

**KWAME NKRUMAH UNIVERSITY OF SCIENCE AND
TECHNOLOGY KUMASI, COLLEGE OF HEALTH SCIENCES
DEPARTMENT OF CLINICAL AND SOCIAL PHARMACY**

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**EVALUATION OF THE LEVEL OF ADHERENCE TO THE
ANTIMALARIAL DRUG POLICY BY PRESCRIBERS IN THE
TREATMENT OF MALARIA IN CHILD HEALTH DIRECTORATE AT
KOMFO ANOKYE TEACHING HOSPITAL.**



BY

JOSEPH ATTAKORAH

FEB 2010

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OF MALARIA IN CHILD HEALTH DIRECTORATE AT KOMFO
ANOKYE TEACHING HOSPITAL**

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**A THESIS SUBMITTED TO THE DEPARTMENT OF CLINICAL AND
SOCIAL PHARMACY, KWAME NKRUMAH UNIVERSITY OF
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**IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE
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MASTER OF SCIENCE

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COLLEGE OF HEALTH SCIENCE

FEB 2010

DECLARARTION

I hereby declare that except for references to other authors, for which I have acknowledged, this work is my own and have not been submitted in any thesis for any award.

Pharm. Joseph Attakorah

(Candidate)

KNUST

Signature

Date

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Certified by:

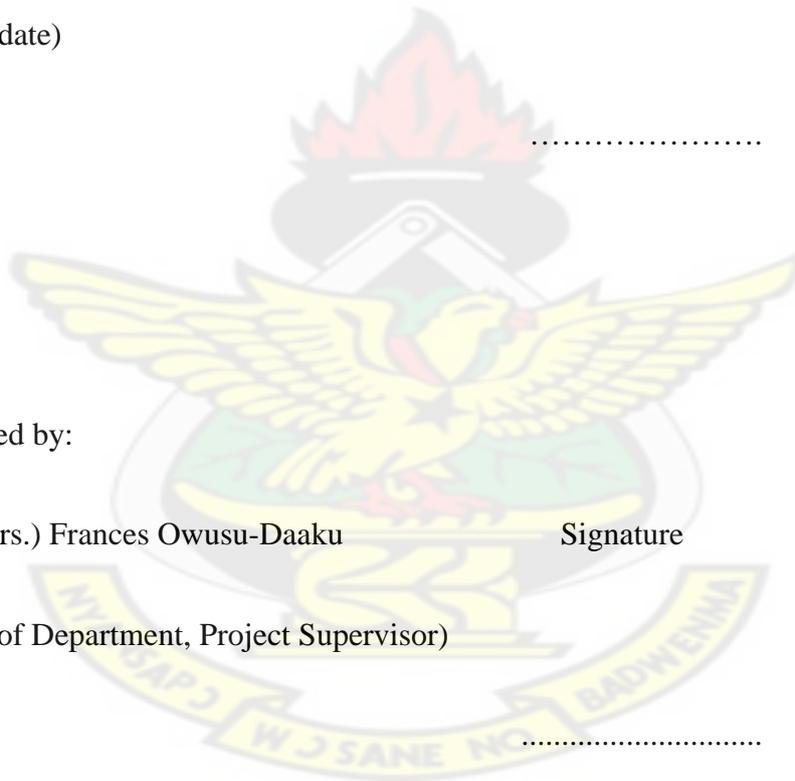
Dr. (Mrs.) Frances Owusu-Daaku

(Head of Department, Project Supervisor)

Signature

Date

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DEDICATON

I dedicate this work first and foremost to Almighty God, because His grace has been sufficient unto me throughout the period of this study.

I also dedicate it to my beloved wife, Mrs. Ivy Attakorah, and my dear mother, Felicia Opoku, for their prayer support.



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ABSTRACT

BACKGROUND

The medicines recommended in the National Drug Policy that was adopted in 2005 for uncomplicated malaria was Artesunate Amodiaquine and that for complicated malaria was Quinine. The aim of this study was to determine the level of adherence by the prescribers at the Child Health Directorate of Komfo Anokye Teaching Hospital (KATH) to the policy for the treatment of malaria.

METHOD: The study design was retrospective, covering a six month period from August 2008 to January 2009. Five hundred paediatric patients aged one month to 14 years who contracted malaria and received treatment at the Child Health Directorate, of KATH was evaluated.

KEY FINDINGS: The ages of the patients ranged from 0.08years (one month) to fourteen years. Sixty percent of the cases were children below five years. Most of the malaria victims were children below five years. The most prescribed anti-malaria drugs for the management of uncomplicated and complicated malaria were Amodiaquine plus Artesunate (90.5%) and Quinine (99.03%) respectively. The mean length of hospital stay for survivors was five days and the percentage mortality was 0.3% (n=1). The dosage form mostly prescribed for the period was syrup, constituting 68.9% followed by injectables (18.1%). The rest were tablets (10.6%) and suppositories (2.4%)

CONCLUSION: the main anti-malarial prescribed for the management of uncomplicated and complicated malaria were Artesunate plus Amodiaquine (90.5%) and Quinine (99.03%) respectively. The level of adherence by the prescribers at the Child Health Directorate of KATH to the anti-malaria drug policy was high. This might have accounted for the high treatment success and the low mortality rate achieved.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND OF STUDY

Malaria is still a global health problem for more than 125 years after the discovery of plasmodium species as the sole cause of malaria. ^[1]

Although malaria has been eradicated from temperate zones, each year an increasing number of travelers from these areas are exposed to the risk of malaria while visiting tropical countries. The risk for travelers to sub-Saharan African countries is estimated to be 1.5% to 2.4% per month of exposure in the absence of chemoprophylaxis. ^[2]

Malaria is a leading cause of child mortality in Africa with one out of every five child deaths resulting from the disease and can also be dangerous in pregnant women. One in every ten deaths during pregnancy in Ghana is due to malaria ^[3].

In Ghana, malaria is still a major problem ^[4] and it is believed to be the most reported disease condition in the hospitals. ^[5] As many as 80,000 children under 5 years die in the country as a result of malaria ^[6] every year. Malaria morbidity in Ghana is about 3.5million every year and 40% of outpatient department attendance. ^[7] An estimated amount of \$760 million is spent on malaria treatment alone every year. ^[8]

Non-immune pregnant women are at high risk of the disease. The illness can result in high miscarriage and cause over 10% of maternal deaths (soaring to a 50% death rate in cases of severe disease) annually.

Semi-immune pregnant women risk severe anemia and impaired fetal growth even if they have no signs of acute disease. An estimated two hundred thousand of their infants die annually as a result of malaria infection during pregnancy. HIV-infection in pregnant women also increases the risk to malaria ^[9]. Economic cost of malaria to Africa is \$12 billion every year ^[10].

