Factors influencing community acceptability of Artemether-Lumefantrine drug for treatment of uncomplicated malaria for under five, Dodoma Municipality – Tanzania.

By

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A dissertation Submitted in partial Fulfillment of the Requirements for the Degree of Master of Applied Epidemiology of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for examination of dissertation entitled "**Factors influencing community acceptability of Artemether-Lumefantrine drug for treatment of uncomplicated malaria for under five, Dodoma Municipality – Tanzania"** in fulfillment of the requirements for the degree of Master of Applied Epidemiology of Muhimbili University of Health and Allied Sciences.

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DECLARATION
AND
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I, Faraja Seraphin Lyamuya, 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.

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Lastly, I offer my regards and blessings to all of those who supported me in any respect during the completion of the dissertation.

DEDICATION

I dedicate this dissertation to my husband Erick J. Kitali, my sons Erick and Emmanuel, my parents Dr. S. H. Lyamuya and Dr S. P. Mtweve and my brother Dr F. S. Lyamuya.

ABSTRACT

Background: Tanzania has changed its first line malaria treatment policy in 2006 from SP to ALu due to drug resistance. There is little information from the community on the barriers to the acceptance of Artemether – Lumefantrine for treatment of uncomplicated malaria in children. The main objective of the study was to determine factors that influence parents/guardians acceptance of Artemether- Lumefantrine (ALu)) for the treatment of uncomplicated malaria for children under five years in Dodoma municipality.

Material and methods: This was a cross section study done among parents/caregivers of children under five years of age in Dodoma municipality. A multistage sampling technique was used. We did simple random selection at the level of wards, villages, hamlets (in sub-urban) or street (in urban) and then households. Data collection was through semi structured questions. Data were entered, cleaned and analysed using Epi info software version 3.5.1.

Results: A total of 380 parents/caregivers were studied. Out of 380, 344 (90%) had reported at least one member in the household being treated for malaria in the previous 3 month and there was no difference between urban and sub-urban households [P- value = 0.42].Malaria episode was reported to have occurred 5 times in children < 5 years than in > 5 years and adults [OR 5.25; 95% CI 3.68, 7.46, P- value 0.0001]. Eighty eight percent (335) of caregiver knew the current advised antimalarial and 66% (251/380) of caregiver/parents knew the previous recommended antimalarial. Disaggregated analysis shows that a higher proportion of urban respondents 150/155 (96.8%) knew ALU is recommended compared to sub urban [185/225 (82.2%)] and this difference was statistically significant [OR 6.49 (CI 2.37, 19.1), P-value 0.0001].

The study found 236 (76.5%) of children who were diagnosed to have malaria were treated with Artemether – Lumefantrine. Syrup formulation was the preferred formulation to use by caretakers/parents for children < 1 year and 1 to 5 years [226(59.5%); 163 (42.9%) respectively]

Out of 380, 320(84%) of caregivers/parents had experience with treating a child by using the antimalarial drug ALu, among them 284 (88.8%) of caregivers/parents who had experience with ALu, had the perception that ALu is an effective drug than others for curing malaria. Only 156 (41%) of caregiver/ parents admitted that use of ALu instruction are easy for them to follow and 237 (64%) would prefer to take first dose at health facility.

Conclusion: Malaria is among the commonest disease in children in Dodoma municipality. ALu is the most commonly used antimalarial which might signify acceptability. Moreover, ALu is perceived as more effective antimalarial than other antimalarials. There is awareness of current recommended antimalarial drug. The preference of syrup formulation by caregivers calls for National Malarial Control Programme to explore the availability of pediatric formulations to be used for treatment of uncomplicated malaria in young children as it will have the benefit of improving acceptability. Despite the recommendation of giving first dose at health facility, less than fifty percent of children were given 1st dose at health facility

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ABREVIATIONS

ACT	Artemisinin based Combination Therapy
ALu	Artemether-Lumefantrine
CQ	Chloroquine
MoHSW	Ministry of Health and Social Welfare
SP	Sulfadoxine-Pyrimethamine
WHO	World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Malaria remains a global problem despite various interventions implemented in various countries [1]. Of an estimated 300–500 million malaria episodes worldwide per annum, 90% occur in Sub Saharan Africa, affecting mainly young children and leading to an estimated 750 000 deaths in this age group each year [2].

Malaria is endemic in almost all parts of Tanzania, accounting for 30– 40% of the disease burden (admissions and outpatient attendances) [3]. Malaria is a major cause of under-five mortality and morbidity; an estimated 70,000–100,000 under-five deaths occur annually in the country due to malaria [3].

Chloroquine (CQ) has been used for many years as first line treatment drug for uncomplicated malaria in many sub-Saharan countries including Tanzania [4]. Nevertheless, because of rapid development and spread of resistance to the drug in African countries, countries were forced to change their anti-malarial drug treatment policies to sulfadoxine-pyrimethamine (SP) [5]. However, SP resistance was reported to develop very fast in most places of sub-Saharan countries [6, 7]. Artemisinin-based combination therapies (ACT) particularly Artemether-Lumefantrine (ALu) have been advocated as treatment of choice in Africa in an effort to improve on drug efficacy following the increasing failure rate of a number of other drugs [8, 9, and 10].

In order to ensure prompt and effective treatment to prevent progression to severe disease and death, Forty African countries with endemic *Plasmodium falciparum* malaria have recently changed antimalarial drug policies from ineffective therapies to highly efficacious artemisinin-based combination therapy (ACT); and among them, 21 countries selected artemether-lumefantrine (ALu) as their first-line ACT for uncomplicated malaria [11].

Tanzania changed its malaria treatment policy from Chloroquine to Sulfadoxine/Pyrimethamine (SP) as the first line drug for the treatment of acute malaria episodes in 2001. Evidence from different sentinel sites in the country indicated that up to the time of policy change chloroquine treatment failure had already reached 52% (ranging 28-72%) [12]. However four years later, mean SP treatment failure was reported to be 25.5%. These findings lead to change in the treatment guideline with Artemether – Lumefantrine (ALu) as first line therapy for uncomplicated malaria while Quinine recommended as the second line drug in case of treatment failure or the presence of a contraindication to the first line [13]. Quinine also remains the drug of choice for the treatment of severe malaria and the drug of choice for pregnant women during first trimester and children weighting below 5 kg [13].

Tanzania adopted malaria treatment policy of using Artemether – Lumefantrine as fist line drug in 2004 and implemented it in 2006 [13]. To implement this policy, several key challenges remained: sustainable financing of Artemether – Lumefantrine which are more expensive drugs, improving prompt access through better care-seeking at health facilities, acceptability by the community and ensuring Artemether - Lumefantrine are used appropriately during clinical management.

