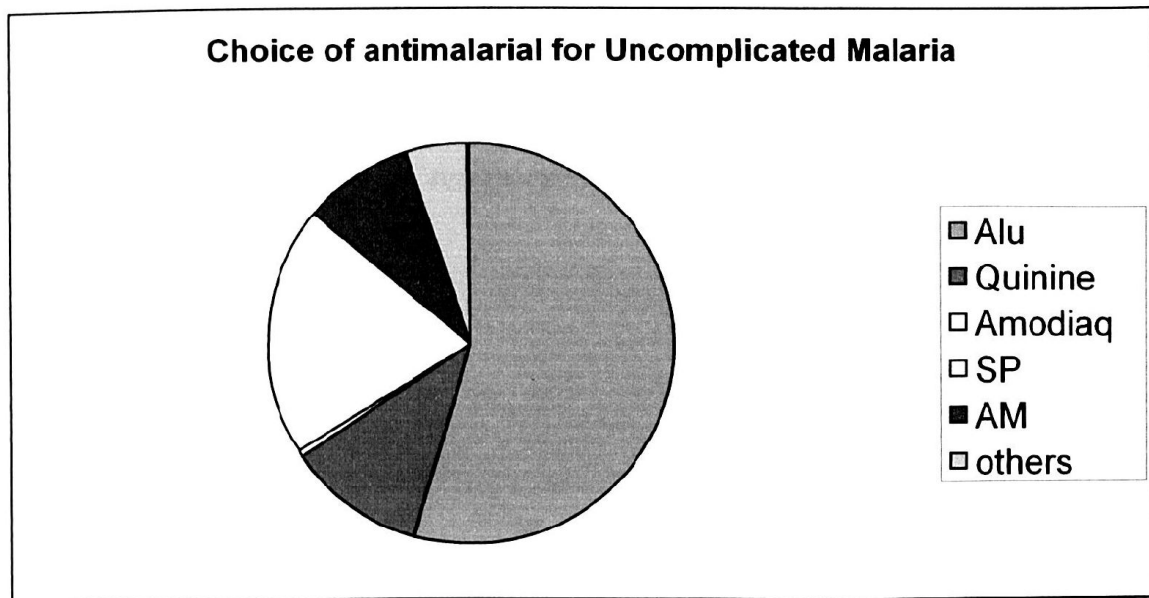
More than half (53.0%) of the patients were not given correct instructions as indicated on the usage of the drug while 60% of the patients were not told of any special instructions required to be followed when taking the drug. Majority (91.6%) of them were not told of any possible side effects which could occur. Almost none of the patients (97.6%) took their first dose at the facility.

Table 12: Distribution of Antimalarials prescribed by the health workers by type of health facility.

Type of Antimalarials	Government		Private		Total	
	Freq	%	Freq	%	Freq	%
ALu	66	68.8	17	24.6	83	50.3
Quinine	10	10.4	6	8.7	16	9.7
AM	6	6.3	15	14.5	14	8.5
SP (Metakelfin /Fansidar)	12	12.5	26	37.7	38	23.0
Amodiaquine	2	2.1	4	5.8	6	3.6
Other Artemisinin combination	0	0.0	1	1.4	1	0.6
Total	96	58.2	69	41.8	165	100

