The perception of patients and clinicians on the use of Artemisinin – Based Combination Therapy for the management of uncomplicated in the St Dominic Hospital, Akwatia.

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CERTIFICATION

I, the undersigned certify to the Department of Clinical & Social Pharmacy, KNUST that, this research work entitled "The Perception of Patients and Clinicians on the use of Artemisinin-Based Combination Therapy (New Malaria Policy In Ghana) for the treatment of Uncomplicated Malaria at the St. Dominic Hospital, Akwatia" was submitted by me in fulfillment of requirements for the award of

MASTER OF SCIENCE (MSc) in CLINICAL PHARMACY

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Student Name & ID	Signature	Date

Certified by:

…….	……	…….
Supervisor(s) Name	Signature	Date

Certified by:

…….	……	…….
Head of Dept. Name	Signature	Date

DECLARATION

I declare that this piece of material is the result of my own research work.

Authors of books and documents from which references were cited as well as websites have however been acknowledged.

DEDICATION

I dedicate this work to my husband Herbert and our children, Comfort, Jessica and Mary.

ACKNOWLEDGEMENT

I wish to express my profound gratitude to the Almighty God for his manifold grace, especially for His direction and protection that have brought this research work to a successful end.

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May the Almighty God abundantly bless you all.

ABSTRACT

It is estimated that malaria contributes about 44% of all out patient cases and about 25% of all deaths in children under five. For nearly two decades several studies and reports in the country have thrown doubts on the efficacy of chloroquine in the management of malaria. Artemisinin - Based combination therapies/Act have replaced chloroquine in the management of malaria.

The objective of this study is to determine the perception of patients and clinicians on the use of ACTs in the management of uncomplicated malaria at the St.

Dominic Hospital in Akwatia.

The design of the research is a cross-sectional. Questionnaires were administered to both clinicians and patients. Patients treated for uncomplicated malaria at the hospital were sampled for the study.

Results showed 86.07% of patients responding to ACTs being effective, and 57.03% also said that the ACTS had no overly unbearable side effects.

Among clinicians 82.4% said the policy is a good one to have been adopted by Ghana and 58.8% of them are very satisfied with treatment outcomes whereas 35% are also satisfied with treatment outcomes. Only 5.9% of them are fairly satisfied. 52.9% of clinicians also said that side effects of the ACTS are quite mild and tolerable.

In conclusion both patients and clinicians see the ACTS as efficacious but with side effects that are quite tolerable.

TABLE OF CONTENT

ABBREVIATIONS / ACRONYMS

AA Amodiaquine+Artesunate

ACT Artemisinin Combination Therapy

AL Artemether+Lumefantrine

AP Artemether+Piperaquine

A S Artesunate

A Q Amodiaquine

BECE	Basic Education Certificate Examination
C N S	Central Nervous System
C Q	Chloroquine
C V S	Cardiovascular System
DERM	Dermatological
EENT	Eye Ear Nose and Throat
GIT	Gastrointestinal Tract
HAEM	Haematological System
ITN	Insecticide Treated (Mosquito) Net
MOH	Ministry of Health
MSLC	Middle School Leaving Certificate
NDIRC	National Drug Information Resource Centre
S P	Sulfadoxine + Pyrimethamine
S S A	Sub – Saharan Africa
U K	United Kingdom
W H O	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

Malaria is a serious, sometimes fatal disease caused by the plasmodium parasite which is spread to humans through the bite of an infected female Anopheles mosquito. Malaria is a problem in every region of the developing world with its greatest impact in Africa where over 80% of malaria cases and deaths occur. It has accounted for about 36% of patients admitted to hospitals for the past ten years.

Malaria is still the leading cause of morbidity and mortality in sub-Saharan Africa. It affects all ages and economic groups with a devastating impact on pregnant women and young children especially under five years of age. (Management Sciences for Health 2003).

The 2000 summit of the Global Ministerial conference on malaria laid emphasis on strategies to improve the prevention and treatment of malaria under the "Roll Back" Malaria programme. One of these strategies was to ensure the prompt supply of effective and affordable Antimalarial medicines and promote their correct use.

Strategies for prevention of malaria include education of the public on personal protection against mosquito bites, maintenance of clean domestic surroundings and the use of insecticide treated mosquito nets (ITN). (Ghana Health Service, 2004).

For more than 50 years, chloroquine (CQ), which is inexpensive, has been used to cure malaria.

CQ has been the first line drug in nearly all malaria endemic Sub-Sahara African countries. This is due to its ready availability in kiosks, shops and drug stores, as well as from formal health facilities, it's relatively low cost per dose and its safety. Until the last day of July 2001, CQ was officially the first-line drug for the treatment of uncomplicated malaria in Tanzania, SP being the second-line drug while quinine was the third-line drug for severe or complicated malaria. As in many other tropical countries, the treatment of malaria has ranged from self-medication using traditional medicines to the use of modern pharmaceuticals. (Mubyazi, & Gonzalez-Block, 2005).

Presently however, the world is faced with a resurgence of malaria partly due to the spread of strains of the parasite that are resistant to chloroquine and other Antimalaria medicines such as Sulfadoxine + Pyrimethamine (SP) and Amodiaquine as monotherapy.

Plasmodium falciparum, one of the parasites that cause malaria has become increasingly resistant to Chloroquine which was the most widely used Antimalaria treatment since the 1940s. (Ghana Health Service, 2004). Conservative figures for malaria treatment failure using chloroquine are between 6% and 25% among different demographic cohorts (Ghana Health Service, 2004), some sources quote as high as 30% treatment failures. Efficacy of chloroquine in the treatment of uncomplicated malaria in six (6) sentinel sites in 1998 – 2001 were as follows: (Ghana Health Service, 2004).

- Treatment failure rates of 8.6% - 26.6%
- Adequate clinical response was 75.65
- Parasitological failure rate was 21.7% - 49.0%

The choice of alternatives to chloroquine have been guided by

- Efficacy levels
- Compliance
- Route of administration
- Side effects
- Cost effectiveness
- Impact on local industry
- Appropriateness for treating malaria in all ages.

Some sources quote as high as 30% treatment failures. The most common replacement for chloroquine in Africa, sulfadoxine-pyrimethamine (SP) is also rapidly losing effectiveness against the parasite. (Ghana Health Service, 2004). Continued use of such ineffective pharmaceuticals results in the spread of drug resistance as well as a disturbing increase in malaria-related morbidity and mortality.

The development of resistance to drugs poses one of the greatest threats to malaria control. In Africa, the efficacy of readily affordable Antimalarial drugs is declining rapidly, while highly efficacious drugs tend to be too expensive. Cost-effective strategies are needed to extend the useful life spans of Antimalarial drugs. (Bloland et al, 2003).