In KATH about 250-300 patients are admitted to the Pediatric ward every month and about 20% are laboratory verified malaria. At the outpatient department approximately 40-45% of the pediatric cases are treated as malaria. ^[11]

Malaria treatment before the inception of the anti malarial drug policy had been the mono-therapy drugs such as Chloroquine, Artesunate, Amodiaquine, etc. For over 50 years, chloroquine which is inexpensive has been the most used drug to cure malaria ^[12].

Presently, the world is faced with resurgence of malaria due partly to the spread of strains of the parasite that are resistant to chloroquine and other anti-malaria medicines. Fortunately or unfortunately, many of the malaria medicines that are sold in Ghana are mono-therapies. As of 2005, chloroquine resistance had reached more than 20% and thus compelled the country to change its drug policy. ^[12]

According to the World Health Organization, there are other forms of mono-therapy anti malaria drugs on the market but these are not recommended for use as resistance can easily develop against them. ^[12]

Since 2005, Ghana has changed its treatment policy for management of malaria and now uses Artemisinin-based combination therapy (ACT) in treating uncomplicated malaria and Quinine for the management of severe or complicated malaria. This means that the effective treatment for uncomplicated malaria is an Artemisinin such as Artesunate or Artemether combined with other anti-malarial drug. ^[12]

Other attempts to control malaria infestation has been the use of mosquito nets and Insecticide Treated Nets which the National (Malaria control program) and international bodies (W.H.O) have increased funds to boost its deployment. Even about half of the African countries have waived taxes and tariffs on nets, netting materials and insecticides net. Others have also used mosquito spray in their homes in attempt to control mosquito infestation. ^[12]

Today one of the biggest challenges in controlling malaria is the drug resistance. *Plasmodium falciparum*, one of the parasites that cause malaria has become increasingly resistant to chloroquine which was the most widely used in anti-malarial treatment. ^[12]

Since 1940s, the most common replacement for chloroquine in Africa is Sulfadoxine-Pyrimethamine (SP). The SPs are also rapidly losing effectiveness against the parasite. Due to resistance of malaria parasite to the mono-therapy anti malaria medicines, W. H. O came out with an anti malaria policy for the treatment of malaria. ^[12] The policy's objective is to provide prompt, safe and appropriate anti-malarial treatment to the entire population.

Recent revision of the National Anti-Malaria drug policy (2008) by the Ministry of Health, Ghana, recommended that ACTs will now be re-classified as Over-The-Counter (OTC) medicines. Many people still resort to buying of chloroquine which is a mono-therapy medicine for the treatment of malaria because it is cheap and moreover it had achieved results for them in the past, which due to resistance now, is no longer effective. ^[12]

A number of clinicians still prescribe mono-therapy medicines for the treatment of malaria. Some of the reasons being that, the costs of Artemisinin-based combination anti malaria therapy medicines, as compared to the mono-therapy anti-malaria medicines, are high. For instance, the cost of Coartem (Artemether-Lumefantrine) which is a combination anti malaria therapy is Gh ¢ 8.40 on the Ghanaian market as compared to chloroquine which is 10p (10 pesewes) for the malaria full course. Also some of the adverse effects of the Artemisinin-based combination anti malarial therapy are very severe and unbearable, especially Amodiaquine plus Artesunate to adults, thus putting people off to embrace the anti malaria policy for treating malaria entirely, leading to non-compliance.

A number of pharmaceutical companies' imports mono-therapy anti-malarial medicines encouraging their use, thus defeating the anti malarial policy.

These have caused the Food and Drugs Board to come out with publication banning the importation of the mono-therapy anti-malarial medicines ^[13].

It is in view of this that the study was undertaken to assess the level of adherence to the anti malaria drug policy.

The policy took off between 2004 and 2005 in Ghana. It presupposes that the message in the policy had gotten down well to the people including the prescribers, hence expecting hundred percent (100%) adherences to the policy.

In reality it was not so, in that some prescribers still resort to mono-therapy drugs for the treatment of malaria. Therefore, there was the need to assess the level of compliance to the anti-malarial policy by the prescribers in the treatment of malaria.

The result of this study would be used to educate stakeholders especially prescribers and the policy makers about the state of the anti-malaria policy. If the anti-malarial drug policy is properly adhered to in the treatment of malaria, a significant reduction in morbidity and mortality from malaria would be achieved.

1.2 STATEMENT OF PURPOSE

The purpose of this study was to determine the level of adherence to the Anti Malaria Policy for the treatment of malaria by prescribers in the Child Health Directorate at KATH.

The study also determined the most prescribed anti-malaria drug for the management of uncomplicated and complicated malaria at Child Health Directorate.

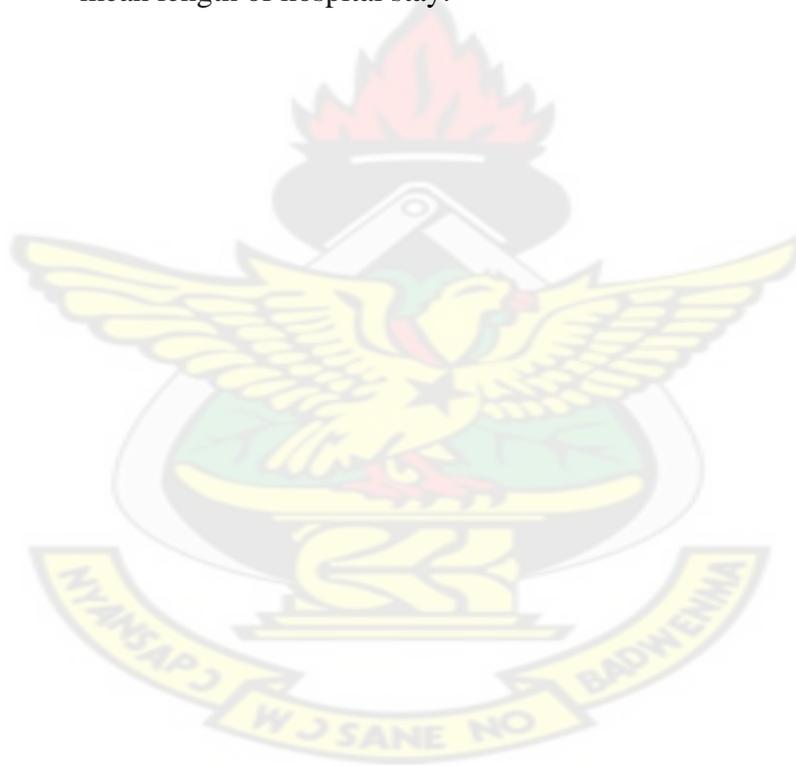
1.3 IMPORTANCE OF STUDY

- ✓ The result could guide the Hospital to improve the management of malaria cases in this era of drug resistance, especially in Child Health Directorate at KATH.
- ✓ It could also help the Procurement Committee in the hospital in the area of drug acquisition, as to which anti-malaria products should be purchased in large quantities and at which dosage form.
- ✓ It could inform the policy makers and stakeholders about the state of the Anti Malarial Policy, whether it is being adhered to or not, and the need for public education.