The recommended method of intake is two daily doses for three days, respecting a strict eight-hour interval between the first and the second dose; also, each dose should be accompanied by a meal so as to maximize lumefantrine absorption [14].

Acceptability and adherence to treatment by patients are major components in the success of any health system and are influenced by individual factors, treatment factors, health facility factors and community beliefs. They are determined by duration of treatment, number of daily doses, speed of clinical response, in particular the antipyretic effect, minor side effects, taste and formulation (tablets, syrup, injectable) of the drug, availability and counseling provided. [15]

Thus it is necessary to study how Artemether- Lumefantrine is accepted by the community as first line drug of treatment for uncomplicated malaria.

1.2 Problem statement

Public health services in Tanzania report 14-18 million clinical malaria cases each year. Health facilities report malaria as the leading cause of outpatient and inpatient health care visits and of deaths especially among children. An estimated 100,000 malaria deaths occur annually in Tanzania.

Designing rational and appropriate antimalarial drug policy does not guarantee acceptability and proper use of antimalarials by providers, dispensers or consumers. Acceptability to users is influenced by past health experiences and perceived effectiveness of drug. New malarial treatment policies that replace drug that have the different dosage regimen and health care practice may fall short of the expectations of care-givers who may re-diagnose the cause of the fever, lose trust to the new drug and resort to alternative treatments. In a study done in Kibaha, Tanzania on policy change from Chloroquine to SP in 2001, the study showed that SP was not preferred by the community due to the fear of severe adverse reaction [16].

One of the factors affecting acceptability of a drug is its dose regimen. Comparing the dosage regimen for CQ and SP, ALu is more complicated as it is administered as a six-dose treatment over 3 days. The familiarity with single SP dose may also have implication on the acceptance of six dose regimen as it may be perceived as too much; and as soon as symptoms subside,

clients may reserve some doses for the next illness or discard the remaining doses. Dose regimen is therefore among the challenges of the health system that may lower acceptability of ALu than with SP [17].

Successful implementation of antimalarial drug policy and effective malaria case management depends on the community perceptions and hence acceptability of the current antimalarial drug i.e. ALu.

1.3 Rationale

In most parts of Tanzania factors that may influence acceptance of the current malaria treatment using ALu among the parents/guardians of children under five years of age has not been evaluated. Studies done in Tanzania on policy change was on previous malaria treatment regimen, reviewing the change from Chloroquine to SP. In 2001, a study done in Kibaha district showed that SP was not accepted by the community [16]. Another study done in 2005 in the same population showed an improved acceptance level by the population. [6] However, a separate study done with quantitative and qualitative component showed negative perceptions about SP, the drug was used in those communities [5].

Information on acceptability and possible factors that might lead to low acceptance and subsequent choice of therapy are important after introduction of a new treatment regimen especially ACT (ALu). Parents/guardians perception on ALu use are important as this will determine compliance and rational drug use practices which may help in prolonging the life span of the available first line anti-malarial drug in the country, and hence increase the cure rates and reduce treatment failures. This will also assist in the formulation of guidelines to improve adherence to treatment and the information will permit recommendations to be made that can increase the probability of correct use of the treatment.

This study will identify gaps for targeting information and education messages on the factors that may influence community acceptability of ALu.

1.4 Study questions

This study aims to address the following questions

1. Which antimalarial drugs are commonly used for treatment of malaria in under five years Dodoma municipality.
2. What is the preferred formulation of antimalarial drugs for children?
3. What is the community perception of using ALu treatment for under five in terms of number of doses, drug safety and clinical improvement

1.5 Objectives

1.5.1 Broad objective

To assess factors that influence parents/guardians acceptance of Artemether- Lumefantrine (ALu) for the treatment of uncomplicated malaria for under five years in Dodoma municipality.

1.5.2 Specific objectives

1. To describe the antimalarial drugs commonly used for treatment of under five years during a malaria episode.
2. To assess community preference of specific formulation of antimalarial drugs according to age categories
3. To assess parents/guardians perceptions on the change from a single dose SP regimen to a six dose ALu regimen
4. To assess community perception on the effectiveness of ALu to cure malaria for under-fives
5. To assess community perception of taking 1st dose of ALu at the Health Facility and subsequent doses at home

CHAPTER TWO

2.0 LITERATURE REVIEW

Intervention study in Nigeria showed people in the community used ALu very well however participant explanations on the use based on illustrations on the pack were mostly incorrect. ALu was perceived to be safe with no report of significant adverse event by the communities. [18] Another study in Nigeria on acceptability of ALu among the patients in private hospitals showed 27% acceptance and 21% acceptance of Artemesinin monotherapy [19].

Study done in Ghana, Nigeria and Uganda in home management of suspected uncomplicated malaria cases showed that most caretakers perceived ACT to be effective in all sites and the proportion of children reported to have experienced adverse events following treatment with ACT was 4–8%, but none of these adverse events were reported to be serious [26].

Study done in Ethiopia to investigate the local perceptions, practices and treatment seeking behaviors for malaria among women with children under the age of five years showed malaria was perceived as the main health problem among children, and most women were familiar with the main signs and symptoms of uncomplicated malaria. Less than 40% of the reported malaria cases among women were treated by public health facilities [20].

Several studies were done in Tanzania on policy change from chloroquine to SP in 2001. Initial study done in Kibaha District showed the drug was not accepted by the community, [21] however, a follow up study in 2005 in the same population showed higher acceptance level by the population [6]. But another study done with quantitative and qualitative component showed negative perceptions about SP. With such a change in anti-malarial drug policy, mothers/guardians had no option except to seek care at the public health care facilities. However, this health seeing behavior by mothers /guardians was accompanied with other consequences related to personal, social and economic problems.

High levels of adherence to Artemether-Lumefantrine has been found to be effective from a study done in Mbarara Uganda. The study suggest that this drug, given in its current WHO formulation, is likely to be very effective in Mbarara and in other regions with high levels of resistance to other antimalarials, provided that clear explanations on how to take the treatment is given to the patient. However, particular attention should be paid to people with a low level of formal education [22].

Study done in Ghana on adherence to malaria treatment for children on use of pre- packed chloroquine tablets verses chloroquine syrup demonstrated that pre-parked tablets are acceptable to caregivers, 90% of caregivers said they found the tablets acceptable, only 76% found them convenient and 65% easy to administer. The adherence with pre-packed tablets was higher than with syrup [23].

The findings of intervention study on adherence to combination therapy done in Rufiji before implementation of ALu in Tanzania showed 75% adherent. The commonest reasons for non-adherence were finished total course of drug earlier [25].

A study done in four countries Benin, Kenya, Mali, Mozambique, and Tanzania on efficacy and safety of ALu comparing dispensable and crushed tablets (which is currently used) found that dispersible formulation is as efficacious as the currently used crushed tablet in infants and children, and has a similar safety profile [24].

