# CARE GIVER'S PERCEPTIONS' OF ARTEMETHER-LUMEFANTRINE (ALU) USE FOR THE TREATMENT OF UNCOMPLICATED CHILD HOOD MALARIA AT ILALA MUNICIPARITY

DAR-ES-SALAAM

By

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A dissertation Submitted in partial Fulfillment of the requirements for the degree of Master of Public health of the Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences

August, 2009

## **CERTIFICATION**

The undersigned certifies that he has read and hereby recommends for acceptance a dissertation entitled "Caregivers' perceptions of Artemether-Lumefantrine (ALu) use for the treatment of uncomplicated childhood malaria at Ilala municipality, Dar-es-Salaam" in fulfillment 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: 10 | 11 | 2009

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# DEDICATION

The study is dedicated to my beloved wife Rose and my three children Derick, Doreen and Doris.

#### **ABSTRACT**

Tanzania changed its malaria treatment policy from Sulfadoxine-Pyrimethamine (SP) to Artemether –Lumefantrine (ALu) in January 2007. ALu differ from SP in that it has no syrup formulation and is given in a complex timely schedule with a fatty meal or milk; factors that might induce caregivers to have negative perceptions and therefore poor uptake of the policy change.

This study examined caregivers' perceptions and uptake of ALu for the treatment of uncomplicated childhood malaria in Ilala Municipality.

A facility based cross section study was carried out at the dispensing point of health facilities with sample size of 304 caregivers. Using structured questionnaires, outlet interviews were conducted with consecutive care givers attending to the reproductive child health (RCH) clinics of Ilala district having a child with fever.

Only about a third (32%) of caregivers reported the correct reasons for change for to Alu.

More than a half (53.3%) preferred once daily antimalarial dosing. About two third (65.1%) suggested syrup as the best formulation for childhood malaria. The large majority (86.0%) reported to accept taking the first ALu dose at the health facilities. A large majority (83.5%) recalled and interpreted correctly the instructions given by health workers on subsequent ALu use and dosage schedule and completion at home.

The large majority of caregivers' are willing to take first ALu dose under observation, can recall and correctly interpret dosage schedules. The subsequent timing for dosage schedules, necessity of meal before intake and absence of syrup formulation may compromise uptake of ALu. Further studies are required to examine the actual adherence and compliance to the dosage schedules.

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#### **ABREVIATIONS**

ACT Artemisinin based combination therapy

ALu Artemether-Lumefantrine

BCC Behaveral change communication

CQ Chloroquine

D.o.t Direct observed treatment

EANMAT East Africa Network for Monitoring Antimalarial Therapy

IEC Information Education and Communication

MoHSW Ministry of Health and Social welfare

PI Principal Investigator

RCH Reproductive child health

RA Researcher assistant

SP Sulfadoxine-Pyrimethamine

WHO World Health Organization

#### **CHAPTER ONE**

## 1.0 INTRODUCTION

#### 1.1 BACKGROUND

Malaria infects more than 300 million people each year resulting in more than one million deaths around the globe. About 90% of these deaths occur in Africa, south of Sahara mostly in young children. Malaria is a leading cause of mortality in children less than five years (20%) and constitutes 10% of the overall disease burden in the continent (WHO, 2006).

In Tanzania malaria is still the most common public health problem. It is estimated that between 16-18 million cases of malaria that occur each year result in over 100,000 deaths of which 70% occur in children aged below five years. Malaria accounts for 30% of the national disease burden (MOHSW, 2006).

The greatest challenge facing Africa in the fight against malaria is the development of drug resistance. This 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 to the individual drug (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 25.5% for SP and 12% for Amodiaquine the second line antimalarial (EANMAT, 2004). 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 (WHO, 2000).

The solutions in place to overcome the emergence of drug resistance to mono therapy has been to replace them with Artemisinin based combination which is more efficacious, high cost, long regimen that lead to many challenges to its deployment (White et al., 1996, White., 1999). Hence their full success to effectiveness depends on the fact that people in the community accept their use in treatment of uncomplicated malaria.

Deployment of Atemether-Lumefantrine as a new first anti malarial, treating of uncomplicated malaria in Tanzania is an important step in reducing malaria morbidity and mortality. However this cannot occur unless a high proportional of cases receive prompt and adequate treatment with effective drug. Effective translation of new malaria guidelines into clinical practice is of importance to maximize the potential impact of improving efficacious therapy.

Measuring baseline level of acceptance and identifying possible barriers for non acceptance are therefore important step in improving Alu use in Ilala municipality which is malaria endemic. Such data should permit rational recommendation to be made that can increase the probability of correct use of the treatment, which may help in prolonging the life span of available first line ant malarial drug and increase cure rate in the country(Nsimba, 2006).

#### 1.2 STATEMENT OF THE PROBLEM

The implementation of a new malaria treatment policy requires community involvement through public information education and communication (I E C) coupled with behavior change communication (BCC) strategies toward the new policy (Williams et al., 2004). Information about the new policy regarding reasons for change and dosage schedule must adequately diffuse to the community to make the policy acceptable (WHO, 2004).