Considering the limited health budgets and the rising cost of medical services, the increasing trends of drug resistance raise critical public health concerns, as this constrains the provision of adequate treatment in countries where the disease is endemic. The increasing evidence on *Plasmodium falciparum* parasite's resistance to chloroquine (CQ) has prompted some countries to revise their treatment guidelines. In the last decade, the immediately considered alternative first-line drug in some southern African countries, such as South Africa, Botswana, Malawi and Kenya, was SP, but now, countries such as Burundi and Rwanda have already opted for Artemisinin drug combination therapy while several others are considering to do so. In many countries, the hesitation by ministries of health to make a policy change decision has been over-influenced by economic budget considerations. In Tanzania, the critical nature of the decision has led to a new policy. (Mubyazi & Gonzalez-Block, 2005).

Observations in South-East Asia on combination therapy with Artemisinin derivatives and mefloquine indicate that the development of resistance to both components is slowed down. This suggests the possibility of a solution to the problem of drug resistance in Africa, where, however, there are major obstacles in the way of deploying combination therapy effectively.

The rates of transmission are relatively high, a large proportion of asymptomatic infection occurs in semi-immune persons, the use of drugs is frequently inappropriate and ill-informed, there is a general lack of laboratory diagnosis, and public health systems in sub-Saharan Africa are generally weak.

The use of Artemisinin-based Combination Therapies: Amodiaquine+Artesunate, Artemether+Lumefantrine, Artesunate+Mefloquine and Dihydroartemisinin +Piperaquine were introduced by the World Health Organization to curb the increasing resistance to Antimalarial medicines. (Majori, 2004).

The WHO concept of combination therapy is based on the synergistic or additive potential of two or more drugs to improve therapeutic efficacy and also delay the development of resistance to the individual components of the combination, hence the need for the new policy. (Shretta & Adeya, 2003).

The policy change was not in the interest of the pharmaceutical manufacturers and traders, who had built up large stocks of CQ and had profited much from its familiarity among most of their client populations. Drug supply companies had already invested in small vans to deliver CQ with a banner 'CHLOROQUINE' on their sides.

Medical practitioners and biomedical researchers considered it was too early to change the policy. One of the reasons stated was that many people still believed that CQ was effective despite variations between different areas and that SP resistance was reported to be on the increase. Some high-ranking government officers at parliamentary

and ministerial levels identified themselves as being among those who were still using CQ effectively. Detractors also relied on a few incidences of patients who had had side effects with other Antimalarial drugs and also pointed paucity of information available regarding SP resistance. It was established that evidence indicated that many health professionals were unaware of the extent of resistance to CQ and did not perceive an urgent need for change.

It was also expressed that the decision to change the policy was a very sensitive issue considering the financial implications of the change, both to the government and to the users of the drugs on one hand, and the lack of expertise to manage the change and the uncertainty of treatment outcomes in the use of the new drug. (Mubyazi & Gonzalez-Block, 2005).

Adherence to the full treatment course has been highlighted as a matter of great concern as this affects preservation against resistance. AL has to be taken twice a day for three days (one or two tablets depending on the age group), AS/AQ once daily for three days but two different tablets (or half tablet) each time. Both of these regimens are different from those for older Antimalarials like chloroquine or sulphadoxine-pyrimethamine (SP). Nonetheless, reported adherence by caregivers to the correct treatment schedule in terms of dose and duration was high for both treatment regimes in all sites of study, ranging from 79% in Uganda to 97% in Ejisu, Ghana (85% on average across the sites). These findings are reassuring with regard to the potential for development of resistance, as exposure to sub-therapeutic drug levels is known to be a

major factor in the development of resistant parasites. (Ajayi O et al, 2008).

1.1.1 ANTIMALARIAL POLICY FOR GHANA

In 2002 Ghana adopted the antimalaria policy based on ACTs and for the choice of drugs, the country strategically selected Amodiaquine+Artesunate on account of its potential for local manufacture among other factors. In the last quarter of 2005, there were reports of serious adverse drug reactions in patients treated with some brands of this combination which came in the strength of 600mg Amodiaquine in one tablet and 200mg Artesunate also in one tablet taken together for three consecutive days. This led to the withdrawal of these brands from the Ghanaian market by the Ministry of Health (MOH). Currently, the dosage regimen of Amodiaquine+Artesunate has been spread into divided doses. With the new revised policy which was implemented in 2005, Amodiaquine comes in the strength of 150 and 75mg whilst Artesunate comes in the strength of 50 and 25mg strengths and given according to body weight. The WHO describes this combination as an efficacious combination drug with low side effects. Studies across the world have shown that it has a high parasite clearance and cure rate with adequate treatment duration.

The specific drugs identified through expert consultation and literature reviews as possible replacement for chloroquine as first line treatment for malaria in the WHO African region are;

Amodiaquine+Artesunate

Artemether+Lumefantrine

Artesunate+Sulphadoxine/Pyrimethamine

Artesunate+Mefloquine

Ghana has selected Artesunate+Amodiaquine, Artemether+Lumefantrine and Dihydroartemisinin+Piperaquine by policy for use.

One great challenge that came with the use of the ACTs was the side effects of the preparations. Amodiaquine appears to be the one most patients have associated this concern with. The adverse effects of the various Antimalarials that were combined with Artesunate are presented below;

Adverse Effects of Amodiaquine

CNS : headache, convulsions, neuromyopathies, psychotic episodes, agitation, personality changes. (NDIRC 2007)

CVS : cardiomyopathy

DERM : pruritus, depigmentation, photosensitivity, urticaria

EENT : visual disturbances, tinnitus, reduced hearing, nerve deafness.

GIT : gastrointestinal disturbances

OTHERS : blood disorders – bone marrow suppression, agranulocytosis.

According to the Martindale 32nd edition (pg 424) , examination of data submitted to the UK committee on safety of medicines, the frequency of adverse reactions to Amodiaquine was about 1 in 1700 for serious reactions, 1 in 2200 for blood disorders, 1 in 15650 for serious hepatic disorders and 1 in 15650 for fatal reactions. Worldwide the risk of severe reactions appears to be between 1 in 1000 and 1 in 5000.

Adverse Effects of Lumefantrine

CNS : headache, dizziness

GIT : anorexia, abdominal pain.

Adverse Effects of Piperaquine

CNS : postural blood pressure changes

GIT : gastrointestinal disturbances.

HAEM : heptotoxicity, blood disorders.

OTHERS : renal tubular cell damage

1.1.2 PERCEPTIONS OF ANTIMALARIAL POLICY

The Oxford Advanced Learners dictionary gives three definitions of Perception:

The way you notice things especially with your senses

- ✓ The ability to understand the true nature of something
- ✓ An idea, a belief or an image you have as result of how you see or understand something.