1.4 OBJECTIVES

- (a) Provide the overview of demographic characteristic of the study and the types of diagnosis of malaria cases encountered at the directorate.

- (b) To determine the kinds of anti-malaria medicines prescribed for the management of uncomplicated and complicated or severe malaria.
- (c) To determine the doses, frequency and duration of anti-malaria medicines prescribed and their dosage forms.
- (d) To determine if prescribers are adhering to the anti-malarial drug policy.
- (e) To determine the prescribers knowledge and awareness to the anti-malarial drug policy for Ghana.
- (f) To make recommendations that would improve malaria patients' clinical care.
- (g) To determine the outcome of patients i.e. discharged or expired, and mean length of hospital stay.



CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 DEFINITION

Anti malaria combination therapy is the simultaneous use of two or more blood schizontocidal drugs (anti-malarials) with independent modes of action and has a different biochemical targets in the parasite.

The concept of anti-malaria combination therapy is based on the synergistic or additive potential of two or more drugs. This is to improve therapeutic effect of the drug and also delay the development of resistance to the individual components of the combination by the *Plasmodium falciparum* which poses a major threat to malaria control. It has been reported from most parts of the world and as a result, mono-therapy (i.e. single drug treatment) available for malaria treatment are either ineffective or has less effect. ^[14]

2.2 RATIONALE FOR THE USE OF COMBINATION ANTIMALARIA DRUGS IN AFRICA

It is currently estimated that 90% of global episodes of clinical malaria and 90% of global malaria mortality occur in Sub-Saharan Africa. Malaria control efforts in the region have been greatly affected by the emergence and spread of chloroquine resistance. This was first recorded in 1979 in East Africa, ^[15] but has now been reported from almost all malaria endemic countries of Africa. Sulfadoxine-Pyrimethamine (SP) was until recently, seen as the obvious successor to chloroquine. ^[15]

However, resistance to SP is developing rapidly even with its current use, thus reducing the useful therapeutic life of this drug. Artemisinin-based combination therapies (ACTs) have been shown to improve treatment efficacy and also contain drug resistance in South-East Asia. ^[15]

ACTs may seem expensive than the traditional low-cost mono-therapy, the mainstay drugs for malaria. Chloroquine and SP have limited lifetime in terms of their clinical

usefulness. These drugs (chloroquine and SP) have been relatively ineffective in Asia for two decades, and rising drug resistance levels have now also rendered them ineffective in many sub-Saharan African countries. ^[15].

2.3 CHALLENGES THAT EXIST IN THE DEPLOYMENT AND USE OF ANTI-MALARIA DRUG COMBINATION THERAPIES

The challenges that exist in the deployment and the use of anti-malarial drug combination therapies in Africa are numerated as follows.

- (1) The costs of anti-malarial combination therapies are over ten times higher than the traditional drugs currently used in Africa. Thus a change to and implementation of combination anti-malarial therapy would involve higher direct and indirect costs to health services, necessitating substantial financial support through higher costs would be out of reach for many developing nations especially in Sub-Saharan Africa.

There are several legitimate concerns about the sustainability of this new policy due to the cost but the change is necessary for effective management of malaria due to the widespread multi-drug resistant strains of malaria parasites in the West Africa sub-region and Ghana in particular. ^[16]

- (2) Although anti-malaria combination therapy is accepted as the rational approach to case management of uncomplicated malaria in Africa, current evidence of its effectiveness within the region is limited. There is also little or no information on the safety and efficacy of combination treatment in pregnant women and young children, which are specific high-risk groups in Africa.
- (3) The operational obstacles to implementation, especially compliance.
- (4) The timing of the introduction of the combination therapy (e.g., should combination therapy be deployed in areas where mono-therapy is still effective).
- (5) The choice of drug combinations best suited for the different epidemiological situations. ^[16]

2.4 W.H.O. RECOMMENDATIONS

Global malaria control is being threatened on an unprecedented scale by rapidly growing resistance of *P. falciparum* to conventional mono-therapies such as chloroquine, Sulfadoxine-Pyrimethamine (SP) and Amodiaquine.

As a response to the anti-malarial drug resistance situation, WHO recommends that treatment policies for falciparum malaria in all countries experiencing resistance to mono-therapies drugs should be combination anti malaria therapies, preferably those containing an Artemisinin derivative (Artemisinin-based Combination Therapy).

The following are the therapeutic options currently recommended by W.H.O.

- ✓ Artemether plus Lumefantrine
- ✓ Artesunate plus Amodiaquine
- ✓ Artesunate plus Sulphadoxine-Pyrimethamine (SP). In areas where SP efficacy remains high.
- ✓ Amodiaquine plus SP in areas where efficacy of both Amodiaquine and SP remain high. This is mainly limited to West Africa
- ✓ Artesunate plus Mefloquine, an additional recommended combination anti-malaria treatment which is reserved for areas of low transmission. ^[16]

2.5 COMBINATION ANTI-MALARIA DRUGS USED IN OTHER PARTS OF AFRICA

The World Health Organization in the mid 1990's recommended change of anti-malaria policy if resistance of anti-malaria medicines reached 25%. During this period, some countries in the Sub-region including Kenya, Botswana, Malawi, Tanzania and South Africa, faced with similar evidence altered their first line anti-malaria therapy due to drug resistance. ^[17]

On August 1, 2001, the Ministry of Health at Tanzania officially changed its malaria treatment from Chloroquine to Sulfadoxine-Pyrimethamine as the first-line anti malaria drug. ^[18]

On January 25, 2005, the government of Nigeria replaced Chloroquine with Sulfadoxine-Pyrimethamine for the treatment of malaria with the use of WHO

recommended Artemisinin-based combination therapy. The selected ACTs in Nigeria now are Co-formulated Artemether/Lumefantrine and Artesunate/Amodiaquine. ^[19]

In Kenya, SP was adopted as first line therapy for uncomplicated malaria in 1998. During the second quarter of 2003, there was convincing evidence that SP was failing and had to be replaced with Artemether plus Lumefantrine as the recommended first-line therapy. ^[17]

In Cairo (Egypt), the Ministry had adopted Coartem which is Artemether plus Lumefantrine as the first-line drug in the treatment of uncomplicated malaria. ^[17]

2.6 THE ANTI-MALARIA DRUG POLICY IN GHANA

A national multi-sector task force formed in 2002 by Ghana government in response to the high and ever increasing levels of chloroquine resistance which was approximated to 23.2% in the country reached a consensus with stakeholders to change the first line treatment in Ghana which was chloroquine.