A study done in Dar-es-salaam on Community response to artemisinin-based combination therapy for childhood malaria had the following findings: more than two-thirds of the mothers had an overall negative disposition toward SP, 97.5% of them spoke favorably about ALu, emphasizing its ability to help their children to rapidly recover from malaria, without undesirable side-effects. 62.5% of the mothers reported that they were spending less money

dealing with malaria than previously when their child was treated with SP. Mothers' knowledge and reporting of ALu's dosage was, in many cases, inconsistent with the recommended dosage schedule for children [27].

A study done in Zambia on community perspective on the efficacy of malaria treatment options for children between SP and chloroquine indicated that the community was aware of malaria as an illness best treated with modern medicines. Parents appreciated efforts to give medicine at the health facility particularly if child vomit or fought them. Parents said that giving medications in the villages was often problematical [28].

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study area

The study was conducted in Dodoma Municipality, Tanzania. This area was chosen because it has stable to unstable for malaria transmission pattern and therefore prone to malaria epidemics.

Population of Dodoma Municipality is 462,968 with an annual growth rate of 2.3% and underfive children are 69,162 (projected from Tanzania census 2002). It's average day time temperature range from 18°c to 31°c. There is one season of rainfall with an average rainfall of 570mm.

Dodoma municipal has 30 wards, 17 in urban setting and 13 wards in sub-urban setting. Urban setting wards are subdivided into streets and sub-urban wards are subdivided into villages and the villages are further subdivided into hamlets. The wards in Dodoma are classified as either sub-urban or urban. The main difference is in occupation of residents with urban wards having mainly government and private employee/business people while sub-urban settings have mainly peasants with people depending on grapes, sunflower, millet and sorghum cultivation.

Dodoma municipality has 57 health facilities including one national hospital for mental health, one regional hospital, five health centre and 50 dispensaries.

3.2 Study design

We conducted a community based cross- sectional study, using semi structured questionnaires, and interviews were conducted with parents or caregiver of children under five.

3.3 Study population

Parents/guardians of selected under-five children in Dodoma municipality

3.4 Sample size

The sample size estimation for a cross-sectional survey was calculated using Epi Info version 3.5.1. Since current prevalence of caregivers/parents who perceive ALu as an effective drug was unknown, assuming that 50% of parents/guardians will perceive Artemesinin-Lumefantrine has higher ability to cure malaria than other antimalarials, with a standard normal deviate (Z) of 1.96 and degree of accuracy of 0.05, the acceptable minimum sample was 380.

3.5 Data collection methods

Data was collected using interviewer administered questionnaires consisting of closed and open ended questions. Questionnaire consisted of socio-demographic information, history of fever in the preceding 3 month, care seeking behaviors (government/private/others), this information is important to understand caregivers knowledge of antimalarial before assessing acceptability.

3.5.1 Dependent variable

The dependent variable was"**Acceptability of ALu**" and this was defined from the caretakers` history of using the ALU drug on the last episode of malaria

3.5.2Independent variable

The independent variables in this study were:-

- Preferred formulation of the antimalarial
- Perceived clinical improvement after treatment with ALu as compared to other drugs
- Experienced and perceived ALu side effects
- Satisfaction of taking 1st dose under observation
- Knowledge of antimalarial policy change
- Duration of treatment
- Number of doses

Mother/caregivers in households with children less than five years were interviewed if present. If they were absent, appointment was made for next visit. The questionnaire was translated into Swahili and pre-tested.

3.6 Pre testing

Pre testing of questionnaire was done in two wards to check if the questions were well understood by the research assistants and participants, if the sequence of the questions were logical and if there was a need for any modification.

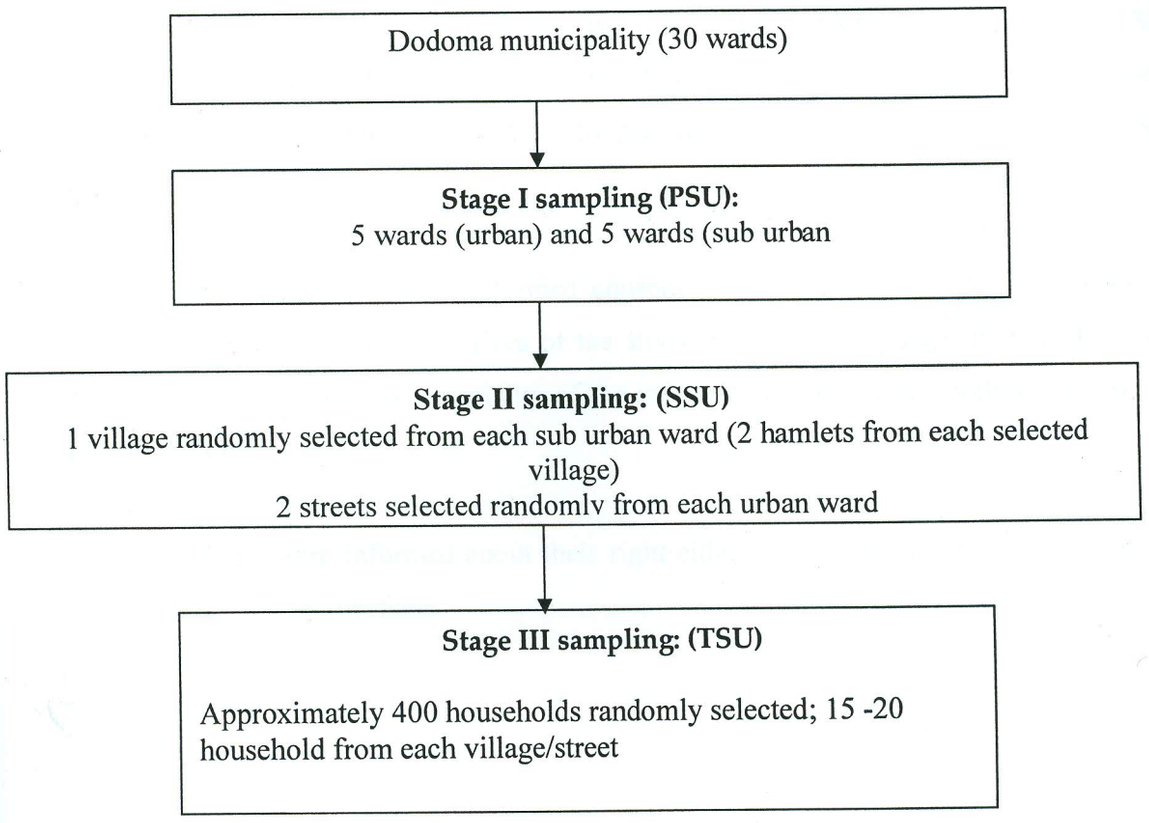
Some of the questions were removed or rephrased and new ones were added. Following this, the need to go to the field with drug samples was added to facilitate recall as well as to ask for past medical records for more correct information the reworked questionnaire was then used for final data collection.