The third definition applies to this attitude towards the prescription and use of ACTs.

The introduction of Artesunate (200mg) + Amodiaquine (600mg) in 2002 which resulted in reports of some adverse drug reactions created a perception of poor safety of the ACTs when they were introduced in most communities in Ghana.

These ideas, beliefs and images (perceptions) if not properly addressed will also lead to the development of resistance strains of the malaria parasite to the ACTs. This is because the perceptions can lead to noncompliance of medication regimen. Also the use of any antimalarial drug is influenced by socio-behavioural factors such as familiarity with the drug, perceived potency and safety which may compromise adherence and therefore impact on morbidity and mortality. (Le Grand et al, 1999).

1.2 RATIONAL FOR STUDY

The burden of malaria continues to take a great toll on Africa especially Sub-Saharan countries of which Ghana is no exception.

Drug resistance is currently one big challenge that exists in the area of malaria chemotherapy. It is therefore very important that patients take their medications in the appropriate quantities and at the appropriate times. Further more with the introduction of the ACTs in the management of malaria more education ought to be given in our

communities if patients are to comply with their medications and reduce the problem of drug resistance with Antimalarial medicines.

Perception is defined as an idea, belief or image that one has as a result of how one sees or understands something. As a result of the withdrawal from market of some brands of Amodiaquine+Artesunate combination in the last quarter of 2005 due to reports of serious adverse drug reactions in patients treated with the medication, a good proportion of our communities now carry this idea, belief or an image (perception) that the ACTs are not safe. Some members of our communities depend on what others say as basis to interrupt or refuse ACTs as treatment when they have malaria. Poor perceptions about malaria and poor malaria drug treatment practices have contributed to widespread resistance of *Plasmodium falciparum* malaria to commonly used monotherapy. (Asante et al, 2009).

There have been studies on perceptions of the disease malaria, perceptions on practices associated with malaria and perceptions on safety and effectiveness of Antimalarials.

A study by Ajayi O et al, 2008 on "safety and perceived effectiveness of ACTs" intimated that although some adverse events were reported in children of their study none of them were reported to be serious. In all sites of the study almost all caretakers perceived ACTs to be effective.

Studies so far done in the area of perception are quite limited; hence there is the need to conduct further studies.

1.3 AIM

To describe if any, the perception of patients and clinicians on the use of Artesunate-Based combination therapy for the treatment of uncomplicated malaria at the St. Dominic Hospital, Akwatia**.**

1.4 OBJECTIVES

1. To determine the adherence of physicians to the treatment guidelines for the management of uncomplicated malaria.
2. To describe the perceptions of patients and clinicians on the safety and efficacy of ARTEMISININ-BASED COMBINATION THERAPY (ACT) for the management of uncomplicated malaria.
3. To determine the awareness and knowledge of the new policy for the management of uncomplicated malaria (ACT). .
4. To make recommendations on the use of Artemisinin-Based Combination Therapy (ACT) for the management of uncomplicated malaria.

CHAPTER TWO

METHODOLOGY

2.1 STUDY METHOD AND DESIGN

The study design used for this study was a cross-sectional descriptive type which described the perception of patients and clinicians.

2.1.1 STUDY POPULATION & STUDY SAMPLE

St. Dominic Hospital Akwatia is located in the South-Western part of the Eastern Region, and precisely in the Kwaebibirem District. The District has a population of two hundred and seven thousand and sixty-four (207,064) with an estimated growth rate of 3.1% per annum and 50.4% males and 49.6% females.

The hospital was purposefully chosen for this study based on proximity and easy access to the researcher within the financial resources available. Recommendations could also be directly integrated into service delivery since the researcher works there.

Moreover, the facility is so well patronized that it is very feasible to carry out research work in it. It has served as the main district hospital for several years until a couple of years ago when the health centre in the district Capital, Kade was elevated to a hospital status.

Out of a study population of patients being treated for uncomplicated malaria daily in the hospital a study sample of four hundred (400) patients was used for this

research. These patients were sampled from seventeen (17) prescribes. The patients aged 14 years and above were randomly sampled for the study. Twenty (20) patients were sampled each day. In all fifteen medical officers and two medical assistants constituted the sample of clinicians. These clinicians all treat uncomplicated malaria. Specialist clinicians were not included because they are usually occupied with patients of their specialties and do not generally see malaria cases. The structured questionnaire was applied and data filled in. Questionnaires for clinicians were given to them after their consent was obtained.

In-patient cases, pregnant women as well as severe malaria cases were excluded. This was to enable the sample of four hundred (400) patients to be interviewed over a period of four weeks with no follow ups and no co-morbidities.

2.1.3 RESEARCH INSTRUMENTS

The following research instruments were used in collection of data for this study;

- Questionnaires- structured and self completing for clinicians. (APPENDIX 1A)
- Questionnaires – structured Interview guide for patients. (APPENDIX 1B)
- Data Collection Tool. (APPENDIX 2)

The questionnaires contained questions that sought to determine the following:

- Perceptions of patients and clinicians on the use of ACTs in the management of uncomplicated malaria.
- An overview of the management of uncomplicated malaria in the hospital.
- Knowledge of the new malaria policy by patients and clinicians.
- Frequency of reported adverse drug reactions.
- Adherence of clinicians to treatment guidelines
- Perception of patients and clinicians on the safety and efficacy of the ACTs in the treatment of uncomplicated malaria.

The data collection tool enabled documentation of the type of antimalarial, strength and dosage that was given to patients.

2.1.4 DATA COLLECTION

Data from patients was collected from the pharmacy when patients who had been seen by the doctor came to collect their medications. This was done during normal working hours. Twenty (20) consenting patients were interviewed each day and this was done from the 15th of April 2009 to the 15th of May 2009.

One Dispensing technician was trained as a data collection assistant so data was collected by both researcher and the data collection assistant.

The structured questionnaire was applied and data filled in. Questionnaires for

clinicians were given to them after their consent was obtained. They were allowed ample time (in days) to complete the questionnaire which the researcher picked at times convenient for the clinician.

A letter was written to the hospital management to seek consent for the research to be carried out.

A data collection tool was used in collecting data from patient folders and clinicians and patients were interviewed by the use of the questionnaires.

CHAPTER THREE

RESULTS

3.1 AN OVERVIEW OF MALARIA MANAGEMENT

An overview of the drug management of malaria in the hospital is shown below (Table 3.1)

Table 3.1: Antimalarial medicines prescribed in the hospital.