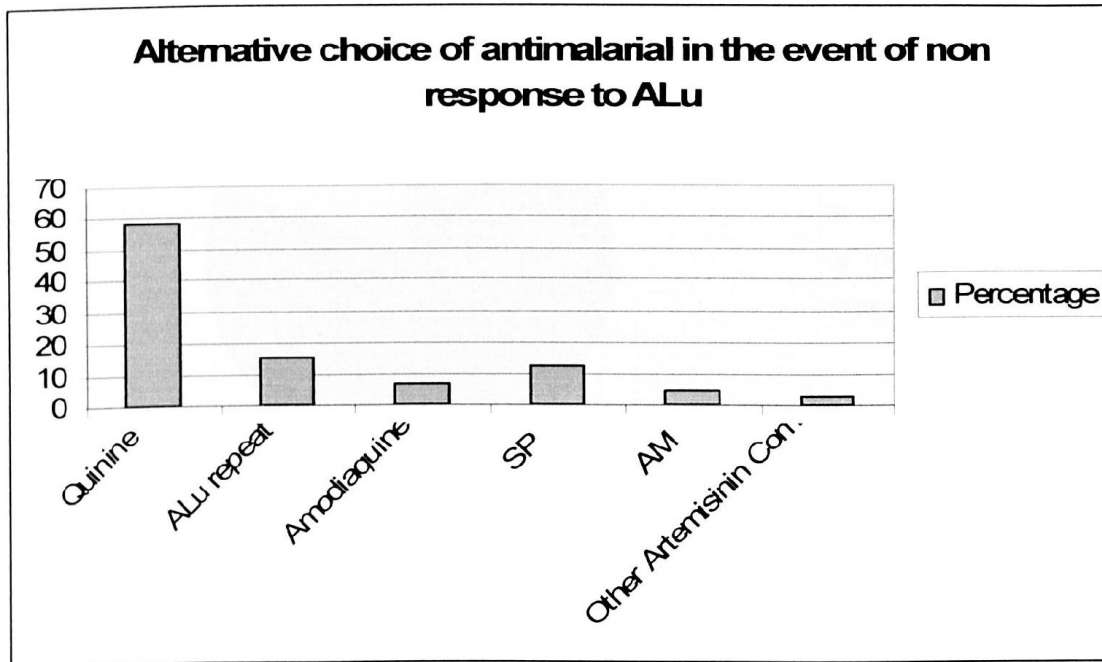
ALu was the most frequently prescribed antimalarial in the government facilities (68.8%) followed by SP (12.5%), Quinine (10.4%) and a very few prescribed AM (6.3%) and Amodiaquine (2.1%). In the private facilities mostly SP was prescribed (37.7%) followed by ALu (24.6%) and AM (14.5%). A few were given Quinine (8.7%) and Amodiaquine (5.8%) respectively.

Figure 4: Distribution of health worker's choice of Antimalarial for uncomplicated malaria by type of health facility.



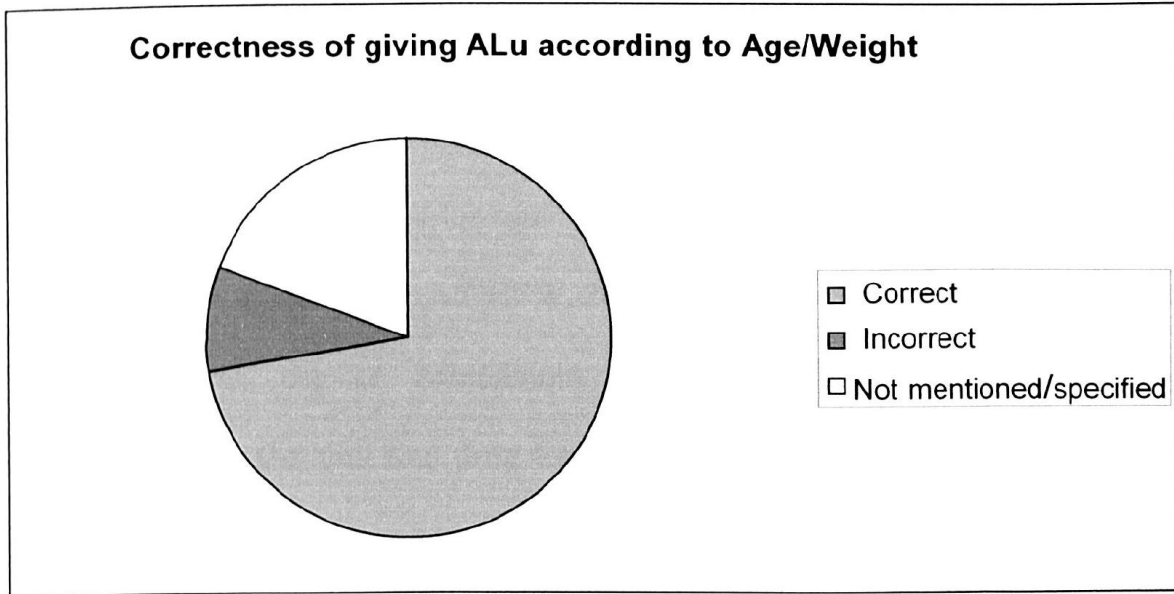
Majority of the health care providers commented on ALu (87%) as their first choice of antimalarial for the treatment of uncomplicated malaria followed by SP (32%), Quinine (18%), AM (14%) and a few commented on other antimalarials such as other artemisinin combinations.