However the change to new policy may be complex when the transition takes place in the presence of familiar drugs for which the community has developed trust (Shiretta et al., 2000,. Williams et al., 2004). Thus the change of policy from CQ to SP met a lot of resistance because people were already too familiar with CQ and continued demand for CQ contrary to guidelines (Tarimo et al., 2000, Manyilizu, 2003). One reason for the continued demand for CQ especially for children was the fact that CQ was 3 dose regimen while SP was single dose which made care givers to have the perception that SP is very strong and that's why is given as a single dose, conceivably making them believe that SP would be too strong for children (Tarimo et al., 2001). The other reason for the dislike of SP was the absence of inject able formulation as was the case with CQ. There is the general perception that drugs in inject-able formulation work faster than oral formulation. However other preferred SP simply because it is a single dose regimen as opposed to CQ that needs to be taken in 3 Doses spaced over 3 days (Tarimo et al., 2001).

The change to ALu may face more problem because it has a complex dosage schedule as the 1<sup>st</sup> dose is given under direct observed treatment (d.o.t), 2nd dose after 8hrs in the first day

while subsequent doses are given twice a day for the next two days making a total of six doses (MoHSW 2006). The short half life  $(t_{1/2})$  of Artemether is a risk for re-infection in high transmission areas that might make client perceive that ALu is not effective (Bukirwa, 2006). Further more the administration of ALu requires a fatty meal and milk which may not be feasible. The absence of syrup and inject able formulation may negatively influence acceptance.

Therefore with all challenges facing ALu much efforts are needed to back down this threat, so if all these are not well addressed may lead to treatment failure and motility due to malaria will increase. It is therefore important to find out Caregiver's perceptions of Artemether- Lumefantrine(ALu) use for the treatment of uncomplicated childhood malaria.

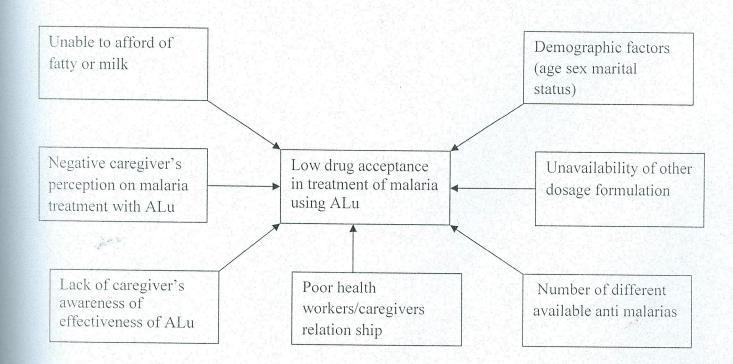
# 1.3 RATIONALE OF THE STUDY

The implementation of the new policy using ALu as the first line drug faces a number of challenges as they occur in an environment with other anti malarial drugs in use. Focus of this study will be to understand the barriers to the acceptance of ALu use for the treatment of uncomplicated childhood malaria. The findings shall be communicated to policy makers for incorporation with IEC materials that focus on care givers counseling regarding perception and acceptance first ALu dose as d.o.t and the necessity of taking subsequent doses with meals and at the given times.

# 1.4 RESEACH QUESTION

- 1. Are caregivers aware of the reasons for change of malaria treatment policy from SP to ALu?
- 2. Were there specific problems associated with SP use?
- 3. Are there specific problems associated with ALu use?
- 4. What are the caregiver's perceptions on the change from a single SP dose to six ALu regimens?
- 5. What are the caregiver's perceptions on child's improvement after taking ALu?
- 6. What are the caregiver's perceptions of taking the 1<sup>st</sup> dose of ALu under d.ot?
- 7. What is the caregiver's perception on the timing for the subsequent dose and the necessity of fatty meal or milk before giving ALu to the child?
- 8. Do caregivers prefer specific formulation of ant malarial drugs for children and why?

# 1.5 CONCEPTUAL FRAMEWORK



#### 1.6 BROAD OBJECTIVE

To assess Caregivers' perceptions of Artemether- Lumefantrine use (ALu) for the treatment of uncomplicated child hood malaria at Ilala municipality, Dar es salaam city.

#### 1.7 SPECIFIC OBJECTIVES

- 1. To explore caregivers perception of the overall change from SP to ALu.
- 2. To explore caregivers perception of the change from a single dose malarial therapy to multiple dose for their children.
- 3. To examine caregivers preference for specific formulation of anti-malarial drugs for their children.
- 4. To examine caregivers perception of taking 1<sup>st</sup> ALu dose under d.o.t.
- 5. To examine whether caregivers receive and understand instruction for dosage schedules and the necessary of having milk or fatty meal.
- 6. To assess caregivers awareness on the necessity of ALu dosage completion.

#### **CHAPTER TWO**

#### 2.0 LITERATURE REVIEW

The previous study pointed out things to be considered when introducing new anti-malarial drugs, the most important being practical aspect of community involvement and acceptability of new ant malarial drug. So strategies which are effective to overcome these problems may be community sensitization approach or strategies such as use of mass media, news, radios and Televisions, but such strategies should carry correct, relevant and short clear messages (Nsimba, 2005).