ANTIMALARIAL PRESCRIBED	FREQUENCY (PERCENTAGE)
Amodiaquine + Artesunate	**203 (51%)**
Artemether + Lumefantrine	**171 (43%)**
Dihydroartemisinin + Piperaquine	**26 (6%)**
TOTAL	**400 (100%)**

The commonest factors that prescribers consider when prescribing Antimalarials are:

- Side effects of medication
- Duration of treatment
- Frequency of administration
- Pill burden (Table 3.2)

Table 3.2 Factors considered by clinicians when prescribing Antimalarial - medications.

Factors considered by clinicians in prescribing	Freq.	%
duration of treatment	1	5.9%
frequency of administration	1	5.9%
side effects of medication	2	11.8%
side effects of medication, duration of treatment, cost	1	5.9%
side effects of medication, duration of treatment, frequency of administration	2	11.8%
side effects of medication, duration of treatment, frequency of administration, pill burden	5	29.4%
side effects of medication, duration of treatment, frequency of administration, pill burden, cost	1	5.9%
side effects of medication, duration of treatment, frequency of administration, pregnancy, severity of condition	1	5.9%
side effects of medication, effectiveness	1	5.9%
side effects of medication, pill burden	2	11.8%
Total	17	100%

3.1.1 Satisfaction on turnover rate from seventeen (17) clinicians interviewed

Out of the seventeen (17) clinicians interviewed, 59% were very satisfied, 35% were satisfied and 6% were fairly satisfied with the turnover rate of patients on review after treatment.

3.1.2. Patients involvement in their management

Out of the 400 patients that were interviewed 97% of them said they were not involved in the decision of their prescription whereas 3% said they were involved in the decision of their prescription with the clinician, stating the issues discussed (Table 3.3).

Also 55% of patients interviewed knew the medication prescribed for their malaria and 45% of them did not know this.

Table 3.3: Issues discussed with patients before prescription.

Issues discussed with patients	Involvement of patient in decision of prescription		Total
	Yes	No	
Patients not involved by clinician in decision of their prescription	0 (0%)	388 (97.0%)	388 (97.0%)
Artesunate+Armodiaquine treatment	1 (3.0%)	0 (0%)	1 (0.3%)
cause of sickness, malaria treatment	1 (0.3%)	0 (0%)	1 (0.3%)
change of treatment due to reaction to Artesunate+Amodiaquine	3 (0.8%)	0 (0%)	3 (0.8%)
Tolerability of Artesunate + Amodiaquine	4 (1.0%)	0 (0%)	4 (1.0%)
Told diagnosis; patient told he will be treated with Artesunate+Armodiaquine	1 (0.3%)	0 (0%)	1 (0.3%)
use of Artesunate+Amodiaquine, eating well before taking it	1 (0.3%)	0 (0%)	1 (0.3%)
whether previous treatment was helpful	1 (0.3%)	0 (0%)	1 (0.3%)
Total	12 (3.0%)	388 (97.0%)	400 (100%)

3.2. CLINICIANS PERCEPTION OF ANTIMALARIAL DRUGS

A total of 17 clinicians were interviewed on their perception of the new Antimalarial Policy. 15 (88%) were medical doctors and 2 (12%) were medical Assistants. Out of this number 1 (6%) has been in clinical practice for more than ten years, 3 (18%) of them have been in clinical practice between five and ten years and 13 (76%) have been practicing for less than five years (figure 3.1).

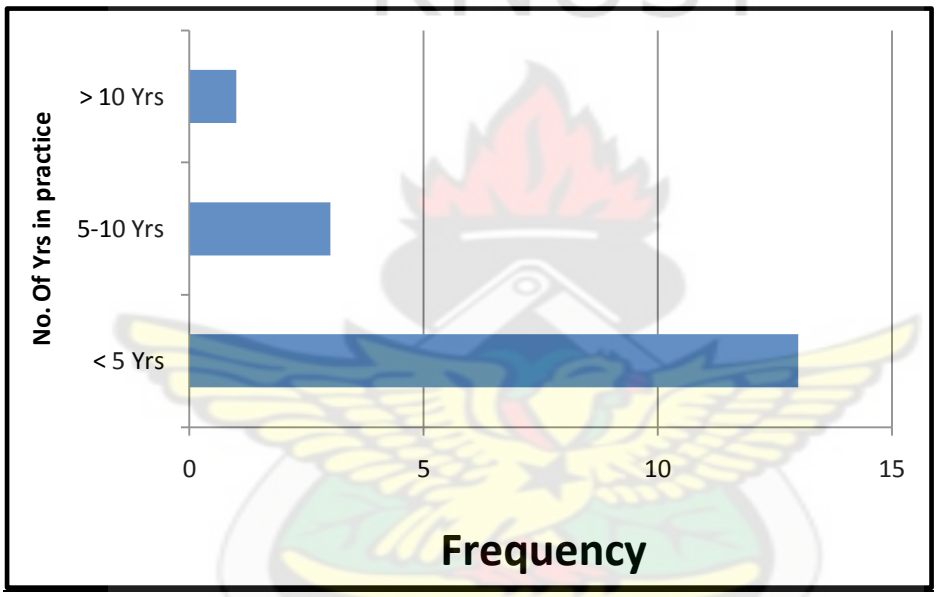

Figure 3.1: Number of years in clinical practice.

3.2.1 Clinicians awareness and knowledge of the new policy

All 17 clinicians responded "yes" to knowledge of the policy.

The policy was described and the frequency of prescribing it was indicated by the clinicians (Table 3.4).

Table 3.4: frequency of prescribing ACTs.

Frequency of prescribing according to the policy.	Description of policy				Total
	None response	use of AA	use of AA as 1st line, quinine tab/iv 1st line for pregnant women	use of ACTs	
1-3 Persons in 10 cases	0 (.0%)	1 (5.9%)	0 (.0%)	1 (5.9%)	2 (11.8%)
4-6 Persons in 10 cases	1 (5.9%)	1 (5.9%)	0 (.0%)	3 (17.6%)	5 (29.4%)
Over 6 Persons in 10 cases	1 (5.9%)	1 (5.9%)	1 (5.9%)	7 (41.2%)	10 (58.8%)
Total	2 (11.8%)	3 (17.6%)	1 (5.9%)	11 (64.7%)	17 (100%)

On the question of whether the combination was the best policy to be adopted by Ghana, 82% of the clinicians responded “yes” and 18% of them said “no”. Out of the 18% of clinicians who said the policy was not the best to be adopted by Ghana, 66.67% gave reasons for their response, and they are:

- Adverse drug reactions
- Development of resistance strains

33.3% of them gave no reason for this response.

In response to Antimalarials commonly prescribed by clinicians diverse choices were given (fig. 3.2).