3.7 Sampling technique

A multistage sampling technique using the administrative structure of the Tanzanian districts as sampling frame was used. Wards, villages, hamlets (in sub-urban) or street (in urban) and then households were selected at different stages of the process. The selection was non-proportional to the population size.

Of the 30 wards in the district, 10 wards which are within 10km from center of town are classified as urban and 20 as sub-urban as they are from 10km to 35km from the centre of the town. In the first stage, five wards in urban and five wards in sub-urban were randomly chosen. One village from each selected sub-urban wards was then randomly selected followed by a random selection of two hamlets from each selected village and two streets from each selected ward in urban setting. From each of the selected hamlets or street, list of under five children were obtained from leaders. The list was made in October 2010 for bed net distribution. Using this as a sample frame, 15 children were randomly selected using table of random number. In households with more than one child under five years, the child with the most recent episode of febrile illness was enlisted for the study.

Schematic presentation of the sampling procedure



3.8 Data analysis

Data were entered, cleaned and analysed using Epi info software version 3.5.1. Descriptive analysis was done for the basic demographic characteristics. Proportion of antimalarial drugs commonly used for treatment of under five years during a malaria episode was calculated. Proportions of responses for preference of various formulation of antimalaria for various ages were also calculated. Perceptions as regards to change of ALU, its effectives and whether 1st dose could be taken at a health facility was assessed using open ended questions which were later coded to quantify proportions of responses from respondents. Data from open ended questions were reviewed to identify consistencies and differences; the data were coded then quantified

3.9 Ethical considerations

This study was reviewed and approved by Muhimbili University of Health and Allied Sciences Research Ethical Review Committee. Permission to conduct the study was requested also from the Dodoma Urban district administrative authorities, ward secretaries and leaders of the hamlet.

Prior to the interviews, written informed consent was obtained from all participants after explaining the purpose and objectives of the study in Swahili language. Participation in the study was voluntary and confidentiality of the information was assured both during and after data collection.

The respondents were informed about their right either not to participate, not to answer any question or all of the questions.

CHAPTER FOUR

4.0 RESULTS

4.1 Social-demographic characteristics of respondents

A total of 380 parents/caregivers of children under five years of age were interviewed of which 155 (40.8%) were from urban setting and 225 (59.2%) from sub-urban setting. The median age was 28 years (range 15 – 67). The mean age was 29.5 years. Out of 380, 336 (80%) were mothers, 13 (3.4%) were fathers of children and others were grandmother, grandfather, sisters, aunts or uncles. Table 1 shows the demographic and socio economic characteristics of respondents.

Table1: Social-demographic characteristics of respondents (N=380)

Variable	N	%
Sex		
Female	364	95.8
Male	16	4.2
Age groups		
≤ 15	4	1
16-25	147	38.7
26-35	164	43.2
36-45	45	11.8
46-55	12	3.2
>55	8	2.1
Marital status		
Married	310	81.6
Single	53	13.9
Widowed	8	2.1
Cohabiting	4	1.1
Separated	5	1.3
Level of education		
None	84	22.1
Primary School	228	60
Secondary school	42	11.1
Collage/ University	23	6.1
Adult education	3	0.8
Occupation		
Employed in private/public	29	7.6
Farmer	183	48.2
Business	90	11.3
Rely on parent or partner	78	20.5

A total of 290 (76.3%) of 380 caregivers/parents were able to read and write. Seventy eight percent (296) had primary education or higher education. Seventy two percent of those who do not know how to read and write were from sub-urban setting. Farming was the main occupation for 183 (48.2%) of caregivers/parents.

4.1.1 Social-demographic characteristics of children

Out of 380 children, 197 (52%) were male and the mean age was 28 months, Median age was 27 months (range 2months to 59 months) see table 2.

Table 2: Social-demographic characteristics of children under five years (N=380)

Variable	N	%
Sex		
Female	183	48.2
Male	197	51.8
Total	380	100%
Age groups (in month)		
0-12	86	22.6
13-24	93	24.5
25-36	84	22.1
37-48	76	20
49-60	41	10.8
Total	380	100%

Figure 1: Reported antimalarial drug given during the last fever episode by source of origin (N=310)

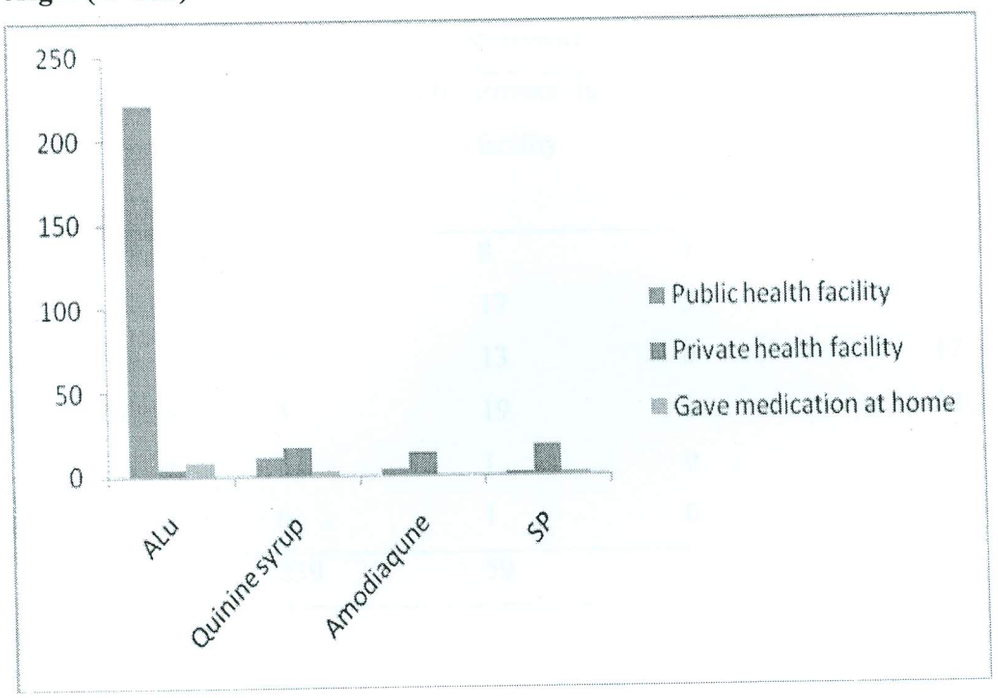


Table 3 shows that most of the antimalaria that were prescribed come from public facilities, followed by private facilities. Few also bought medicine from drug stores