In 2002, Ghana adopted the new anti-malarial drug policy based on ACTs and for the choice of drugs, the country strategically selected Artesunate plus Amodiaquine as the first line on account of its potential for production by the local manufacturers among other factors for the management of uncomplicated malaria and Quinine for the management of severe or complicated malaria. ^[20]

ACTs RECOMMENDED IN GHANA

The following ACTs are currently recommended for use in Ghana on the basis of availability, efficacy and safety.

- ✓ Artesunate plus Amodiaquine
- ✓ Artemether plus Amodiaquine
- ✓ Dihydroartemisinin plus Piperaquine ^[21]

Details of the two most widely used combinations anti malarial therapies in Ghana are summarized below.

ARTESUNATE + AMODIAQUINE

Efficacy and Advantages: Better efficacy than Amodiaquine alone (cure rate >90%) and well tolerated

Disadvantages: Neutropenia; Pharmacokinetic mismatch

Dose: Artesunate 4mg/kg and Amodiaquine 10mg base/kg once a day for three days

Status: Approved ^[21]

ARTEMETHER + LUMEFANTRINE

Efficacy and Advantages: Effective and better tolerated, as Artesunate plus Mefloquine; No serious adverse reactions documented.

Disadvantages: Irreversible hearing impairment

Dose: Artemether 1.5mg/kg and Lumefantrine 9mg/kg at 0, 8, 24, 36, 48 and 60 hours

Status: Approved; not recommended for use in pregnancy (first trimester) and pre-lactating women.

In all, Artesunate/Amodiaquine combination has been approved to be the first line for the treatment of uncomplicated Malaria. Artemether/Lumefantrine and Dihydroartemisinin/Piperaquine are the second line treatment for uncomplicated malaria. ^[21]

Other combination therapies used in other countries include;

ARTESUNATE + MEFLOQUINE

Efficacy and Advantages: In use for many years and the first-line treatment in several parts of South East Asia

Disadvantages: Pharmacokinetic mismatch; Mefloquine induced neuropsychiatric effects, cardio-toxic effects, incidents of vomiting in Children; but combination with Artesunate results in less adverse reactions than the use of Mefloquine alone

Dose: Artesunate (4mg/kg once daily) for 3 days + Mefloquine

(25mg base/kg) as a split dose of 15mg/kg on Day 2, and 10mg/kg on Day 3 (Alternatively, 8mg/kg Mefloquine for Three days) ^[21]

ARTESUNATE + SULFADOXINE/PYRIMETHAMINE (SP)

Efficacy and Advantages: Well tolerated; Efficacy dependent on the level of pre-existing resistance to SP

Disadvantages: Pharmacokinetic mismatch; adverse effects to SP

Dose: Artesunate 4mg/kg once daily for 3 days and SP single dose of 25mg/kg and 1.25mg/kg respectively.

Status: Approved (in areas where SP efficacy is high); resistance to SP limits the use [21]

2.7 ADHERENCE AND WHY PRESCRIBERS DO NOT ADHERE TO ANTI-MALARIAL DRUG POLICY

Adherence to a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers. The participants at the WHO adherence meeting in June 2001 concluded that adherence is defined as the extent to which the patient follows medical instructions⁽²²⁾.

A number of reasons cited for non-adherence on the part of prescribers to the anti-malaria drug policy were,

- (1) High cost of Artemisinin-base anti-malaria drug therapy for the management of uncomplicated malaria, especially Artemether plus Lumefantrine.
- (2) Adverse effect of some Artemisinin-based anti-malaria drugs e.g. Artemether plus Lumefantrine and Artesunate plus Amodiaquine
- (3) Some believe chloroquine is still effective in the management of severe and uncomplicated malaria.

2.8 WHY PATIENTS DO NOT ADHERE TO MEDICATIONS

Non-adherence on the part of patients could be accidental or deliberate. Patients cite many reasons for non-adherence. These include;

- (1) Adverse effects
- (2) Forgetfulness
- (3) Asymptomatic; patients think drug is not needed, feels well without medication.
- (4) Regimen complexity
- (5) Lack of information
- (6) Poor patient-provider relationship or communications
- (7) High cost of drugs
- (8) Unclear about proper administration

Physicians also contribute to patient's non-adherence to medications by prescribing complex regimens, failing to explain the benefit and side effects of medication adequately not giving consideration to the patient's lifestyle or cost of the medications and having poor therapeutic relationships with their patients. ^[22]

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CHAPTER THREE

3.0 METHOD

3.1 STUDY TYPE

The study was a retrospective study, covering a period of six months period from August 2008 to January 2009.

3.2 SAMPLING METHOD

The patient folders used for study was randomly selected. The first and the last with two others from the middle were randomly selected each day. Four patient folders were selected each day from the Child Health Directorate (KATH).

3.2.1 Inclusion criteria

1. All admitted malaria cases at Child Health Directorate from birth to below 14 years

3.2.2 Exclusion criteria

1. All outpatients
2. All patients aged above 14 years

3.3 PILOT STUDY

A registered pharmacist and a pharmacy technician were trained on the study and the data collection. The questionnaires were pre-tested using fifteen prescribers. After this, actual data collection was carried out.

3.4 DATA COLLECTION TOOLS

Data collection forms (DCF) 1 (Appendix 1) and 2 (Appendix 2) were used to collect data on patients admitted to the Child Health Directorate from August 2008 to January 2009 and opinions from prescribers respectively.

The folders for the patients admitted during this period were retrieved from the medical records for the data collection. The information in the data collection form one was grouped into three main sections.

SECTION A: - Patients details

SECTION B: - Anti-malaria treatment

SECTION C: - Outcome

3.5 DATA PROCESSING AND ANALYSIS

The data collected using data collection forms I and II were entered separately into SPSS version sixteenth software and analysed.



CHAPTER FOUR

4.0 RESULTS

During the six months period, five hundred patients were randomly selected for the project, out of the estimated number of thousand five hundred patients admitted.