In 2001 WHO recommended the use of artemisinin based combination therapies as first line treatment for countries experiencing resistance to monotherapy in the treatment of non-complicated malaria.

In recent years there has been a dramatic change of anti malaria treatment guideline, this has been replacing either Chloquine (CQ) or sulfadoxine – pyrimethamine (SP) with artemisinin based combination therapy (ACT). All these were done due to observable malaria treatment failures and the need to prevent further drug resistance (Bosman 2007).

several concerns have been raised with the use of ACT in the community (Charlwood, et al 2004, D'Alessandro et a.,12005), the main concerns being feasibility and acceptability of ACT's, the adherence by care givers and the dosing schemes which is complex, the like hood of increasing and spread of drug resistance and the high cost of ACT's, but the only available efficacy drug that can face increasing drug resistance being ACTs(Pagnon et al.,2005).

Despite good efficacy of ACTs drugs adherence to the therapeutic scheme is poor. Strategy to promote patient adherence would improve drug performance and that might help to prevent the rapid emergence of drug resistance (Souares et al., 2008).

For the successful deployment of ACTs, the issue of patients' adherence needs to be considered (Bloland et al., 2000). Poor levels of adherence are likely to decrease cure rate that expose parasite to low blood drug concentration that may favor the development of drug resistance (White at el., 1996). So measuring baseline levels of adherence and identifying possible risk factors for non adherence was therefore important steps before the introduction of ACTs, and to date there is little evidence concerning adherence to ACTs in Africa (Depoortere et al., 2004).

It is suggested that a systematically short explanation on drug intake to patient at the point of prescription is a simple but important intervention to enhance adherence (Piola etal, 2005).

So rational use of Alu in malaria treatment in children may be more complex because requires precise dosage, acceptance of drug by both children and parents or care takers. And premature discontinuation of medication despite having full course is a major contributing factor to non adherence (Gomes et al., 1998)

# 2.1 ARTEMISININ BASED COMBINATION (ACT)

The main concept of combination of two drugs is the synergistic activities to ward clearing of Plasmodium parasites. And these may improve treatment efficacy, and delay the emergence

of drug resistance. Although the combination are very expensive their advantage over monotherapies out way the cost (Majori, 2004).

#### 2.2 THE NEW MALARIA POLICY

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 which was about 25.5% according to the study done in 2004 which is above WHO recommendation (EANMAT, 2004), in second option the Amodiaquine shows 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 (MoHSW, 2006).

The guiding principal of ant malarial drug policy is to promote safe, effective, good quality, affordable, accessible and acceptable malaria treatment in achieving high efficacy.

#### 2.3 THE PURPOSE OF NEW MALARIA POLICY.

The aim 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.

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.

# 2.4 NEW APROACH OF TREATING UNCOMPLICATED MALARIA.

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 anemia
- 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 Artemether- Lumefantrine. The second line malaria treatment 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. It is also the drug of choice in first trimester of pregnancy, in lactating mothers with children below 5kg and in children weighing below 5kg (MOHSW, 2006).

## 2.5 ARTEMETHER- LUMEFANTRINE (ALu)

An oral fixed combination of 20mg Artemether 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. In addition to that doses of Alu are being taken twice daily for three days. Though for practical purposes to improve compliance it is recommended that the first dose be given as d.o.t 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 dose. And the following are number of tablets classified into four categories: recommended one tablet twice a day over three days for a 5–14 kg patient; two tablets twice a day over three days for a 15–24 kg patient; three tablets twice a day over three days for a 25–34 kg patient; and four tablets twice a day over three days for a patient 35kg and above (MoHSW, 2006).

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, diarrhea and central nervous systems such as headache and dizziness. Prurities and rash was reported in a few patients.

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. A study done on how much fat was required to optimize Lumefantrine oral bioavailability showed that a relatively small amount of fat such as peanuts and breast milk was required to ensure maximum absorption of Lumefantrine (Zurovac et al., 2008).

#### **CHAPTER THREE**

#### 3.0 METHODOLOGY

# 3.1 The Study area.

The study area was in Dar es salaam city, with estimated of 2497940 people (Buereau of statistics, 2002). The study was concentrated in one of its municipality namely Ilala. It borders the Indian Ocean to the east, and Coast region to the west, Kinondoni municipality to the north. Administratively Ilala is divided into three divisions that include Ilala, Ukonga and Kariakoo. It has 22 wards which are Ilala, Mchikichini, Mchafukoge, Kipawa, Pugu, Upanga east, Upanga west, Vingunguti, Chanika, Segerea, Kitunda, Kiwalani, Kisutu, Jangwani, Gerezani and Tabata. Others are Msongola, Buguruni, Kariakoo, Kinyerezi, and Kivukoni.

It has nine villages which includes, Buyuni, Kitunda, Pugu station, Pugu Kajiungeni, Mvuti, Msongola, Majohe, Kinyerezi and Chanika. The district covers an area of 210 sq KM with an average of 637573 people.

Choice of Ilala as study district was because it is the most malaria transmission place in Dar es Salaam, where many activities are done especially along Msimbazi River which provides a lot of mosquito bleeding sites and hence cause emergences of many malaria cases in the area.