Figure 5: Distribution of health worker's alternative choice of drug in the event of non response to the first line drug.(N=148)



More than half of the health workers (58.1%) commented on Quinine as their alternative choice of drug while the others commented on repeating ALu (15.5%) and giving SP(12.2%) as their alternative choices, a few also commented on Amodiaquine (6.8%) and AM (4.7%) as their alternative choices.

Figure 6: Distribution of the frequency of Prescriber's correctness of giving the first line drug in accordance to age/weight.(N=83)



Out of the 83 patients given the first line drug, it was noted from their treatment cards that 72.3% of them were given the dose of ALu correctly according to their weight or age while a few were given the dose incorrectly (8.4%) and in 19.3% the dose was not mentioned at all.

CHAPTER FIVE

5.0 DISCUSSION

The guiding principle of an antimalarial drug policy is to promote safe, effective and acceptable malaria treatment at the same time encourage rational drug use and minimise the development of resistance (MOHSW, 2006). With the change in the malaria policy in Tanzania to the use of Artemisinin based combination therapy, Artemether-Lumefantrine as the first line drug for the treatment of uncomplicated malaria, this study aimed at investigating how this drug was being deployed by the health workers and how did they fare in their acceptance and usage of this drug.

The study focused on their awareness, knowledge and perception as well as their prescribing and dispensing practices in relation to the new combination, it also looked at the availability of this drug, other antimalarials and the new guidelines in the facilities. The proportion of the health workers who had undergone training on this new chemotherapy was also accounted for.

Most of the health workers were aware that the malaria policy had changed although when asked as to when it was changed about three quarters knew that it was less than a year ago. Since the Ministry of health and social welfare had conducted training to the journalists and especially the editors so as to ensure that the public was well informed about this new treatment policy (Daily News, 25/4/2007), Public health education

through mass communication using the radios and the newspapers could have very well contributed to that.

Training is an essential component to not only ensure that the change in the policy is communicated through but also to ensure that it is well understood and would facilitate proper implementation. Some studies do agree in this favour as was shown by a study done in Kenya that several commonly used interventions for improving HW practices such as in-service training, possession of the NMCP guidelines, treatment wall charts, and supervision were significantly associated with prescribing the recommended treatment (Zurevac *et al.*, 2004).

The findings in this study show that almost a half of the health workers had received training, and a significant proportion came from the public facilities rather than the private facilities (18.4%). Most of these trainings which one had attended were reported to be organised by the MOHSW. Though this was in line with the fact that the ministry had conducted training to health workers at all levels prior to distribution of ALu to all the public health facilities (Daily News, 25/4/ 2007), It was noted in this study that a significantly greater portion of the health workers who had received training were the clinical staff rather than the nursing and the pharmacy staff. Such findings necessitate that the ministry revisit the outcome and ensure extensive training of the other cadres.

When it came to assessing the knowledge of the health workers on the new malaria treatment policy it was seen that 44.8% of them were highly knowledgeable on the criteria and the contra indications in prescribing the first line drug. However when it came to knowledge on the possible side effects more than a half (54%) only mentioned one side effect and a very few (6.8%) mentioned more than two. This could be, probably because majority of the health workers had received very little, if any, complaints of side effects and since the drug use was in its infancy and the guidelines also stated that the overall incidence of side effects to ALu was low (MOHSW, 2006), it might have made the health worker feel that there was no need to report any adverse effects.

Health workers in the government facilities were found to be more highly knowledgeable on the drug ALu, This could be attributed to the fact that majority of the health workers from the public health facilities had received training by the MOHSW. A study done in Sudan may support this explanation. It was noted in that study that, only a half of the health workers knew the recommended dose according to the new protocol to treat malaria as only one tenth were received training on it. Hence there was a tendency of many to stick to the old protocol of prescribing CQ to which they were familiar (Abbas, 2006).