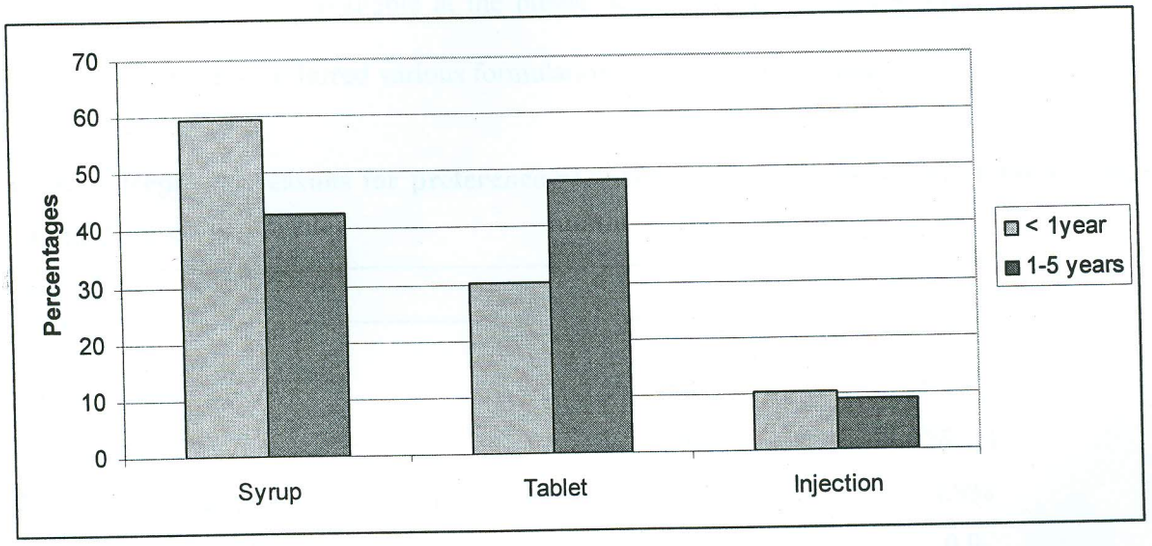
Table 3: Reported antimalarial drug given during the last fever episode by source of origin (N=310)

	Source of the drug			
Variable	Public health facility	Private health facility	Gave medication at home/Drug shops	Total
ALu	221	8	7	236
Quinine syrup	11	17	3	31
Amodiaqune	4	13	0	17
SP/Metakelfin	3	19	2	24
Duo-cortexine	0	1	0	1
Cortexine	0	1	0	1
Total	239	59	12	310

4.3 Community preference of specific formulation of antimalarial drugs according to age categories

Caretakers were asked about the preference of various antimalaria formulations. Figure 2 shows the preference according to age group

Figure 2: Various antimalaria drug formulations preferred according to age categories (N=380)



For children below 1 year, out of 380 caregivers/parents, 226 (59.5%) preferred to use syrup formulation; while for children above 1 year, out of 380 parents/caregivers 183 (48.2%) preferred to use tablet formulation.

4.3.1 Reported reasons for preference of various formulations of antimalarial drugs for children < 1 year

Out of 226 who preferred syrup 154 (68.1%) said that is easy to administer, 59 (26.1%) said is safe to administer to children of this age.

Out of 115 caregivers/parents who preferred tablets 57 (49.6%) said because is the only antimalarial formulation available at the public health facilities. Table 4 shows the reasons why the respondents preferred various formulations for children < 1 year.

Table 4: Reported reasons for preference of various formulations of antimalarial drugs for children < 1 year

Reasons	n	%
Syrup		
Easier to administer	154	68.1%
More safe for children	59	26.1%
Works better than other formulation	11	4.9%
Works faster than other formulation	2	0.9
Tablets		
Able to swallow tablets	1	0.9%
Easier to administer	3	2.6%
Is only formulation available	57	49.6%
Work better than other formulation	51	44.3%
Works faster than other formulation	3	2.6%
Injections		
Children vomit drugs	10	25.6%
Do not like to swallow medication	3	7.7%
Works better than other formulation	17	43.6%
Works faster than other formulation	9	23.1%

4.3.2 Reported reasons for preference of various formulations of antimalarial drugs for children 1 year to 5 years.

Out of 183 caregivers/parents who preferred tablet formulation, 64 (35%) gave the reason that tablets works better than other formulation, 63 (34.4%) said because tablets are only formulation available at the public health facilities. Table 5 shows the reasons why the respondents preferred various formulations for children 1 year to 5 years

Table 5: Reported reasons for preference of various formulations of antimalarial drugs for children 1 year to 5 years.

Reasons	n	%
Syrup		
Easier to swallow	111	68.1%
More safe for children	41	25.2%
Works better than others	9	5.5%
Works faster than others	2	1.2%
Tablets		
Able to swallow drugs	49	26.8%
Child is used to it	1	0.5%
More safe for children	1	0.5%
Only formulation available	63	34.4%
works better than others	64	35.0%
Works faster than other	5	2.7%
Injections		
Children don't want to swallow medication	1	2.9%
Children vomit drugs	10	29.4%
Works better than other formulation	14	41.2%
Works faster than other	1	2.9%

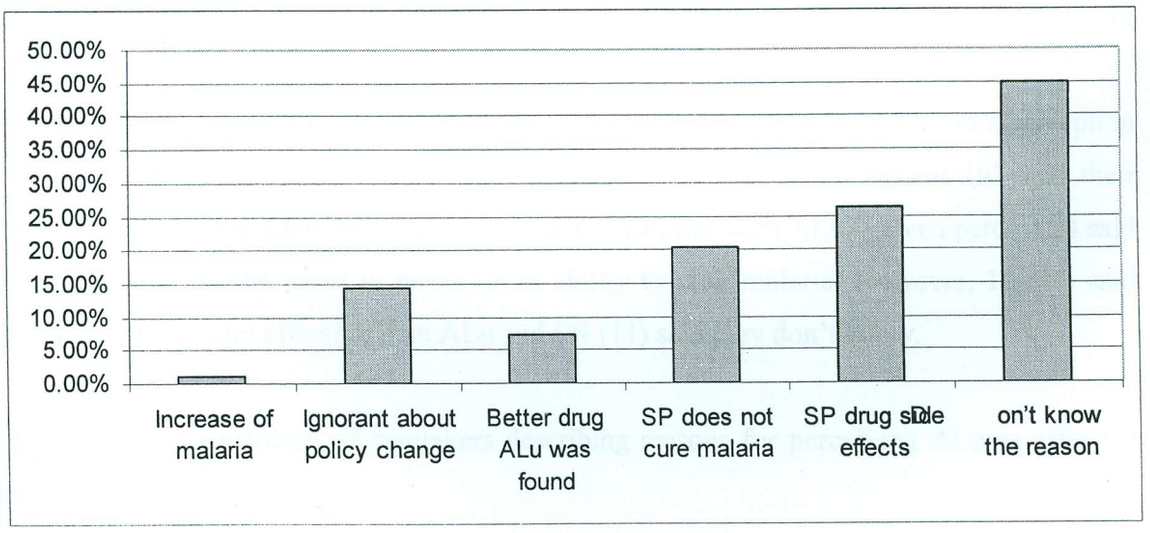
4.4 Perceptions on the change from a single dose SP regimen to a six dose ALu regimen