# 3.2 Study design and setting.

We conducted a health facility- based cross section study at the dispensing point, using structured questionnaires, outlet interviews were conducted with givers attending to the reproductive child health (RCH) clinics, Hospitals and health centers selected for conducting the study, who met the inclusion criteria.

# 3.2 Study Population

The inclusion criteria for study population were met if caregivers who treated children below five years of age with malaria and given ALu at the health facilities under the study in Ilala district.

## Sample size

\* Number of caregivers at the facility.

Only caregivers with children below five years treated non complicated malaria with ALu chemotherapy were included in the study.

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

$$n = z^2 P (100-P)$$

 $E^2$ 

Where P = Expected proportion of caregivers that would be present at health facilities with children under five years treated non complicated malaria which have a highest rate of treatment with ALu chemotherapy. This is said to be 50% (MoHSW, 2006)

E= 5.7%, margin of error

z = 1.96, standard deviation

n=Minimum sample size of caregivers

$$n = 1.96^2 \times 50(100-50) = 296$$

 $5.7^{2}$ 

So the minimum calculated sample for this study was 296. We interviewed 304 caregivers from three health facilities.

# 3.3 Recruitment and training of interviewers

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

## 3.4 Sampling procedures

## 3.4.1 Selection of exiting patients

A purposive sampling procedure was used, where parents / caregivers with children less than five years attended for treatment of uncomplicated malaria with ALu chemotherapy on the day of the study at the selected health facility were being considered for interview. After receiving drug care giver were asked to participate and directed by a researcher or research

assistant to an area where interview took place. Only those who gave consent were interviewed.

# 3.5 Study variables

- Dosage form, number of dose and frequency
- Caregivers perception on ALu
- Strategy to caregivers on sensitization / mobilization on ALu use
- Number of different available anti malarials
- Caregivers awareness of effectiveness of ALu

#### 3.6 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.

# Correct Alu description of instruction.

This referred to the correctly interpretation of pictorial on blister pack, and correctly recall of instruction given by health workers or instruction written on the blister pack.

## Perception

The individuals feeling / notions concerning the introduction of ALu. Which caregivers are knowledgeable about ALu and experience usually influence individual decision and actions as well as influence others around him/her.

#### Acceptance

The very good appraisal of treatment schedule by care givers, like finding easy administration of ALu to their children, caregivers preference of dosage formulation and being comfortable when their children taking the first dose at health facilities and dosage frequency per day.

# Caregivers

Parents / Guardians of children below five years attending at heath facilities

## 3.7 Pre testing

Prior to commencing study the questionnaires was pre tested in a public health facility in Temeke municipality to check if the questionnaire were 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. There after amendments of the questionnaires was made. The questionnaire was then used for final data collection.

#### 3.8 Data collection.

Three research assistants with medical background and a research experience were recruited and given orientation to the study.

The interview concerned on gathering information on social-demographic profile of both care givers and children and presenting complaints for the children. Also focused on caregiver's perception on commonly used antimalarials drugs on their effectiveness and what could be the reasons for change from SP to ALu as the first line drug in treatment of uncomplicated childhood malaria. Other concerned was on to understand which kind of antimalarial formulation was most preferred for the childhood malaria.

This study also examined whether caregivers accept taking of first dose of ALu at the health facilities, and the questions also focused on examining to what extent care givers understood the given instructions for dosage schedules and necessary of fatty meal during ALu administration at home. This was based on correct interpretation of pictorial presentation of dosage on blister packs and correctly recall of instruction given by health workers about

proper time and meal needed during ALu chemotherapy. The interviews determined whether caregivers had enough information about necessity of dose completion of ALu doses from different sources of in formations. In general the study measured factors that influence ALu acceptance to care givers for the treatment of uncomplicated childhood malaria. Interview sessions took about five to eight minutes, Approximately 8 caregivers were interviewed in each health facility daily. Data collection was done in July 2009 for 14 days.

The principal investigator (P.I) actively participated in the data collection and supervision of the research assistant for quality assurance.

# 3.9 Data management and analysis.

Collected data was edited during and after collection, coded, classified and tabulated to adjust for any missing information and correction of outliers. Data entry was done using SPSS version 13 software program, and the data was cleaned, validated and analysed using the SPSS version 13. Both Univariate and Bivariate were used in data analysis.

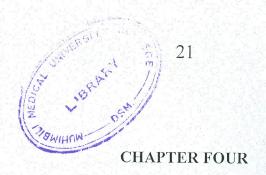
Frequency tables and cross tabulations was computed where appropriate and statistical associations was made for the independent and the dependent variables using the chi square test and the significance level set at p=0.05.

# 3.10 Ethical clearance

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 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 care givers were asked for their consent and told the purpose of the study before asking them to participate in the 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.

#### Limitation

Children below 5kg were not included as they use 2<sup>nd</sup> line treatment which is quinine.



# 4.0 RESULTS

# 4.1: Social-demographic characteristics of study sample

A total of 304 caregivers participated in the study. The social demographic characteristics of respondents are shown in Table 1. The large majority (90.1%) of the respondent were females, and the age group 19-35 years comprised the greater majority (93.4%). Literacy level was very high as 94.4 reported to be able to read and write (Table 1).