4.1 DEMOGRAPHIC CHARACTERISTIC

AGE DISTRIBUTION

The ages of the patients ranged from one month to fourteen years with more than 60% of patients below five years. The mean age was 3.13 years with standard deviation 2.31 and mean weight was 12.08 with standard deviation 6.19

TABLE 4.1: Descriptive Statistics of Age and Weight

Statistics	Minimum	Maximum	Mean	Std. Deviation	Skewness	Standard error
Age (month/yrs)	1	14	3.13	2.311	1.729	.110
Weight(Kg)	4	41	12.08	6.196	1.617	.110

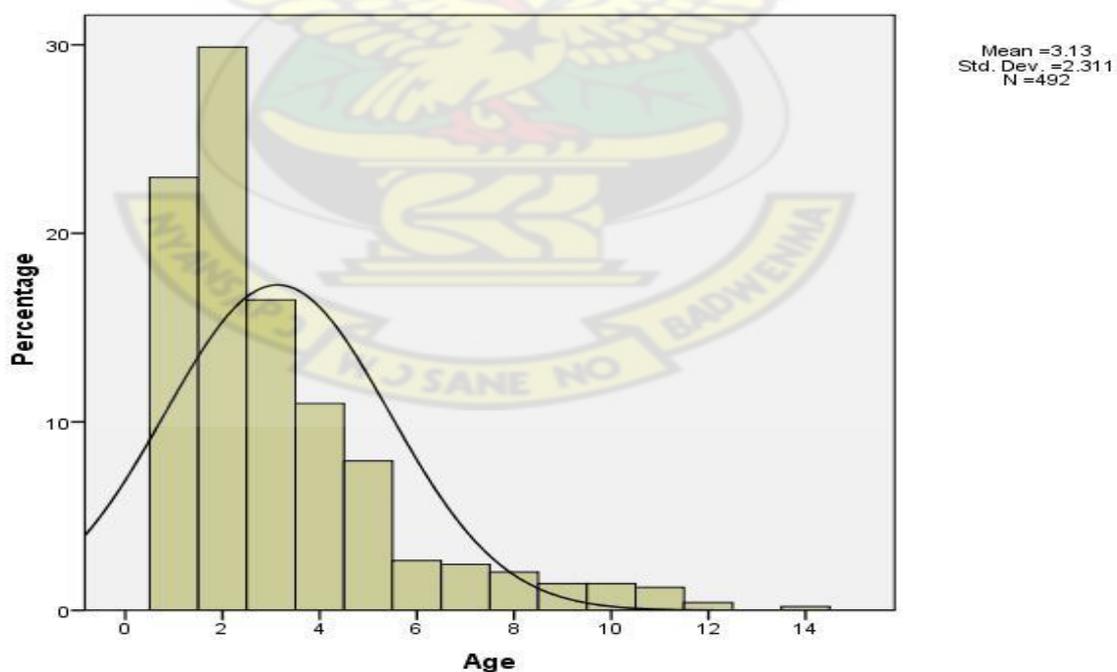


Fig 4.1: Age distribution in years

4.2 TYPES OF IMPRESSION OR DIAGNOSIS OF MALARIA

Two different diagnosis of malaria were observed from the doctor's clerking notes namely, severe or complicated malaria and uncomplicated malaria. The malaria cases diagnosed at the Child Health Directorate were uncomplicated malaria (58.6%) and severe or complicated malaria (41.4%).

TABLE 4.2: TYPES OF DIAGNOSIS OF MALARIA AT THE CHILD HEALTH DIRECTORATE

Diagnosis	Frequency	Percent	Cumulative Percent
Uncomplicated Malaria	293	58.6	58.6
complicated Malaria	207	41.4	100
Total	500	100	

4.3 ANTIMALARIAL TREATMENT

4.3.1 ANTIMALARIA DRUGS PRESCRIBED FOR THE MANAGEMENT OF UNCOMPLICATED MALARIA

The percentage distribution for the anti-malaria drugs, Artesunate plus Amodiaquine and Artemether plus Lumefantrine were 90% and 7% respectively for the management of uncomplicated malaria.

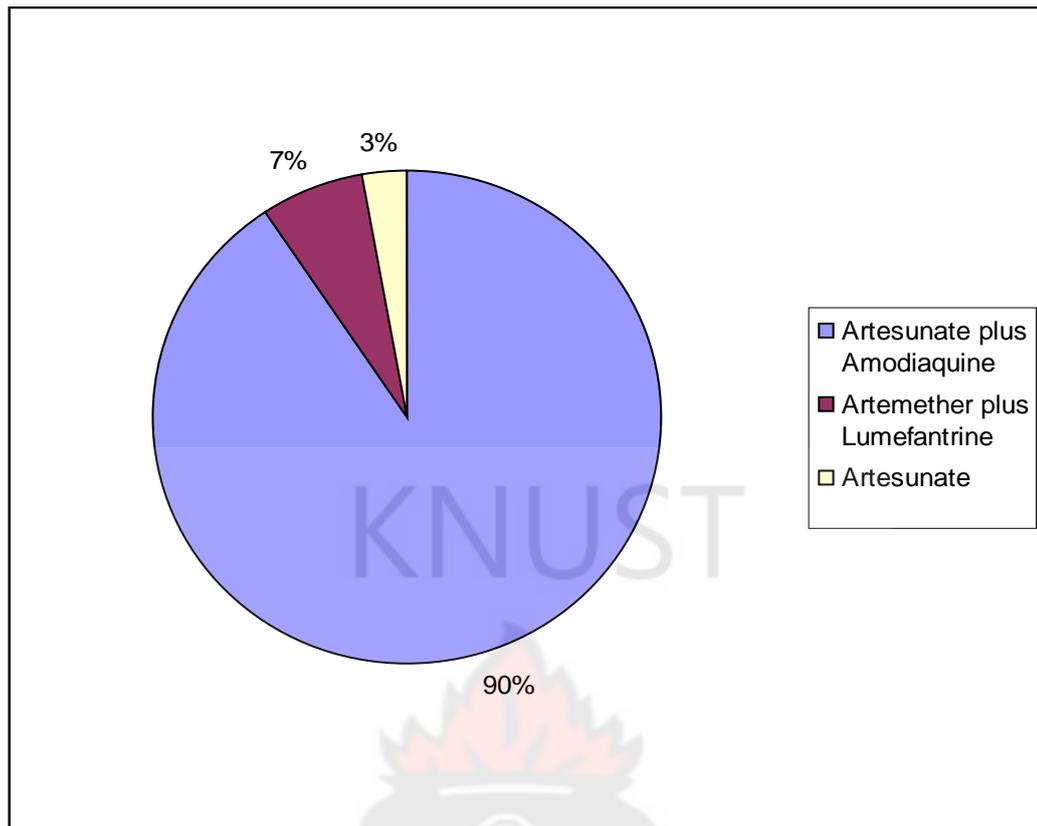


Fig 4.2: Anti Malaria Drugs prescribed for the Management of uncomplicated Malaria at the child directorate (KATH)

4.3.2 ANTIMALARIA DRUGS PRESCRIBED FOR THE MANAGEMENT OF COMPLICATED OR SEVERE MALARIA

The majority of the anti-malarials prescribed for the management of severe malaria were Quinine and Artesunate plus Amodiaquine representing 99.03% and 0.97% respectively.