4.4.1 Perceptions of change of the antimalaria drug

Of 380 parents/caretakers studied, 335 (80%) were aware of the current first line antimalarial for treatment of uncomplicated malaria i.e. Artemether-Lumefantrine (ALu). Sixty six percent (251) of respondents mentioned Fansidar/Metakelfin as the previously recommended antimalarial for treatment of uncomplicated malaria. Disa ggregated analysis shows that a higher proportion of urban respondents 150/155 (96.8%) were aware ALu is recommended compared to sub urban [185/225 (82.2%)] and this difference was statistically significant [OR 6.49 (CI 2.37, 19.1), P-value 0.0001].

Figure 3 shows various reasons mentioned by participants on the reason why SP was changed to ALu.

Figure 3: Perceived reasons for MoHSW to change antimalarial drugs from SP to ALu (N=380)



Of the 380 caregivers/parents , 100 (26%) held the perception that SP side effects prompted the Ministry of Health and Social Welfare to change first line drug to ALu. Less than a quarter 77 (20%) had a perception because SP was not able to cure malaria. About 171 (45%) did not know the reason and 25 (14.5%) did not know if there was antimalarial drug policy change at all.

4.4.2 Preference of antimalarial drug to be given as a single dose or multiple doses

Out of 380, 279 (73%) of all caretakers/parents would prefer to take any antimalarial regimen which has more than one dose. Some of the reasons given were multiple doses works better than single dose and SP had side effects because it was given as a single dose How ever only 191 (50%) responded multiple doses of ALu should be continue given as it is in the current regime..

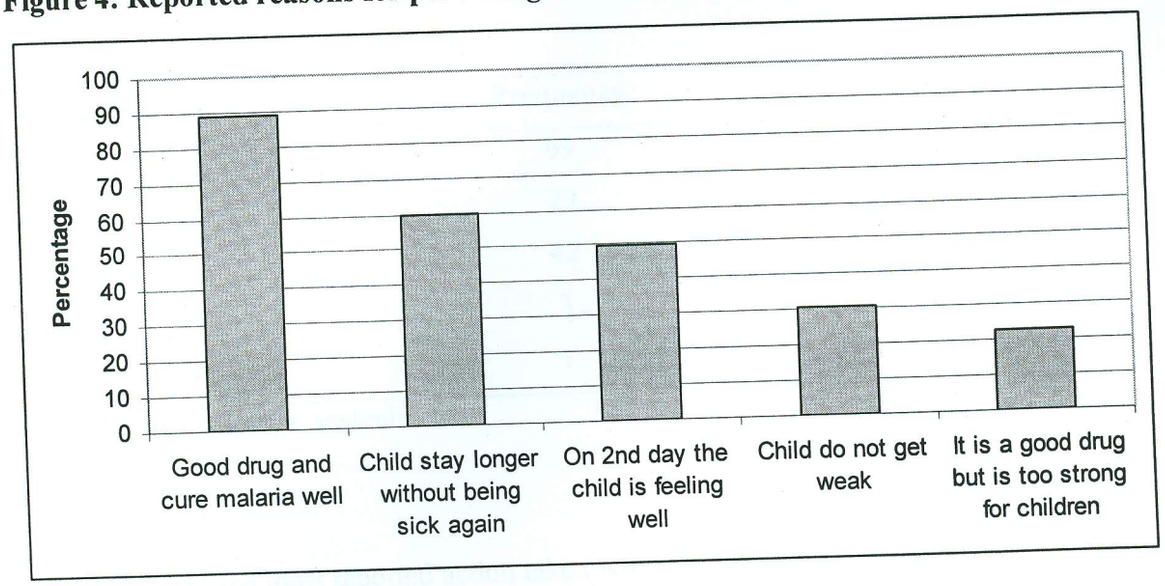
4.5 Community perception on the effectiveness of ALU to cure malaria for under fives

Out of 380, 320 (84%) of caretakers/parents had experience with treating a child by using the antimalarial drug ALu and 271 (71%) had experience with at least one of the following antimalarial Metakelfin, Fansidar, Amodiaquine, Quinine or Chloroquine. More than half of the respondents (221/380) had experience with both ALu and at least one of the above mentioned antimalarials.

Of these 320 caregivers/parents who had experience with ALu, 284 (88.8%) had a perception that ALu is an effective drug than others for curing malaria. Sixty percent 192 said their children stay longer without being sick again after treatment with ALu. Eleven percent 24 said all antimalarial are the same in terms of its ability to cure malaria. However, 11(5%) said Quinine syrup is more effective than ALu and 5% (11) said they don't know.

Figure 4 shows percentage of caretakers describing reasons for perceiving ALu as effective antimalaria

Figure 4: Reported reasons for perceiving ALu as effective antimalaria (N=320)



Among 320 caretakers/parents who had experience with ALu, 102 (31.9%) reported their children had problems during treatment; 69 (67.6%) of them mentioned increase body temperature after intake of the first dose and other mentioned body weakness, vomiting, rashes and sores in mouth. Table 6 describes experience encountered after using ALu in the treatment of malaria

Table 6: Mentioned experience encountered after using ALu (N=102)

Experience encountered	Frequency	%
Increase body temperature	69	67.6
Body weakness	29	28.4
Vomiting	42	41.2
Rashes	3	2.9
Sores in mouth	1	0.9

N.B Multiple response analysis

Table 7 shows the most reported action taken when a bad experience with ALu was observed. The frequent reported experience was to continue with medication (62.7%) followed by reducing dose to half (34.3%) as shown below

Table 7: Mentioned actions taken when a bad experience with ALu encountered (N=102)

Action taken	Frequency	%
Continue with medication	64	62.7
Stop medication	21	20.6
Sent child to hospital	14	13.7
Reduce dose to half	35	34.3
Gave Paracetamol	46	45

N.B Multiple response analysis

4.6 Community perception of taking 1st dose of ALU at the Health Facility and subsequent doses at home

About 153 (40%) of the 380 caretakers/parents normally receive their fist dose at the health facility and subsequent doses at home among them while 34(22%) said their children got the first dose at the health facility because their children had high temperature.