Table 1.1: Social- demographic characteristics of care givers. (N=304)

Attribute	N (%)
Sex	
Female	274 (90.1)
Male	30 (9.9
Age in (years)	
≤ 18	10 (3.3)
19-35	284 (93.4)
36-49	10 (3.3)
Ability to read and write	
Able	287 (94.4)
Not able	17 (5.6)
Educational level	
None	17 (5.6)
Primary	167 (54.9)
Secondary	117 (38.5)
College/University	3 (1.0)
Marital status	
Single	34 (11.2)
Cohabiting	79 (26.0)
Divorced/Separated	14 (4.6)
Married	169 (55,6)
Widow	8 (2.6)

The large majority (80.0%) of the children brought by caregivers to the health facilities were aged 0-24 months, the age mostly affected by malaria (Table 2).

Table 2; Social demographic characteristics of the children brought by caregivers at the health facilities (N=304)

Attribute	N (%)
Sex	
Female	151 (49.7)
Male	153 (50.3)
Age (month)	
0-12	165 (54.3)
13-24	78 (25.7)
25-36	27 (8.9)
37-48	23 (7.6)
49+	11 (3.6)

# 4.2: Perception on antimalarial change from SP to ALu.

Fever (97.4%) and malaria (91.5%) were the most common health problems reported by the caregivers respectively (Table 3).

Table 3: Child's reported health problems (N=304).

Reported health problem N (%)	
Fever (hotness of body)	296 (97.4)
Malaria	278(91.5)
Gastro-enteric condition	109 (34.9)
Respiratory condition	102 (33.6)
Low hemoglobin	24 (7.9)
Urinary tract infection	44 (14.5)
Others	1 (0.3)

<sup>\*</sup>Multiple responses.

The majority (97.4%) had experienced a malaria episode in the past three months including the day of interview (Table 4).

Table 4: Frequency of fever episodes in the past three months (N=304)

Number of episodes	N (%)
Once (today)	192 (63.2)
Twice	86 (28.3)
Thrice	18 (5.9)
More than three	8 (2.6)

In a multiple response analysis the antimalarial drug reported to be commonly used were ALu (98.4%) and SP (83%) as shown in Table 5.

Table 5: Commonly used antimalarias (N=304).

*Type of antimalarial	N (%)
Chloroquine	164 (54)
Amodiaquine	211 (69.4)
SP	253 (83.5)
Alu	299 (98.4)
Others	

<sup>\*</sup>Multiple responses

About two thirds (65.5%) of the caregivers held the perception that parasite resistance or ineffectiveness of an antimalaria drug are the reasons for not getting better after treatment (Table 6).

Table 6: Reason for not getting better after taking an anti malarial drug (N=304).

'Attribute	N (%)	
Inappropriate anti malarial drug	46 (15.1)	
Ineffective anti malarial	68 (22.4)	
Parasites resistance	131 (43.1)	
Inappropriate use	102 (33.6)	

<sup>\*</sup>Multiple responses.

All who were interviewed (100%) their child were given Alu as treatment of uncomplicated malaria, where (30.9%) were given antibiotics, and 91.8% were also given antipyretics. Only a third (32.9%) of caregivers reported parasite resistance as the reason that necessitated a change of policy from SP to ALu (Table 7).

Table 7: Care givers reported reasons for the necessity of changing SP to ALu (N=304)-Multiple response.

* Reason	N (%)
SP not good	89 (29.3)
SP not effective	64 (21.1)
Parasite resistance	100 (32.9)
SP not safe	102 (33.6)
Alu more effective than SP	58 (19.1)
Don't know	116 (38.2)

<sup>\*</sup>Multiple responses.

## 4.3 Perception on change from single dose to six doses malarial therapy

More than half (53.3%) of the caregivers preferred an antimalarial drug that is given once.

Only a small percentage (10%) preferred an antimalarial drug to be given more than once per day.

Close to a half (45.5%) of the respondents held the perception that six doses may be more effective than single dose (Table 8).

Table 8: Perceived reasons for antimalarial drug to be given as a single dose or multiple doses (N=304).

Perceived reason	N (%)	
Single dose more strong	32 (10.5)	
Six doses may be more effective	137 (45.1)	
Six doses less effective	42 (13.8)	
Depend on medical advice	30 (9.9)	
Not sure	63 (20.7)	

## 4.4: Preference for specific antimalarial formulation.

About two third (65.1%) of caregivers believed that antimalarial drug in syrup formulation is the best for the treatment of childhood malaria (Table 9).

Table 9: Formulation of antimalarial perceived to be more effective. (N=304)

Formulation	N (%)
Tablets	58 (19.1)
Syrup	198 (65.1)
Injection	18 (5.9)
All equally effective	23 (7.6)
Not sure	7 (2.3)

Majority (69.3%) of female caregivers preferred to give their children antimalarials in syrup formulations as compared to few (43.3%) males that preferred syrup formulations for their children. The difference was statistically significant (p-value<0.05)(Table 10).

Table 10: Relationship between antimalarial formulation preferences with sex of caregivers (N=304).