4.4 DOSAGES AND FREQUENCIES OF ANTIMALARIALS PRESCRIBED

For the drug administration to the patients, the results for the dose, frequency and duration were encouraging. 91.8% of doses were administered according to the prescribed doses whilst 8.2% of the doses were administered wrongly.

Administration of the drug doses according to the frequency administered as prescribed appropriately was 84.4% whilst 14.6% had the frequency wrong.

The duration administered appropriately as per prescribed was 95.2% whilst 4.8% had the prescribed duration wrongly. (Fig 4.3)

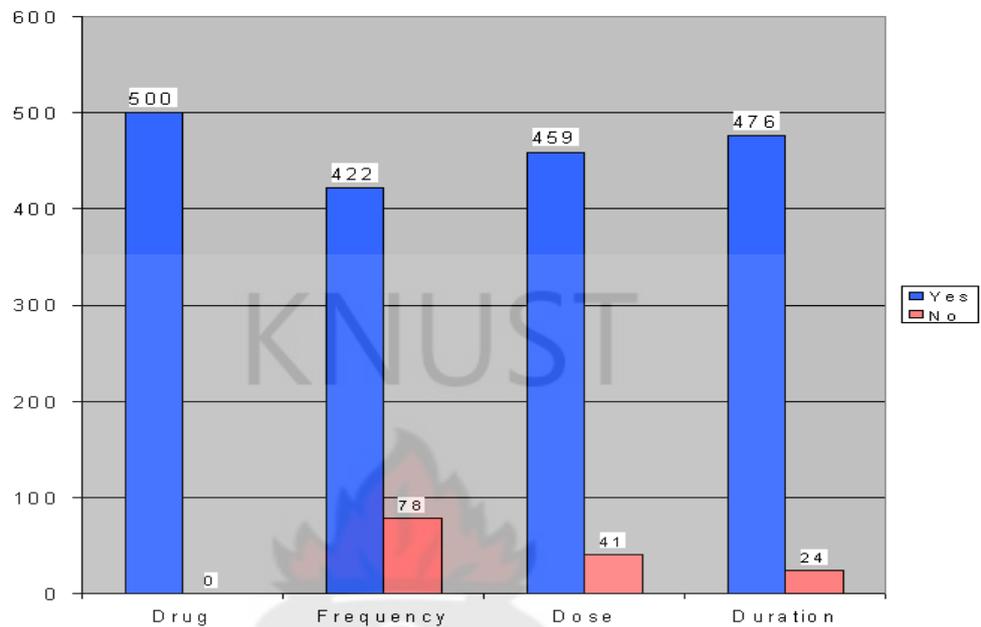


Figure 4.3: Appropriateness of drug administration

Most of the dosage forms prescribed over the six months period were syrups (68.9%), injectables (18.1%), tablets (10.6%) and suppository (2.4%). From Table 4.3

Table 4.3: DOSAGE FORMS

Dosage form	Frequency	Percentage (%)	Cumulative Percent
Syrup	852	68.9	68.9
Tablet	130	10.5	79.4
Suppository	31	2.5	81.9
Injection	224	18.1	100
Total	1237	100	

4.4 OUTCOME

The overall mortality for the six months period for five hundred patients was 0.3% which was very low as compared to 99.7% survival.

The mean length of the hospital stay for survivors was five days.

4.5 DETERMINATION OF THE KNOWLEDGE AND AWARENESS OF PRESCRIBERS TO THE ANTIMALARIA DRUG POLICY FOR GHANA IN DCF 2

A total of one hundred structured questionnaires were issued to prescribers. Out of this total, 97% of the prescribers indicated that they were aware of the new anti-malaria policy, 2% indicated that they were not aware and 1% indicated that they have fair idea of the policy.

For the management of severe or complicated malaria, 95% of the prescribers opted for Quinine, whilst 5% opted for chloroquine.

In the case of uncomplicated malaria, 82% of the prescribers opted for the use of Artesunate plus Amodiaquine, 12% opted for Artemether plus Lumefantrine, and 5% Artesunate and 1% chloroquine for its management.

Table 4.4: Anti-malarial drugs for the management of uncomplicated malaria

Anti-malarial Drugs	Frequency	Percentage (%)
Artesunate plus Amodiaquine	82	82
Artemether plus Lumefantrine	12	12
Artesunate	5	5
Chloroquine	1	1

However, none of the prescribers stated that they vary the anti-malaria drug regimen based on the weight or age of their client but rather stated that doses of client especially children was based on weight.

From the **Data Collection Form 2**, 91% of the prescribers indicated that their patients adhere to the anti-malaria drug policy, 85% indicated that their patient tolerate the anti-malaria drug policy, whilst 91% indicated for good treatment response. (Table 4.5)

TABLE 4.5: Various Responses to the new anti malaria drug policy.

Response	Adherence		Tolerance	
	No.	Percentage (%)	No.	Percentage (%)
Good	91	91	85	85
Fairly Good	5	5	10	10
Poor	4	4	5	5

CHAPTER FIVE

5:0 DISCUSSIONS

5.1 DEMOGRAPHIC CHARACTERISTICS

For the period of six months, children found to be more frequently affected by malaria were those below five years. More than 60% of the patients were below 5 years.

This finding corroborates with that in reports from other countries. ^[3, 6, 17, 18]

Young children are not adequately supervised because of large family size and the lack of domestic safety measures like the use of mosquito net and etc.

Again, it could also be attributed to negligence on the part of parents and caregivers in caring for children.

5.2 ANTI-MALARIA TREATMENT

Before the anti malaria drug policy for the treatment of malaria, the non-existence of anti malaria treatment protocol for the management of uncomplicated and severe malaria had led to all kinds of anti-malaria drugs being prescribed namely, chloroquine the mostly used drug, Lumefantrine, Amodiaquine, Artesunate and Quinine the least used drug.

It has been reported in several countries that the most common organism in malaria infestation *Plasmodium falciparum* ^[24] has become resistant to these traditional anti-malaria drugs especially chloroquine ^[16].

The new anti malarial drug policy for the treatment of uncomplicated and severe malaria consisted of combination anti-malarial therapy with Artemisinin base (ACTs) and the use of Quinine respectively. ^[23] The Artemisinin combination anti malaria therapy adopted in Ghana consisted of Artesunate plus Amodiaquine, Artemether plus Lumefantrine and Dihydroartemisinin plus Piperaquine ^[14].

This anti-malarial drug policy for the management of uncomplicated malaria concurs with recommended policies in other countries. ^[20] Cambodia was the first country to switch national anti-malarial drug policy to an ACTs of Artesunate and Mefloquine ^[20]. In January 25, 2005, Nigeria changed their anti-malarial drug policy from the use

of chloroquine to co-formulated Artemether plus Lumefantrine and Artesunate plus Amodiaquine ^[19] for the management of uncomplicated malaria and also recommended Artesunate Injection and Injection Quinine for the management of severe malaria.