Out of 380 parents/caregivers, 237 (62%) would prefer to take first dose at health facility. Thirty percent 114 prefer to take first dose at home, among them 92 (80%) gave the reason that at home they would prefer to give their children food first before medication. About 134 (35%) said ALu instructions are easy to follow; however 50 (37%) of the 134 would like the time of giving the medication to be written on the pack.

Table 8 shows mentioned reasons by respondents for preference of taking first dose at the health facility.

Table 8: Mentioned reasons for preference of taking first dose at the health facility (N=380)

Reasons	n	%
Get better instruction on following dose	95	40.1%
Get early treatment	81	34.2%
Home is far from the health facility	30	12.7%
If the child vomits they get more drugs	11	4.6%
In case a drug give a child problem to get help	20	8.4%

4.7 Other findings

This study also found that caregivers (5 of them) did not attend any health facility and they gave ALu leftover from previous prescriptions, as after recovery, drugs were kept for anticipated future malaria episodes. This practice is likely to occur more frequently with ALu treatment, as patients are more likely to recover quicker and therefore less motivated to complete the full course of treatment and may result to drug resistance.

CHAPTER FIVE

5.0 DISCUSSION

This study found that more than ninety percent of house visited had a member who was treated for malaria in the past 3 months however there was no significant different between people living in urban setting classified as stable for malaria transmission and sub-urban setting classified as unstable for malaria transmission Over three quarters of children who diagnosed to have malaria were treated with Artemether – Lumefantrine mostly from public health facilities.

This study found that the factors that may influence acceptability of ALu include the drug formulation which is easy to administer, perceived effectiveness of the drug, less side effects and number of doses in the regimen. In a qualitative study done in south west Nigeria on the feasibility and community perception on effectiveness of ALu, caregivers, were found also to be very receptive to the new drug ALu and factors cited included also perceived effectiveness and less side effects [18] Knowledge on the reason to change first line antimalaria was not found to be important as majority of caregivers did not know the reason of the antimalarial policy change but they are giving the new drug to their children and talk favourably about the drug.

A high proportion of caregiver were aware of the current advised antimalarial (ALu); however disaggregated data show a higher awareness as observed in urban population than sub-urban population. More than eight percent of caregiver/parents perceive ALu as effective drug than other antimalarial and would prefer to take any antimalarial regimen which has more than one dose; however only half of them would want the current multiple doses regimen of ALu to continue. Less than half of caregivers admitted that use of ALu instruction are easy for them to follow and most prefer to take first dose of antimalarial at the health facility.

5.1 Antimalarial drugs commonly used for treatment of under five years during a malaria episode.

This study found that there are alternative drugs for treating uncomplicated malaria apart from ALu and these include Artemether monotherapy, SP/Metakelfine, Amodiaquine and Quinine syrup. These alternative products are in contrary with the National Malaria Policy Guidelines which recommend ALu as the first line and Quinine injection as the second line. In Tanzania, thee public health facilities and private retail sectors are important complementary sources of antimalaria treatment especially in rural areas. In the study done by Goodman C *et al* on retail supply of malaria-related drugs in rural Tanzania showed 98% of drug shops had antimalarial including Quinine, SP and Amodiaquine [29]. On the other hand, this study found ALu to be predominantly in public health facilities than private facilities, a factor which has been found to affect accessibility of ALu in rural community as cited in a study done in Ifakara [30]. This study was done in urban and semi urban areas where public health facilities predominate. Moreover, in Dodoma the accredited drug dispensing outlets (ADDO) have not yet started so the availability of the ALu from the drug shops is limited.

In this study, ALu was found to be used by majority (76.5%) caretakers for treating malaria for their children; moreover this study also found that most caretakers/parents (72.6%) send their children to public health facilities when they are sick. The reason might be that in all public health facilities in Tanzania, underfive are treated free of charge and that there is availability of ALu. This might explain the high proportions of caretakers/parents who had use ALu in treating their children.

This study also found that the source for antimalaria includes drug stores; which suggests that self-treatment of febrile children with a store-bought anti-malarial in Dodoma region is not uncommon. However, the proportion of caretakers/parents who self treat their children were low (3.9 %) suggesting this was not a common phenomenon. This observation is consistent with findings of recent studies in Tanzanian, which have reported there is a noticeable reduction among the people of Tanzania to use a store-bought anti-malarial to treat childhood

malaria as a first resort [25]. However SP and ALu are not over the counter drug as it was with CQ.

Of particular importance was also a finding that caregivers/parents (5.2%) would prefer to check for malaria parasites even in private laboratories before seeking treatment. This finding is consistent to a study done in Dar es Salaam, which also showed that participants were pleased when their children are tested to confirm that they had malaria before prescribing ALu [28]. Thus, blood test for malaria before prescription might be a reason to improve caretaker's acceptability of ALu.

5.2 Community preference of specific formulation of antimalarial drugs according to age categories

This study found that syrup antimalarial formulation is preferred by caregivers/parents for their children under one year of age and tablets formulation for their children one year to five years of age. Among those who preferred tablets to other formulation, it was explained that it is the only formulation available for free in the public health facilities as such this may mean that if they had no choice to other formulations preference. This is an important finding because problems with drug administration may influence acceptability. In a systematic review and meta-analysis of studies on drug formulations of artemisinin combination therapies for treatment of children with malaria showed tolerability is improved by paediatric formulation. [31]. Basing on the results of this study on formulation preference, there might be need for alternative formulations that offer increased easy of administration and compliance for infants and children.

In general, in this study, parents/caregivers perceive syrup formulation is safer for children. However studies done in four countries Benin, Kenya, Mali, Mozambique, and Tanzania on efficacy and safety of ALu dispersible tablets and crushed tablets which are used widely currently showed similar safety profile between dispersible tablet and crushed tablet [29].

5.2.1 Dispersible formulation Vs Syrup formulation

Artemether- Lumefantrine paediatric formulations available include syrups, suspensions and dispersible tablets [32].This study did not evaluate the preference of dispersible tablets because it was not available to the community during the study. This study showed syrup formulation is preferred by caregivers because of easy administration but this formulation need volume measurement which may result to inaccurate dosage and result to parasite resistance.