Sex	Tablet	Syrup (n%)	Injections	All are	Don't	Total (N%)
	(n %)		(n %)	equal (n%)	know (n%)	
Females	45(16.4)	190 (69.3)	15(5.5)	20 (7.3)	4(1.5)	274(90.1)
Males	13(43.3)	13 (43.3)	3(10)	3 (10)	3 (10)	30 (9.9)
Total	58 (19.1)	198 (65.1)	18(5.9)	23(7.6)	7 (2.3)	304(100)
$\chi^2 = 27.58$	p<0.001	df=4				

4.5: Perception of taking 1<sup>st</sup> ALu dose at health facility and subsequent doses at home.

The large majority (85.9%) of the respondents said they prefer taking the 1<sup>st</sup> ALu dose under supervision at the health facilities.

Those who accepted first dose to be given at health facilities was very high (89.1%) in female care givers, and was few (56.7%) in male care givers. Analysis revealed that the difference observed was statically significant (with p-value<0.001) (Table 11).

Table 11: Sex of caregivers in relation to accepting of first ALu dose taken at health facilities(N=304).

Sex	Don't accept DOT (n	%) Accept DOT (n %)	Total (N%)
Females	30 (10.9)	244 (89.1)	274 (90.1)
Males	13 (43.3)	17 (56.7)	30 (9.9)
Total	43 (14.1)	261 (85.9)	304 (100)
$\chi^2 = 23.351$	n<0.001 df=1		

# 4.6 Caregivers understanding of instruction for dosage and necessary of having fatty meal.

The large majority had received and retained the correct information on the timing for subsequent doses of Alu at home (Table 10). Thus the timing for the 2<sup>nd</sup>, 3<sup>rd</sup>&4<sup>th</sup> and5<sup>th</sup> & 6<sup>th</sup> doses of ALu were mentioned at the frequencies of 85.2%, 83.6% and 81.6% respectively(Table 12). This reflects appropriate counseling by health care workers on dosage schedules and corrects interpretation of the pictorial presentation of dosage instruction on the blister packs.

Table 12: Care givers awareness on timing for ALu use at home. N=(304)

Attribute .	N (%)
Timing for 2 <sup>nd</sup> dose	
Correct	259 (85.2)
Not correct	45 (14.8)
Timing for 3 <sup>rd</sup> and 4 <sup>th</sup> dose	
Correct	254 (83.6)
Not correct	50 (16.4)
Timing 5 <sup>th</sup> and 6 <sup>th</sup> dose	
Correct	248 (81.6)
Not correct	56 (18.4)

Most (73.4%) of caregivers were not given any advice on what to do in case of vomiting. For those who got instruction from health care workers about vomiting within half an hour, about (18.1%) were told not to give extra dose, but only (8.6%) were told to give another dose and go back to the hospital for dose addition (Table 13).

Table 13: Type of instruction given in case of vomiting within half an hour (N=304,n=81)

Reported instruction	N (%)
Stop giving more dose	55 (18.1)
Give another dose	26 (8.6)
Did not receive any instruction	223 (73.4)

More than three quarter (78.9%) of the respondent who attended health facilities under study were not given any instructions on best food preferred during Alu administration. Only (14%) was correctly got advice on necessity of fatty meal.

Table 14: Caregivers instructed on type of food to be given when using ALu. (N=304, n=64).

*Attribute	N (%)
Not instructed	240 (78.9)
Fatty meal	44 (14.5)
Milk	44 (14.5)
Carbohydrate	33 (10.9)
Vegetables	31 (10.2)

<sup>\*</sup>Multiple responses.

More than half (53.6%) of care givers held the perception that the appropriate time for giving ALu to a child is soon after a meal (Tabe 15).

Table 15: Caregivers perceived time for giving ALu in relation to meals (N=304)

Time	N (%)
Soon after meal	163 (53.6)
Before meal	13 (4.3)
Not sure	128 (42.1)

The large majority (93.0%) held the perception that antimalaria drug is effective after administration to sick child when fever drops(Table 16). This may be encouraging or discouraging the dosage completion in one way or another. Thus given that ALu has rapid fever clearance, more than three quarters (78.0%) of the caregivers perceived ALu to be superior to other anti malarials.

Table 16; Care givers criteria for judging antimalarial drug work (N=304)

*Attribute	N (%)
Child's condition improves	143 (47)
Child appetite becomes better	154 (50.7)
Fever drops	282 (92.8)
Child well in a week	140 (46.1)

<sup>\*</sup>Multiple responses.

## 4.7: Care givers perception of the necessity to complete ALu dose

The large majority (96.4%) of caregivers said they had already heard information about necessity of Alu dose completion from different media mentioning Radios and Televisions programs referring James and his mother who are given advice at the health facility that it is very important to complete antimalaria doses given. Thus the large majority (95.4%) indicated that there is a need to administer all the doses of Alu prescribed to their children. Only few respondents answered that there is no reason of completing the doses given. The reasons put forward were because the condition of their child improve after 2<sup>nd</sup> dose, other being due to doses too many may harm the child, also they said may keep few for future use, and other thinking was many doses make child to become tired, and lastly said they didn't get any counseling about dosage completion.