At the same time, findings from the study show that more than a half of the health workers in the private facilities were having low knowledge regarding the new malaria treatment policy. Looking at this there was an urgent need to ensure that the health

partners in the private sector, who also carry the burden of treating patients, were well conversed with the new policy. Otherwise this could be detrimental in efficient deployment of ALu. Leading to non-adherence of the new policy, use of other alternatives and poor communication regarding the proper usage of the drug.

Furthermore, interestingly it was seen that, though 32.6% of the health workers in the public facilities had not received training they were found to be highly knowledgeable on the new malaria treatment, perhaps the availability of ALu in the public facilities would motivate one to be fully aware of the details regarding the appropriate treatment in relation to the new policy.

The use of national guidelines for diagnosis and treatment of malaria is to provide standard management and reference for the care of patients with malaria. In this study when the participants were asked regarding the availability of the guidelines, many in the government facilities reported having received them. However paradoxically in only three facilities out of the thirteen government facilities visited the guidelines were physically seen. The possible explanation could be that most of them did not possess the guidelines individually and at one time or the other the guidelines could be in possession of another or perhaps was kept by the facility in charge, because many commented that they did have access to it and had used it sometimes.

In the private facilities however most of the health workers reported non availability of the guidelines and when verified physically the guidelines were seen in only two of the thirteen facilities, interestingly when having an oral discussion with one of the private facility supervisors at the municipality it was mentioned that the guidelines had also been distributed to the private facilities. Apparently there appears to be some uncertainty in regard to this issue, hence a need to address it in its right perspective.

Availability of ALu was reported to be good in all public facilities as majority claimed that ALu was present in their facilities and in addition when this was verified physically it was seen that almost all the facilities did have the drug available but in some of these facilities some of the pre-packed blisters for different ages/ body weight were missing. However, remarkably it was noted that, despite that being the fact the practice was that other pre- packed blisters were used to compensate for the dosage requirement.

At the same time, reported availability of SP was also found to be high in the public facilities. Its continued use for intermittent preventive treatment during pregnancy may necessitate its availability, but this could hinder effective implementation of phasing out SP and using ALu implicitly as the first line drug by the health workers. As many, may have still have preferences for the former drug.

In the private facilities ALu as Coartem was present in few facilities, this could be because Coartem is a very expensive drug, costing in the range of 10,000 – 12,000/= to

the patient and not subsidised by the government as in the case of ALu (300/=) hence an expensive antimalarial for facilities to keep as well as majority of the patients using private facilities to afford. In this respect many health workers in the private facilities actually commented that they did not implement the new policy in their facilities because the drug was expensive for patients in private to afford and that to ensure availability of these drugs, the prices for private facilities should also be subsidised. A study done in Sudan showed a similar scenario where for dispensaries getting their supplies from the private market had a tendency to provide cheaper drugs that the patients could afford and hence avoid drugs such as Artemisinin based combinations, and thus there was weak adherence to the national protocol (Abbas, 2006).

In the past effective policy changes have been with much difficulty especially when the recommended drugs are viewed with much perceived threats or in terms of individual experiences of successes or failures of the drug, as was shown by a study done in some rural communities where, when CQ was being phased out as the first line drug for uncomplicated malaria in Tanzania, people feared adverse reactions from SP and projected a lack of confidence in the drug because of its slow ability of reducing fever. Not only did the public demonstrated lack of confidence in the drug but some of the health workers also expressed obvious fear and negative perception about SP drug. (Nsimba, 2006).

However majority of the health workers who participated in this study strongly agreed that ALu should be used as a first line drug rather than SP. And when asked for their opinion, many of the respondents who were prescribing the drug especially in the government facilities were very positive about the drug and felt that it was a good medicine and its use should be continued. However their main concern was that the tablets were very many per dose and would affect the compliance of the patient. Indeed a minority did complain that some of the patients did not recover fully when given ALu and had to come back for treatment .Reflecting on this, could be, that since the dosage regimen is long and after feeling a little better the patient may not finish the required dose or due to the complexity of the dosage timings may not partake the medication as is required. If such was the case then more emphasis should be put on educating the patient and ensuring that the dosage was taken in a right way and the dose completed.