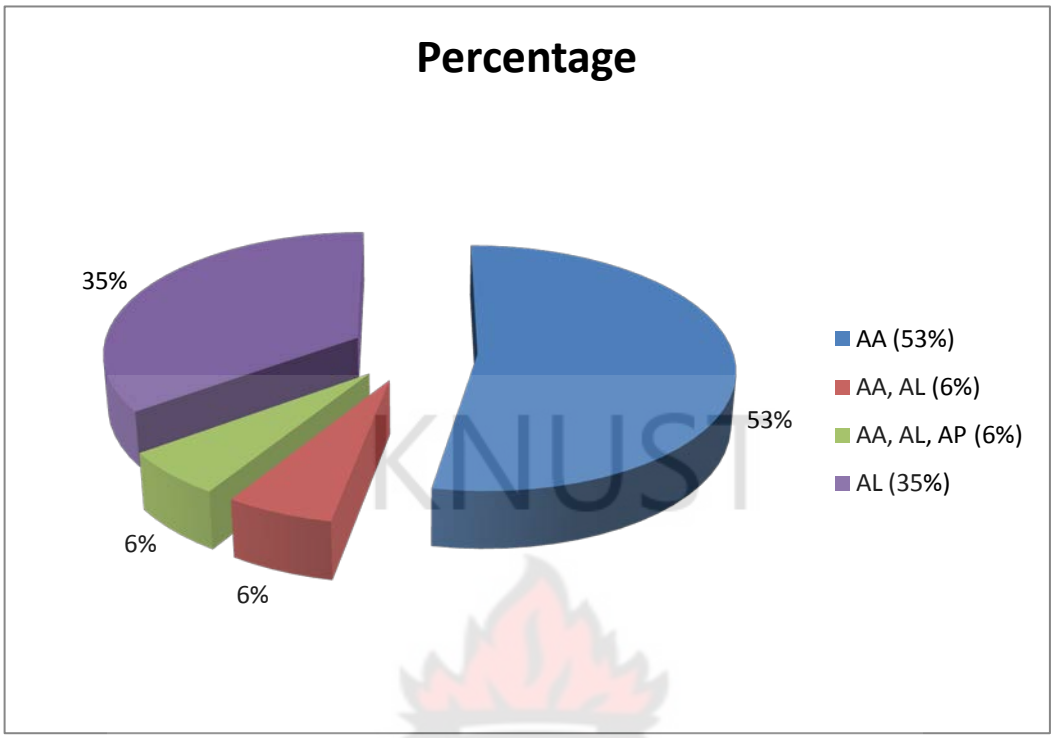

Fig. 3.2: Antimalarials commonly prescribed by clinicians.

3.2.2. Clinicians Perception on Efficacy of the new policy

94% of clinicians said that the combinations are effective and 6% said that they are not effective.

Considering the most effective combination according to the clinicians, Amodiaquine + Artesunate had a score of 53% and Artemether + Lumefantrine scored 47%.

The perception of efficacy is presented below in the combinations as prescribed mostly (Table 3.5)

Table 3.5 Most effective combinations verses. Side effects

Combinations considered most effective.		Side Effects		Total
		Yes	No	
MOST EFFECTIVE	AA	8 (47.1%)	1 (5.9%)	9 (52.9%)
	AL	8 (47.0%)	0 (.0%)	8 (47.0%)
Total		16 (94.0%)	1 (6.0%)	17 (100%)

3.2.3 Clinicians Perception of Safety

94% of clinicians said that the combinations have side effects and 6% said that they have no side effects. AA and AL have the same level of side effects (47%). AP was not cited for side effects neither was it cited for efficacy. The graded side effects are found below (Fig. 3.3) and the range of side effects cited by clinicians is tabulated in Table 3.6. 65% of clinicians do documentation on adverse reactions, 29% of them do not do any documentation and 6% was non responsive to this question. Clinicians who responded "no" to documentation gave reasons (Table 3.7)

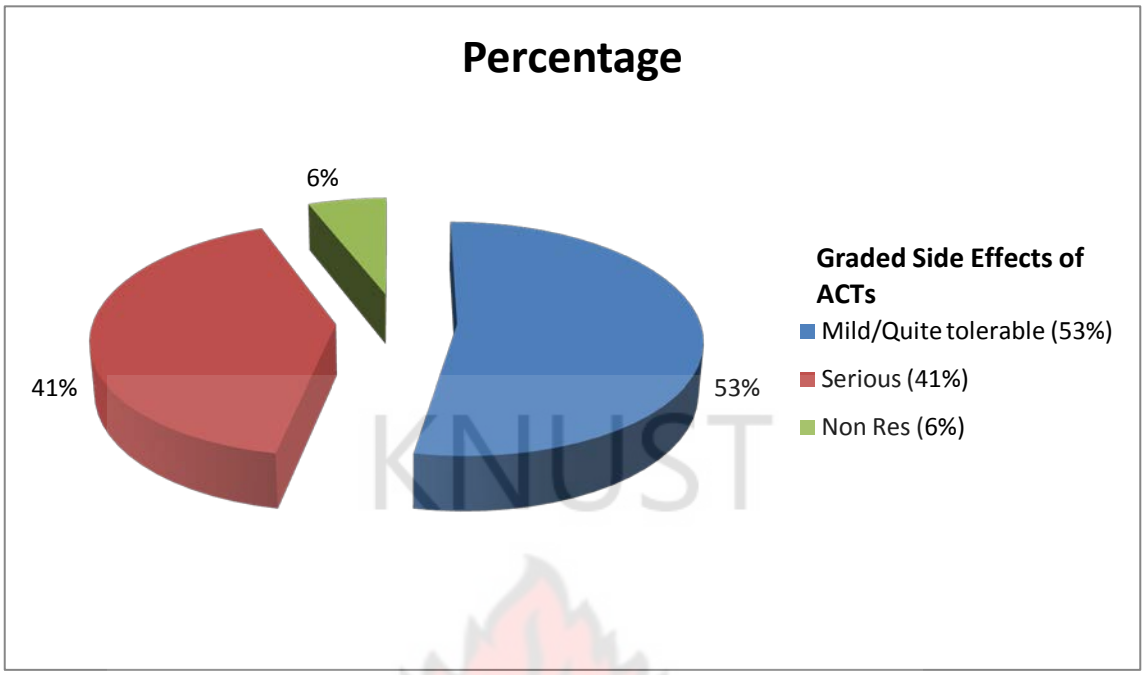

Fig. 3.3: Graded side effects.

Table 3.6: Side Effects commonly reported.