## CHAPTER FIVE

#### 5.0: DISCUSSION

This study was undertaken three years after policy change from SP to ALu, and one year after the beginning of implementation activities of that policy. At this time all public health facilities were already being supplied with subsidized ALu of different dosage packages according to the weight of the patient. So health workers and patient were familiar with this new treatment regimen.

## 5.1: Perception on antimalarial change from SP to ALu

Generally fever and malaria was recognized the most common childhood health problem as fever (hot body) and malaria were reported as the most common health problem in the study area. This implies that caregivers would seek for antimalaria treatment for illness presenting with fever (hot body) or perceived to be malaria (McCombie, 2002). The fact that the majority (97.4%) had experienced a malaria episodes in the past three month re-affirm that malaria is a major problem in the area and a change of policy would be welcomed by caregivers. Since this study was conducted in the transition from SP to ALu, the two drugs were still commonly in use. Indeed all caregivers had received ALu for their children. There is a very low (32.9%) knowledge on the correct reasons for change from SP to ALu. This implies that majority of people are not aware on why government changed antimalarial drug which may have negative implication on acceptance.

## 5.2: Perception on change from single dose to multiple dose drugs.

The fact that more than a half of the respondents preferred antimalarial drugs given in once a day dose indicates that they maintained perception based on the previous policy. This implies that they may continue to demand for SP contrary to guidelines (Tarimo et al., 2001). The present doses of Alu are given twice per day for three days. So care givers may just try to give Alu as a single dose simply because the previous antimalarial treatment (SP) was single dose. More emphasize should be put on trying to educate care givers on the differences in dosage schedule between ALu and SP, saying that these are pharmacologically working differently and no way one can mimic the other. The fact that Artemether have a very short lifespan (shot half-life) in human body than Sulfadoxine-Pyrimethamine which has got very long half-life must be addressed so that caregivers understand the importance of taking ALu dose twice daily and the previous SP given once as a single dose. Close to a half (45.1%) of care givers perceived that having antimalarial drug with six doses may be more effective than antimalarial drug with single daily doses that have a positive implication on acceptance. Artemether-Lumefantine is currently the first line antimalaria in Tanzania having six doses to be taken for three days. It means that care givers ought to use Artemether-Lumefantrine whenever their children suffered from malaria believing that the drug having six doses is very effective against malaria

## 5.3: Preference of specific antimalarials formulation

While the most commonly available formulation of ALu is tablets, the majority (65.1%) would prefer antimalaria drug as syrup. This might be contributed by many things which include the ease of administration of syrup to children than tablets which need grinding and

them mixing wifh water before giving to the children, compared to syrup which are already in powder form or liquid form. From pharmacological point of view, syrup formulations minimize the amount of active ingredient lost during administration at home compared to tablet form which needs grinding before giving to children. So if syrup formulation for ALu could have been available the uptake of drug could have increased than what is going on now. Even though caregivers believe tables are effective against childhood malaria. But this observation might have been contributed largely by not having an alternative formulation available so far of Artemether-Lumefantrine drug for childhood malaria. Even WHO said the current used Artemether Lumearine fixed combination when prescribed to infants and small children, has to be crushed and mixed with water, which may lead to the loss of active ingredient and thus under dosing (WHO, 2004). The findings is also supported by study done previously showing poorly tolerated, inconvenient route of administration and complex antimalarials carry a substantial risk of inadequate acceptance, compliance and adherence (Fungladda et al., 1998).

## 5.4: Perceptions of taking first ALu dose at health facilities.

Majority (85.9%) of caregivers accepted the first dose of Artemether-Lumefantrine to be given at the health facilities in the presence of health workers improve adherence and appropriate use as per guidelines provided by Ministry of health and Social welfare (MoHSW, 2006). From the observation at health facilities this could have contributed by condition made so that there was no sharing of cup. This was made possible as caregivers were asked to bring /buy mineral water and use bottle cups as the tool for tablet grinding and mixing with water

before giving to the respective child. This is supported by the study done in Pangani on Assessment of implementation of intermittent presumptive treatment (IPT) using sulfadoxine-Pyrimethamine (SP) for malaria control, where majority (66.7%) of pregnant women refused Intermittent presumptive treatment using SP to be taken at health facilities for the reason of sharing cups during drug administration(Ajuza, 2004).

## 5.5: The extent of understanding dosage instructions and important of fat meal.

Many care givers understood and recalled well the instruction given from health care workers. This could have been contributed by the current ALu blister pack having pictorial presentations showing at what time the drug should be taken, but also the health care workers would commonly write the instruction on the pack in order to emphasize more on the appropriate time to take ALu medication. This could be due to issues concerning counseling about timing of subsequent dose taken at home are now well addressed at the level of prescribers and dispensers. Any future manufacturer of antimalarials should consider the blister pack with pictorial presentation since it has proved to help in easy understanding of instruction given on dose schedule of ALu regimen. Previous studies indicated that the latest WHO-approved blister pack, which contains pictorial instructions on how to take the drug, is very important factor that has been shown to improve understanding of instruction to ALu users (Qingjun et al., 1998). Also a detail verbal explanation given to care givers contributed the easy of understanding and correct recall of instruction on ALu dosage schedule (Okonkwo et al., 2001).