Although a positive attitude on the part of the health worker may reflect on the possibility of the first line drug being prescribed as recommended, the patient's knowledge on the correct use of the drug is a very important aspect to ensure the therapeutic efficacy and the rational use of the drug. When the exiting patients in this study were asked to explain the instructions given to them regarding the usage of the drug, the findings show that more than a half of them were not able to explain them correctly. Effective use and adherence to a drug use, does depend on how well the message is imparted to the patient, a study done in Uganda on adherence to Artemether-Lumefantrine for treatment of uncomplicated malaria showed high levels of adherence

and it was pointed out that one of the factors which could have contributed to this was giving clear correct instructions to the patients (Fogg *et al.*, 2004).

However this study also had a limitation that the dispensers were not observed directly while giving instructions so the patient's level of understanding and education could have compromised on the fact that the message was not efficiently received. This was also highlighted by the findings in the same study mentioned above (Fogg *et al.*, 2004). But again the bottom line is that the patient is the final user hence it is very important that the drug is correctly understood by the user.

The guidelines also recommend that the drug should be taken with fatty meals to enhance absorption (MOHSW 2006), co administration of Artemether-lumefantrine with a relatively small amount of fat ensures maximum absorption of Lumefantrine component of the drug (Ashley *et al.*, 2007). When the exiting patients were asked, if they were given any special instructions when taking the first line drug more than a half commented that they were not given any, with such findings it becomes necessary that the health worker understands the relative importance of giving these instructions to the patients.

Majority of them were also not told of any possible side effects as even when the health workers were asked if they knew any possible side effects, majority had reported only one and a very few more than two. The argument could be that the health workers had

not yet heard of any significant side effects and since ALu was reported to have low incidences of side effects (MOHSW, 2006) this could be the reason. However since the policy change is in its infancy it would be too soon to say.

The first dose is normally supposed to be taken as DOT under the direct supervision of the health worker as it is instructed by the guidelines (MOHSW, 2006) however majority of them did not take their first doses in the health facilities this was in breach of what was recommended by the guidelines. Although the reasons for not doing so were not asked to the patients.

Furthermore findings from this study show that three drugs Alu, SP and Quinine were commonly given to exiting patients treated for uncomplicated malaria in the public facilities, ALu being the most commonly prescribed drug. A few were also given Artemisinin monotherapies which meant the patients having to buy from outside the facilities. The fact that ALu was being mostly prescribed showed that though the policy change was in its infancy already there was a positive response to the change such that the health workers were adhering to the use of ALu as a first line drug for uncomplicated malaria. This was in contrast to a study done in Zambia in which during the drug transition to Artemisinin-Lumefantrine most clinicians opted for more familiar SP rather than the introduced Artemether-Lumefantrine (Zurevac *et al.*, 2005).

Adding to this it was also noted that when the health workers were asked about their choice of antimalarial for uncomplicated malaria majority mentioned ALu. Practice in the past has been that whenever there is a policy change, adherence in the initial stages is always difficult, as was shown by a study done in Songea Urban on health worker's practices, when the policy changed from CQ to SP, a highly significant percentage of health workers reported continued use of Chloroquine (Tarimo *et al.*, 2007).

With CQ the long use together with its anti inflammatory and antipyretic properties lacking in SP could be a reason (Warrell, 1993). However this time round perhaps because SP has always been viewed with a threat of severe cutaneous and mucocutaneous reactions due to hypersensitivity to the sulphonamide component ie. Sulfadoxine (Warrell, 1993) especially in the background of HIV/AIDS (Raviglione *et al.*, 1988) and perhaps with ALu having no such perceived threats as the incidence of side effects being rated as mild to moderate, commonly involving the gastro intestinal and the central nervous systems and a very minor percentage of rash and pruritus reported (Bakshi *et al.*, 2000) this could have led the health workers to accept the drug more readily and adhere to the recommended prescribing practices.