Side Effect	Frequency	Percent
dystonia, hypoglycemia, abdominal pains	1	5.9%
dystonia, pruritus	1	5.9%
extreme weakness	1	5.9%
haemolysis, shock, skin rashes	1	5.9%
None response	2	11.8%
pruritus, dystonia	1	5.9%
pruritus, dystonia, headache, vomiting	1	5.9%
pruritus, dystonia, occulogyric	1	5.9%
pruritus, vomiting, abdominal discomfort	1	5.9%
skin rashes	1	5.9%
weakness, dizziness	1	5.9%
weakness, dizziness, extra pyramidal symptoms	1	5.9%
weakness, dystonia	2	11.8%
weakness, dystonia, vomiting	1	5.9%
weakness, headaches, dizziness, nausea, vomiting, abdominal pain, itching	1	5.9%
Total	17	100%

Table 3.7: Documentation of adverse drug reactions

Documentation Status		Documentation of adverse drug reactions.			Total
		Yes	No	None responsive	
Documentation done		11 (64.7%)	0 (.0%)	0 (.0%)	11 (64.7%)
Documentation not done					
Reasons for not documenting.	because they are mild and tolerable	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)
	Lack of time	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)
	No avenue for that here	0 (0%)	1 (5.9%)	0 (0%)	1 (5.9%)
	None response	0 (0%)	2 (11.8%)	1 (5.9%)	3 (17.6%)
Total		11 (64.7%)	5 (29.4%)	1 (5.9%)	17 (100%)

3.3 PATIENTS' PERCEPTION OF THE NEW ANTIMALARIAL POLICY

A total of 400 patients were interviewed on their perception on the new Antimalarial policy. Twenty seven percent (27%) of them were males and 73% of them females. Further more a higher proportion of the patients were aged 30-45 years (Fig3.4) and a high proportion of the patients were traders (Fig3.5)

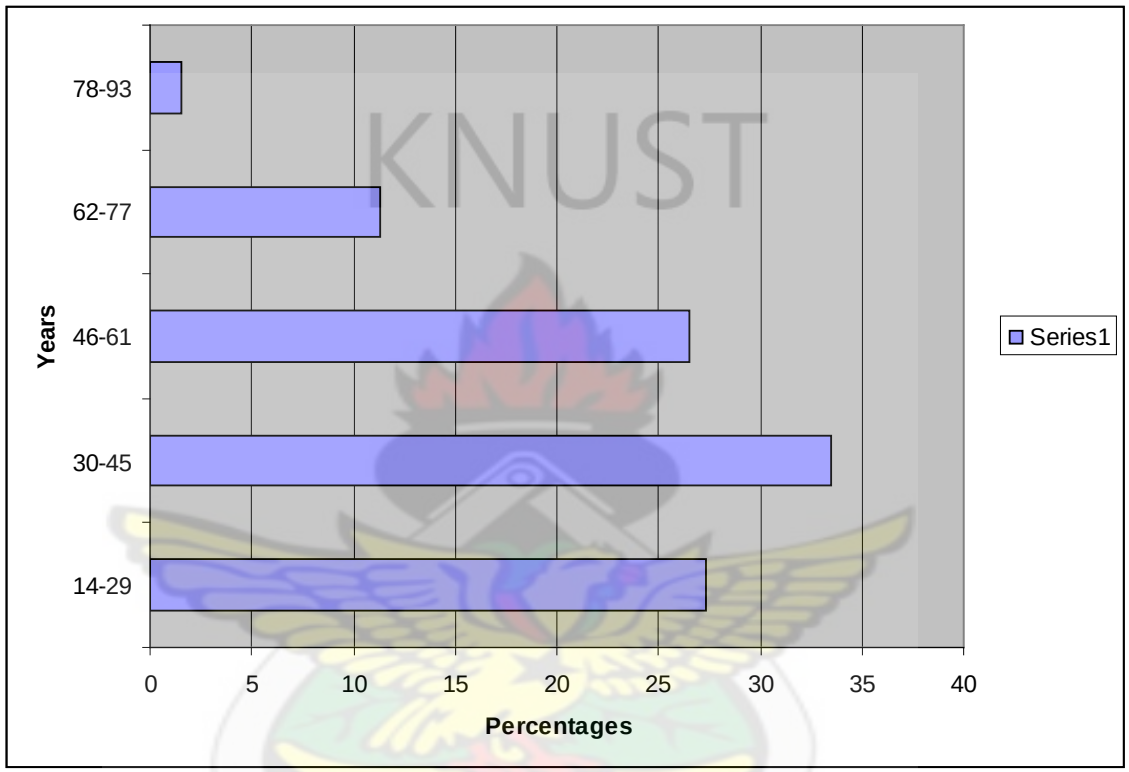

Fig 3.4: Age groups of patients

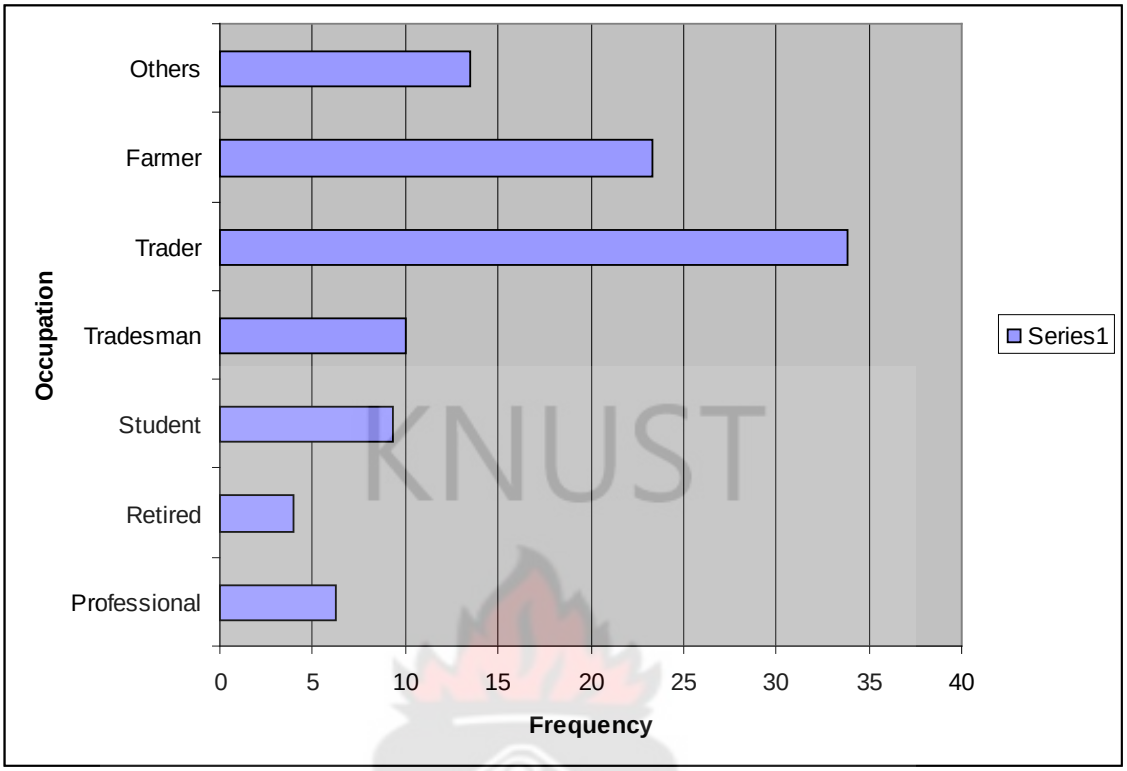

Fig 3.5: Occupation of patients

On educational background majority of the patients sampled had basic education certificate or the middle school leaving certificate. (Fig. 3.6)