In Kenya SP was adopted as first line therapeutic for uncomplicated malaria and was changed to Artemether-Lumefantrine as the recommended first line therapy ^[17].

90.5 % of the anti-malarial drug prescribed for the management of uncomplicated malaria was Artesunate plus Amodiaquine, 6.8% for Artemether plus Lumefantrine and then 2.7% for Artesunate. Higher percentage of Artesunate plus Amodiaquine could probably be attributed to the fact that it is the first line Artemisinin combination anti malaria therapy adopted in Ghana ⁽²⁴⁾ and also cheaper, effective and better tolerated by the children than the adults.

It was also found from the study that Artemisinin derivatives were occasionally used alone to manage uncomplicated malaria cases. This is a deviation from the national treatment guide lines which recommended Artemisinin based combination anti-malarial therapy for the management of uncomplicated malaria. ^[23]

This was also confirmed by the questionnaire issued to the prescribers; 82% of prescribers opted for Artesunate plus Amodiaquine for the management of uncomplicated malaria followed by Artemether plus Lumefantrine (12%) and Artesunate (6%).

The Artemisinin derivative used alone for the management of uncomplicated malaria cases in DCF 1 and 2 could be attributed to the fact that a number of prescribers are more comfortable prescribing preparations that are easy to administer. Also preference for Artemisinin derivatives could probably been due to the aggressive marketing of the product by Pharmaceutical company representatives in the country to clear their stocks due to the ban on mono-therapy anti malaria drugs by food and drug board for the treatment of uncomplicated malaria. ^[13]

About ninety nine percent (99.03%) of the anti-malaria drug prescribed for the management of severe or complicated malaria was Quinine followed by Artesunate

plus Amodiaquine 0.97%. In Child Health Directorate at KATH, Quinine is the preferred anti-malaria drug for the management of severe or complicated malaria cases.

Quinine has been and is still reserved for severe malaria treatment in Ghana ^[23], this may be due to the fact that Quinine is still very effective as compared to Chloroquine and Sulphadoxine–Pyrimethamine. Quinine has retained its efficacy because it is mostly available in the health facilities like hospitals and clinics, and usually given as injectables and tablets for a period of five or seven days for management of severe malaria.

It was also found from the study that Artemisinin based combination anti malaria drugs constituting (0.97%) in the DCF 1 were occasionally used to manage severe malaria cases. This is a deviation from the national treatment guide line which recommends Quinine for the management of severe malaria. ^[23] Further investigation is required to ascertain whether the Artemisinin base combination anti-malaria treatment is more effective than quinine alone in the management of severe or complicated malaria.

The use of Quinine for the management of severe malaria was also confirmed by the questionnaires issued to prescribers.

Ninety five percent of the prescribers opted for the use of Quinine in the management of severe malaria whilst 5% opted for the use of Chloroquine in management of severe malaria.

A number of reasons given by the 5% of the prescribers who still preferred to treat malaria with traditional anti malaria medicines such as Chloroquine, Artesunate etc in data collection form two were that, chloroquine especially, to them is still effective in the treatment of malaria.

Also the cost of the traditional medicines such as chloroquine for full treatment course is far lower than the drugs under the new anti-malarial drug policy e.g. Artemether plus Lumefantrine. There are several legitimate concerns about the sustainability of this policy due to the expensive nature of the drugs under the anti-malaria drug policy.

Part of the solution to the above issue is the introduction of the National Health Insurance Scheme which has been instituted in the country supported by an Act of Parliament that allows the public to access health care for diseases of public health concern without making an out-of-pocket payment for attending a health institution or payment for drug prescription.

This means that effective implementation of this scheme may provide respite economically for use of ACTs for treatment of uncomplicated malaria in Ghana.

Last but not least, the adverse effects of a number of the anti-malarial drugs under the new anti malaria policy e.g. Artesunate plus Amodiaquine are unbearable especially to the adults such as protruding tongue and weakness thus affecting compliance.

Drug administration to patients in terms of the dose, frequency and duration were very impressive. This could probably be due to the increased awareness of the importance of administering the prescribed dose at the right time and for the required period. This improvement contributed to the reduction of the mortality.

Inappropriate doses, frequency and duration were also realized. Inappropriate doses could be due to wrong calculation of the doses by the prescribers because doses of children are calculated based on the weight of the patients and this could also lead to sub-therapeutic doses of drugs to patients.

Example of inappropriate dose was observed in a child weighing 14kg and was given injection Quinine of 70mg three times daily. The dose for a child weighing 14kg should be 140mg of Quinine injection three times daily.

Inappropriate frequency and duration were also observed in the drug administration chart especially and from the prescription. There were cases where Injection Quinine was given twice a day instead of three times a day and also Artesunate plus Amodiaquine was twice a day instead of once a day. This could probably be attributed to the emergency nature of cases that were reported to the directorate, making the workload intense for the staff instigating occasional lapses in the writing of prescription and administration of drugs to the patients.

The treatment response, tolerability and adherence level were very encouraging, thus 85%, 85%, 91% respectively via the questionnaire given to prescribers in data collection form 2. This could be attributed to the fact that the new anti-malarial drug regimen for the management of malaria is very effective and has minimal or less adverse effects such as vomiting and itching in children. This result is comparable to what pertains in other countries. In the area of tolerability and mortality, a study was done comparing efficacy of Artesunate plus SP and Amodiaquine plus SP for uncomplicated falciparum Malaria in Equatorial Guinea in Central Africa ^[26]. Both combinations were well tolerated with low percentage of adverse effects such as vomiting and itching. No deaths were also recorded ^[26]. Also in a study carried out in Madagascar, using combination of Amodiaquine plus SP. The combination was well tolerated; no severe reaction was realized in a three day treatment schedule ^[27].

Furthermore a study was carried out in Cambodia comparing adherence of most anti-malarial drugs. It was found out that adherence was better to the three-day regimen of Artesunate plus Mefloquine than to the three-day regimen of Chloroquine at the ratio of 77% and 35% respectively ^[20].

For the awareness of the new anti-malarial drug policy, 97% of the prescribers stated that they have knowledge of the new anti-malarial drug policy. The high level of awareness could be attributed to the massive campaign and publicity of the new anti-malaria drug policy at the time of its implementation (4). One percent of the prescribers stated that they have fair idea of the policy. Two percent of the prescribers stated that they do not have knowledge of the policy. Although the percentage is low, there is still the need for educational campaign and publicity of the new anti-malaria drug policy should be designed and carried out every year for the stake holders especially the newly recruited doctors, nurses and pharmacists.

5.3 OUTCOME

The introduction of the new anti-malarial drug policy had led to the improvement in the patient outcome. Mortality is the most important and most readily quantifiable outcome in malaria patients.