Syrup, suspension and dispersible formulations are easy to administer for infants and children as documented in the review paper on dispersible formulations of ALu [24]. Dispersible tablets have the advantage of accurate dose to be contained in the tablet and require small amount of water for dispersion [32].The packaging of dispersible tablets can be adapted from the current crushed tablets and instruction for use be build on the existing understanding of the caregivers [32]

In a study done in Ghana comparing adherence of chloroquine syrup and chloroquine pre-packed tablets showed adherence was good with pre-packed tablets than with the syrup. Caregivers responded that labeling of pre-packed tablets made it easy to remember the dosage, and that administering the dissolved tablet was easier because the volume was less. [33]

Pre-packaging of dispersible tablets and pictorial illustration are not enough for proper drug use by the caregivers verbal instruction and training on how to use the drugs for better understanding is important. [18]

5.3 Parents/guardians perceptions on the change from a single dose SP regimen to a six dose ALu regimen

Majority (80%) of the parents/caregivers knew the current recommended antimalarial for uncomplicated malaria, fewer knew the previous recommended drug was SP/Metakelfin. Only twenty percent mentioned the correct reason why MoHSW changed the drug policy. One of the reasons might be due to the awareness campaign concentrating on what is the current treatment rather than why there was change and this might contribute to selected people which were found in this study to still continuing using SP/Metakelfin.

This study found seventy three percent of all respondents would prefer to take antimalarial regimen with more than one dose because they perceive single dose as not effective and associate this drug regimen with drug side effects. Only half of the caretakers however said the current regimen of multiple doses of ALu should continue. On the other hand, this study found that only about 40% saying ALu instructions are easy to follow. This is in contrast to a study done in Ulanga and Kilombero, where 87% of respondents find ALu easier to administer/take than SP. [31]

5.4 Community perception on the effectiveness of ALu to cure malaria for under fives

Focusing on perception of effectiveness of ALu, this study found that more than quarters of the caretakers had opinion that the drug was a good one, cured malaria well and fast, and that children stayed longer post treatment without being sick again.

Our figure obtained here on perceived ALu effectiveness are comparable to a previous study done in Dar es Salaam [27] and another study done in Kilombero and Ulanga in which 87.7% believed that ALu was more effective than SP [34]. Another study from Ghana showed respondents perceived that ALu treatment "worked" definitely "quicker" compared to other treatments [35].

Majority agreed that their children did not experience any significant side effect with ALu. The few who experience side effects cited increased body temperature as one of the commonest side effect observed. This could be possible due to prescription of the antimalarial without antipyretic. In the study done in Dar es Salaam where 85% of study participants were given antimalarial and antipyretic and increased body temperature was mentioned by fewer parents [27]. This study, however, did not ask on the co administration of ALu and antipyretic as Vomiting was mentioned by some parents as observed in other studies which suggested that drug induced vomiting can be improved by use of syrup formulations [24].

This study found rashes as a side effect mentioned by three parents. We however, in this study cannot explain whether the rash proceeded treatment or was actually part of the treatment side effects. Other studies have documented scenarios where the patients presented with rash during treatment and clinical examination revealed that they had other skin conditions [27, 36].

5.5 Community perception of taking 1st dose of ALu at the Health Facility and subsequent doses at home

WHO recommend first dose of antimalarial to be taken under observation to increase first dose efficacy [37]. This study found that, less than half of the caregivers/parents interviewed did not normally receive first dose at the health facility. However, there were few caregivers (30%) who would prefer to take first dose at home, most of them giving a reason that at home they would be able to give food first before medication. Other possible reason might be lack of safe drinking water at the health facility and some they feel they are familiar to the drug as such; there is no need to give their children under observation. Other reason might be due to health workers not giving this directive. Unfortunately this study didn't explore on these factors. These findings are the similar to the findings of a study done in Zambia. [38] The findings of case management in Angola showed that lower percentage of patient receive first dose at the hospital [39].

The importance of giving the first dose at the health facility has been also been cited by Kokwaro et al as they concluded that if a time is written for the next dose on the park eight hours after the first dose, there is quickly achievement and maintenance of the blood concentration of artemether above the minimum effective inhibitory concentration [40].
In a study done in Kenya reported understaffing in health facilities is a barrier to counseling and observation of the first dose [41]. Non-supervision of the first dose is one of the main reason of non adherence [41]. Study done in Zanzibar on adherence to artesunate-amodiaquine combination therapy showed all caretakers of children who were administered the first dose at the health facility had adhered to the treatment [42].

5.6 Limitations of study

This study has several limitations. First this study was conducted in a region with few private health facilities and among a population that is relatively well served by the public health care system, and where people have good access to ACT. Caution must be taken in extrapolating the findings of the study to other regions of Tanzania where there are remarkable differences in population configurations and health infrastructure.

Secondly, the correct measurement of acceptability of drugs like ALU involve longer follow up of patients while they are on treatment; however this study was done during a short duration and hence only the factors that may influence acceptability are documented.

Thirdly, the fact that data are self reported is a limitation due to recall and information biases. We have tried to reduce this by providing antimalarial drug samples for caregivers/parents to recognize. This study did not verify the reports given by mothers/caregivers, we are aware that responses may be due to the phenomenon that patients or caregivers provided answers they thought would be expected or desired by the interviewer.

Lastly, malaria was assessed by symptoms which might be due to other illness, resulting in misclassification problem, however most malaria cases in Tanzania are treated based on the signs and symptoms of the disease.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

This study found that malaria is a problem in most household, more among children under 5 years of age. Most caregivers/parents send their children to the public health facilities and most common used antimalarial is Artemether – Lumefantrine tablets. Artemether – Lumefantrine is perceived as more effective antimalarial than other antimalarials and majority agreed that their children did not experience any significant side effect with ALu. These could be early indicator of acceptability of ALu by caregivers/ parents. Many caregiver/ parents would however prefer syrup formulation for treatment of uncomplicated malaria in children and would want simple instruction be written in the pack. This study also found that there is awareness of current recommended antimalarial drug, however disaggregated data show a higher awareness was observed in urban population than peri-urban population. Although most people are aware of current regimen most do not know the reasons why the change from SP to ALu was made.

Despite the recommendation of giving first dose at health facility, less than fifty percent of children were given 1st dose at health facility.

6.2 RECOMMENDATIONS

6.2 1 Policy

The high burden of Malaria calls for strengthening implementation of preventive strategies including Inside Residual Spray laid down by National Malarial Control Programme for reducing the burden of malaria within the country.

6.2.2 Repackage Health Education on Malaria treatment

Ministry of Health and Social Welfare, through National Malarial Control Programme, to repackage information to address issues of formulation and side effect.

Health care providers need to be better trained to communicate more effectively with mothers whose children have been diagnosed with malaria. This may reduce the number of caregivers who stop the medication due to fever or vomiting which can be due to malaria.

Antimalarial pediatric formulations

ALu suspension or the ALu pediatric dispersible tablet will be useful alternatives for treatment of uncomplicated malaria in young children who takes ALu tablets with difficulties. Easy administration of antimalarial will increase adherence, improve the situation of malaria morbidity and mortality among children and reduce the chance of drug resistance.

6.2.3 Research

There is a need to explore the reasons why the first dose of ALu is not given at the health facilities as instructed in Tanzania malaria treatment guidelines.

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