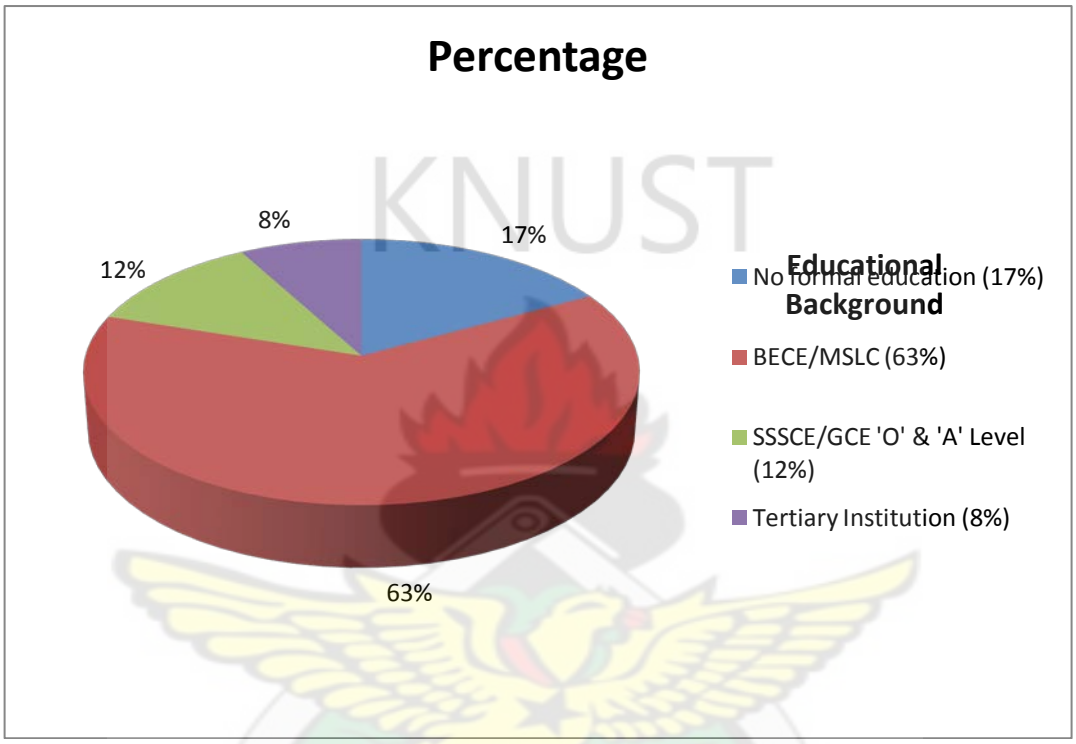

Fig. 3.6: Educational Background

3.3.1 Patients Awareness and Knowledge of the new policy.

65.5% of patients had knowledge of the policy and 34.5% of them had no knowledge of the policy. Those who answered yes to knowing the policy gave the source of their information (Fig. 3.7)

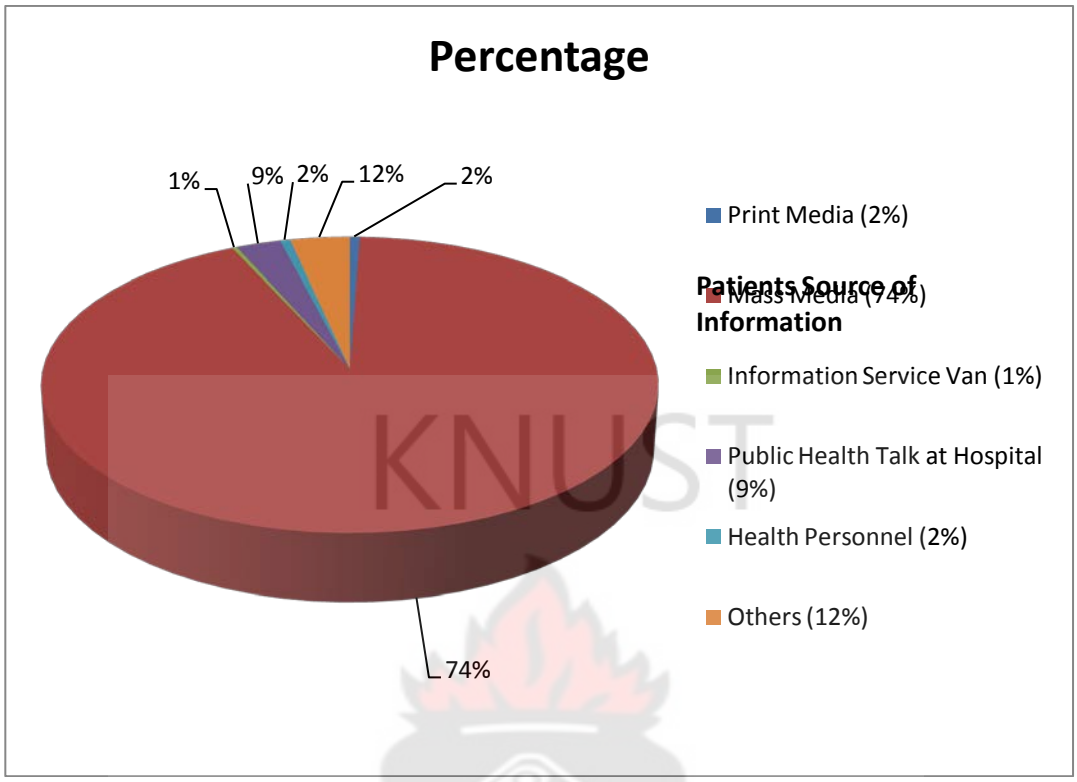

Fig. 3.7: Source of information on Antimalaria policy.

The others (8.0%) are sources such as school, the home and from friends,

Table 3.8 indicates the impact of patient's educational background on knowledge of policy

Table 3.8: Impact of patients' educational background on knowledge of policy.