The overall mortality for the six months period for five hundred patients was 0.3% as compared to 99.7% survived. This could probably be due to

- (1) Awareness of the new anti-malarial drug policy for the management of malaria owing to drug resistance by malaria parasites to traditional anti malaria drugs such as chloroquine.^[23]
- (2) Effectiveness of the anti malaria drug policy for the management of malaria, and
- (3) The appropriateness of drug administration to the patients admitted at the Child Health Directorate.

The mean length of the hospital stay for survivors was five days.

The treatment duration for uncomplicated malaria with combination anti-malarial therapy is 3 days, but the mean hospital stay for the survivors was 5 days. This could be attributed to the fact that considerable number of malaria victims who visited the directorate came with complicated malaria that could have prolonged their hospital stay. This finding correlates with that in reports from other country.

Work was done comparing the mean hospital stay of Mefloquine plus Artesunate and quinine plus SP for treatment of uncomplicated malaria. The mean hospital stay was shorter in patients treated with Mefloquine plus Artesunate than in patients treated with quinine-SP, 3.9 and 4.6 days respectively^[28].

5.4 LIMITATIONS OF STUDY

As a result of the retrospective nature of the study, a number of folders could not be traced at the medical records and also some vital information on patients could not be obtained due to poor documentation in the admission and discharge books at the wards. Some names and folder numbers retrieved from the admission and discharge

books at the ward could not be traced also from the medical records department due to poor arrangements of folders. This has potential of affecting the result.

Again, not all the questionnaires issued out to prescribers were obtained for analysis. This could also affect the result.

Another limitation was that the thesis only targeted patients at the Child Health Directorate and not the whole hospital. This means that the reported results may therefore not fully represent the hospital as a whole but most likely to serve as a fair estimate of the situation in the hospital.



CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

More than two thirds of the malaria victims were children below five years.

The most prescribed anti malarial medicine drug for the management of uncomplicated malaria for the six months period was Artesunate plus Amodiaquine followed by Artemether plus Lumefantrine. The most prescribed anti malaria medicine for the management of severe or complicated malaria was Quinine. Syrups constituted of the dosage form of anti-malarials dispensed followed by injections, tablets, and suppository.

The overall mortality for the six months period was 0.3% (death) which was very low as compare to 499 survivors. The mean length of the hospital stay for survivors was five days.

In summary, adherence to the anti-malarial policy was high. The introduction of the anti-malarial policy may have contributed to the significant improvement in the patient outcomes.

6.2 RECOMMENDATIONS

- (1) Effective and pragmatic strategies must be adopted to enhance public health education on safe and effective use of combination anti-malarial drugs in the community. It is strongly recommended that appropriate training be provided for staff in the pharmacies, licensed chemical shops and other dispensers in health care facilities in Ghana, on the need to advice clients or patients on adherence to treatment regimen for malaria and other interventions for malaria control to reduce morbidity and mortality. Parents should also be targeted to avoid exposing children to malaria parasite.
- (2) Stringent measures should be put in place to reduce importation of mono-therapies, adulterated, defective or counterfeit anti-malarial medicines into the country.
- (3) Further research may be needed or carried out to determine the safety and efficacy of the use of combination anti-malarial therapies in neonates or

young children and pregnant women which are specific high-risk groups in Africa.

- (4) The anti malaria policy for the treatment of malaria should be made available as over-the-counter drugs to the public.
- (5) There should be a regular review of the efficacy of the Combination anti malaria medicines approved in Ghana to avoid drug resistance by the malaria parasite. Also the National Policy should be reviewed regularly to reflect the local current trend of *Plasmodium falciparum* sensitivity pattern.

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APPENDIX I

DATA COLLECTION FORM 1

SECTION A: PATIENT'S DETAIL

- (1) Folder No.:
- (2) Date:
- (3) Age:
- (4) Weight (kg):
- (5) Impression/Diagnosis: Uncomplicated malaria Complicated malaria.

SECTION B: ANTIMALARIAL TREATMENT

(6) Which anti malaria drug was used for the treatment of uncomplicated malaria?

- (a) Artesunate plus Amodiaquine.
- (b) Artemether plus Lumefantrine.
- (c) Dihydroartemisinin plus Piperaquine
- (d) Artesunate

(7) Which anti malaria drug was used for the treatment of complicated malaria?

- (a) Quinine.
- (b) Chloroquine
- (c) Lumefantrine
- (d) Amodiaquine
- (e) Artesunate plus Artesunate

(8) Details of antimalarial medicine(s) prescribed on admission.

Drug 1: Drug 2:

Dose: Dose:

Frequency: Frequency:

Duration: Duration:

(9) What was the dosage form(s)?

Syrup: Tablet: Suppository: injection:

(10) Was the antimalarial medicine in (6) and (7) above administered correctly?

Drug: Yes:	<input type="checkbox"/>	No:	<input type="checkbox"/>
Dose: Yes:	<input type="checkbox"/>	No:	<input type="checkbox"/>
Frequency: Yes:	<input type="checkbox"/>	No:	<input type="checkbox"/>
Duration Yes:	<input type="checkbox"/>	No:	<input type="checkbox"/>

SECTION C: STATUS OF PATIENT

(11) Duration of stay.....

(12) Patient Outcome:

(a) Improved and Discharged: (b) Died:



APPENDIX II

DATA COLLECTION FORM 2

Questionnaire to determine the knowledge and awareness of prescribers to the new anti malaria drug policy

(1) Professional background

Nursing Officer Medical Assistant House Officer
Medical Officer Senior Medical Officer Pharmacist

(2) How long have you been in the clinical practice?
.....

(3) Do you have knowledge of the new anti malaria drug Policy for the management of malaria? YES NO Fair knowledge

(4) Which anti malaria drug do you use for the management of severe or complicated malaria?

- (a) Chloroquine:
(b) Quinine:
(c) Artesunate:
(d) Lumefantrine:
(e) Amodiaquine:

(5) Which anti malaria drug do you use for the treatment of uncomplicated malaria?

- (a) Artesunate plus Amodiaquine:
(b) Artesunate plus Lumefantrine:
(c) Dihydroartemisinin plus Piperaquine
(d) Artesunate
(e) Chloroquine

(6) Do you have reason(s) for prescribing the above drugs for the management of either complicated or uncomplicated malaria?
.....

(7) Do you vary your anti malaria regimen depending on the age or weight of patient?

Yes: No:

(8) If Yes why?

.....
.....
.....

(9) Do your patients tolerate the new anti malaria drug regimen? Yes: No:

(10) If No, which other medicine do you prescribe?

.....

(11) What is the adherence response of the patient to the new anti malaria drug policy?

Poor Fairly Good Good

(12) What is the treatment response of the patient to the new anti malaria drug policy?

Poor Fairly Good Good