When drugs administered it is first dissolved and then absorbed in the stomach to the blood to make it available for killing malarial parasites. In most cases these processes are effective within half an hour. So when in one reason or another child vomits Artemether-Lumefantrine drug within thirty minutes of administration it should be replaced otherwise it would be considered as a missing dose. The study showed very poor advice on the important of replacing missed dose as a result of vomiting when subsequent doses are taken at home. Health workers failed to give appropriate advice on the issue of vomiting due to absence of extra replacing doses at the blister pack, But the health worker could still advice caregivers that if that happen, caregiver should report back to the health facility to obtain a replacement dose before finishing all six doses.

The study showed very poor advice (14.5%) on the important of fat meal in other word necessity of fat meal for ALu intake was not emphasized by those health care workers at the point of dispensing. But given the prevailing economic situation in the country is a big challenge. Because if fatty uptake was over emphasized it may discourage rather than encourage the use of ALu among the society, and decrease acceptance and which might cause premature discontinuation of ALu medication may cause delay of subsequent doses till the time when such food could be accessed. Fat meal is very important to insure Lumefatrine bioavailability; however pharmacokinetics evidence suggested that only a very small amount of dietary fat is required for lumefantrine bioavailability to be optimal (Ashley et al., 2007). This was proved by studies done previously, where there was an event of varying dietary intake such as during unsupervised dosing of ALu as fat consumption was not controlled (Piola et al., 2005), or in the study where was no specifically advice on fat meal (Mutabingwa

et al., 2005), Which collectively showed the efficiency of ALu doses didn't appear to have been impaired. So the most important to put effort is to advice caregivers that children should strictly take Alu medication soon after meal not in empty stomach. The study indicated majority (92.8%) of caregivers judge the effectiveness of antimalarial being fever on their children drops after administering antimalarial drug. From the pharmacological point of view ALu clears malaria parasite very fast and recovery in term of fever drop can be attained in few hours after second dose is administered. This situation is encouraging for that in use of such treatment. This was supported by study done earlier that rapid clinical improvement under Artemisinin combination therapy (Nosten et al., 2002) may also have encouraged patients to complete the regimen.

## 5.6: Awareness on necessity of ALu doses completion.

Many caregivers had already heard health information about the important of Artemether-Lumefantrine and necessity of dose completion by listening to the various programs in TVand Radios presented by Ministry of health and social welfare, and also through Brochures. The completion of doses in any antimalarial drug including Artemether-Lumefantrine is very important to insure maximum bioavailability sufficient to kill all malaria parasites in the body. However this observation may be affected by very high cure rate of Artemether-Lumefantrine that can drop fever after second dose. Since some caregivers may perceive otherwise thinking that so long the fever has dropped no need of continuing administering of subsequent ALu dose at home.

#### **CHAPTER SIX**

## 6.0 CONCLUSIONS AND RECOMMENDATIONS

#### 6.1 CONCLUSIONS

There is very poor understanding by care givers on the malaria policy change. Health information is needed to clarify about change of antimalarials from SP to Alu , And describe why there was a need for such change to happen.

Finding indicated that majority preferred antimalaria with single dose per day, so caregivers have to be informed on why some antimalarials have to be given twice daily while others once per day and the importance of complying with such instructions.

Many care givers preferred syrup formulation for the treatment of uncomplicated malaria in children. Whenever possible effort have to be done to manufacture antimalarial combination drug with syrup formulation in coming future. This may be accomplished by either talking to international pharmaceutical manufacturers or local manufactures, because the availability of syrup formulation at the health facility may increase acceptance and uptake of such combination drug.

Majority of caregivers accepted the first dose to be taken at health facilities as required by Ministry of health and social welfare. This could have been contributed by condition whereby no sharing of cups during drug administration, it was possible as every caregivers was asked

to by a bottle of mineral water for his/her child. So sharing of water and cups at health facilities is a contributing factor for caregiver to refuse Dot.

There is high understanding of instruction on timing of subsequent doses at home. The presence of blister pack with pictorial description could be the reason behind.

Counseling on the important of fatty meal was not very low. Overloading and lack of appropriate knowledge by health workers may be reason on this issue. Using IEC material with sensitization campaign at different communication media help the appropriate implementation of policy change of antimalaria from SP to Alu. This was proved positive as majority of caregivers had already heard information about necessity of Alu doses completion from different media such as TV, Radio, Billboards and many others.

#### 6.1 Recommendations

There is a need to provide a comprehensive health education package to all RCH clinic stuff so that go hand in hand with education sessions undertaken daily at the clinics. Health education given should focus on what have to be done by caregiver in case of vomiting and important of fatty meal during Alu administration at home.

The government should find the possibility of manufacturing syrup formulation by conducting research in collaboration with international pharmaceutical manufacturer and local manufacturer. Availability of syrup formulation may improve Alu uptake and acceptance by whole community.

Follow-up study should be done that focus on extent of caregivers' acceptance for Artemether-Lumefantrine fot the treatment of uncomplicated childhood malaria and associated factors.

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