Availability of the drug could have also contributed to this fact. A repeat cross sectional study done in Zambia showed that facilities where ALu was in stock, the proportion of children weighing 10kg who should have received this drug increased from 22% in 2004 to 59% in 2006 (Zurevac *et al.*, 2007) and adding to this the results from this study also

shows that since many of the private facilities did not have ALu in stock, more of SP and Artemisinin monotherapies were prescribed in respect to ALu.

Again this time around as was noted from this study that majority had undergone training this could have also motivated the health workers to understand the importance of adhering to the recommended standard treatment.

When it came to the alternative choice of antimalarial in the event of non response to the first line drug, majority commented on Quinine. However a few did comment on repeating ALu. This was inline with the recommendations of the guidelines and again quinine with its long term use and its perceived efficacy as studies in the past have shown that, even during the first policy change of malaria treatment in Tanzania Quinine was significantly perceived by the health workers as the alternative antimalarial drug for the replacement of Chloroquine and not SP or Amodiaquine (Tarimo *et al.*, 2007).

Study findings also show that in majority of the cases, for patients who had been treated with ALu, when their treatment cards were reviewed, showed that the dose of ALu was prescribed correctly according to the body weight or their age, this findings were similar to a repeat cross sectional study done in Zambia where the correctness of prescribed Artemether-Lumefantrine was assessed according to the weight-specific criteria and the correctness was found to be very high (81 to 96%) in all weight groups (Zurevac *et al.*,

2007). This could be because majority of the health workers had undergone training on the new treatment policy and especially a significant number of clinical staff had undergone training, hence were knowledgeable on how the drug should be used in each case and thus give the dose correctly.

Disappointingly though, it was noted that in 19.3% of the patients' treatment cards the dosages were not indicated. Such a finding needs to be addressed as soon as possible otherwise successful implementation of the new policy will be difficult. As it is the dosage regimen of ALu is already complex and there is much need to ensure that correct dosages are indicated. Otherwise wrong dosages may lead to the drug, not being used properly and thus leading to resistance. Hindering the ultimate aim of reducing morbidity and mortality due to malaria.

Finally though the study findings may reflect on some of the health workers' practices this study had its limitations considering that the dispensers and the prescribers were not directly observed to verify their practices physically. The facilities were conveniently chosen and the study was done in an urban setting not a pure rural setting hence the findings may not really reflect practices in the rural settings, making it difficult to generalise the practices.

CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSION

The study findings show that on average ALu has been generally accepted by the public health workers, considering that majority have received training, are highly knowledgeable and perceive the use of ALu in a positive way. It is also being prescribed especially in public health facilities where its availability is ensured. However such is not the case in the private facilities where the availability of the drug being expensive is questionable and making the implementation of the new policy difficult. It is to be noted however that the dispensing practices of the health workers need to be improved to ensure rational and efficient use of the drug. Prescribing the recommended drugs effectively and efficiently is one of the determining elements in decreasing the burden of malaria, thus such positive findings with the use of ALu if sustained, may help to decrease this burden of malaria morbidity and mortality.

6.2 RECOMMENDATIONS

- To ensure full implementation of the new malaria treatment policy the government should ensure that ALu should be available in private facilities at subsidised prices. Though the problem with private facilities is that they tend to maximise on profit, thus, if they are to be given ALu at subsidised prices strict vigilance should be kept, such that, this is not the case.
- Constant supervision should be done to ensure that the new policy continues to be effectively implemented.
- Capacity building should be further strengthened to the health workers in the private facilities and other cadres especially the nursing cadre and the pharmaceutical personnel.
- Further studies should be done in the communities to see whether ALu is being used as it is supposed to be and that patients are complying to the dosage regimen to ensure that maximum efficacy of the drug is achieved and to delay the development of drug resistance.
- Since the study was conducted in a more of an urban setting rather than a typical rural setting, more studies should be conducted in such areas so as to get the real picture in that type of scenario.
- Due to complexity of the dosage regimen more emphasis should be put on education to patients regarding the correct instructions on the use of the drug; every dispensing of the drug should be accompanied with an illustrated dosing instructions to assist in better understanding of the drug.

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