Educational Background		Knowledge of Antimalarial Policy		Total	Percentage of each level of education that has knowledge of the policy
		Yes	No		
Level of Education	No formal education	30	40	70	42.85%
	BECE/MSLC	172	80	252	68.25%
	SSSCE/GCE 'O' & 'A' Level	33	15	48	68.75%
	Tertiary Institution	27	3	30	90%
Total		262	138	400	65.5%

Table 3.9 indicates the patients' understanding and knowledge of the new malaria policy.

Table 3.9: Patient Description of Antimalarial Policy

Description of Policy	Frequency	Percent
	138	34.5%
clean environment	56	14.0%
clean environment, cleaning gutters	1	.3%
clean environment, use Artesunate+Armodiaquine	2	.5%
use of Artesunate Amodiaquine	7	1.8%
use of Artesunate Amodiaquine, no more single therapy	4	1.0%
use of dual therapy to treat malaria	1	.3%
use of insecticide	5	1.3%
use of ITN	28	7.0%
use of ITN, clean environment	41	10.3%
use of ITN, clean environment, use of Artesunate+Armodiaquine	2	0.5%
use of ITN, clean environment, use of insecticide	92	23.0%
use of ITN, clean environment, use of insecticide, use of Artesunate+Armodiaquine	1	0.3%
use of ITN, clean environment, use of Artesunate+Armodiaquine	1	0.3%
use of ITN, use medication	3	0.8%
use of ITN, use of Artesunate+Armodiaquine	4	1.0%
use of ITN, use of insecticide	11	2.8%
use of ITN, use of insecticide, use of Artesunate+Armodiaquine	2	0.5%
use of medication	1	0.3%
Total	400	100%

Patients' description of the new antimalaria policy barely covered the preventive aspect. They do not have knowledge of the antimalaria drug policy. Only five patients (1.9% of those who said they knew the policy) stated that single agent therapy should no longer be used.

Furthermore to ascertain if patients really knew about the combination therapy they were asked if they had taken an ACT before. 26 % of the total sample (400) had previously taken an ACT on their own before and 74 % had not taken it before. Some patients had taken more than one type of ACT before. (Figure 3.8) Also majority of the patients had ACTs previously prescribed for them by a doctor (Table 3.10)

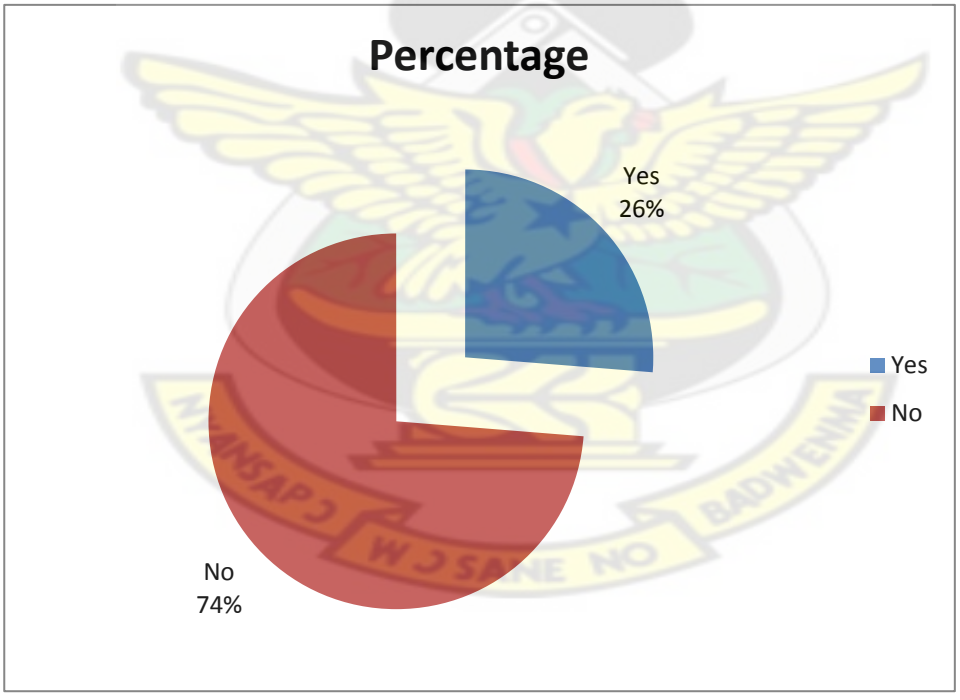

Fig. 3.8: Patients who acquired ACTs on their own.

Table 3.10: Patients who were prescribed ACTs previously.

ACTs Prescribed		Patients who have been prescribed ACT before		Total
		Yes	No	
Type of ACT Prescribed	AA	263 (65.8%)	0 (0%)	263 (65.8%)
	AL	53 (13.3%)	0 (0%)	53 (13.3%)
	AP	5 (1.3%)	0 (0%)	5 (1.3%)
	AA,AL	11 (2.8%)	0 (0%)	11 (2.8%)
	AA,AP	2 (0.5%)	0 (0%)	2 (0.5%)
	AL, AP	1 (0.3%)	0 (0%)	1 (0.3%)
	Other	0 (0%)	65 (16.3%)	65 (16.3%)
Total		335 (83.8%)	65 (16.3%)	400 (100.0%)

3.3.2 Patients' Perception on Efficacy of the new policy

Out of a total of the 335 patients who have taken ACTs before, 86.87% (291) said that the ACTs are efficacious and13.13%% (44) said that they are not effective.

3.3.3 Patients Perception of Safety

Out of the 335 patients who had taken ACTs 41.2% (138) said the combinations have side effects and 56.7% (190) said the combinations did not have side effects. 2.08% did not respond.

Again, 96.4% (323) of patients who had taken an ACT knew about some precautions to observe whilst administering the medication and 2.4% (8) did not know of any precautions to observe. 1.2% did not respond.

Precautions mostly cited were:

- after meals
- complete treatment
- take right dose
- before meals

The commonest side effects also cited were:

- Dizziness
- Weakness
- Abdominal pain and
- Palpitation

With another episode of malaria, some patients would still like to take an ACT (Table 3.11) and others not.

Table 3.11: Distribution of patients who are ready to take an ACT with another episode of malaria.

ACTs taken		ACT with another episode of malaria			Total
		Yes	No	Will take what the clinician gives	
Preferred Antimalarial medicine.	AA	225 (56.3%)	0 (0%)	0 (0%)	225 (56.3%)
	AL	60 (15.0%)	0 (0%)	0 (0%)	60 (15.0%)
	AP	8 (2.0%)	0 (0%)	0 (0%)	8 (2.0%)
	AA,AL	5 (1.3%)	0 (0%)	0 (0%)	5 (1.3%)
	AA,AP	3 (0.8%)	0 (0%)	0 (0%)	3 (0.8%)
	AL, AP	1 (0.3%)	0 (0%)	0 (0.0%)	1 (0.3%)
	Other	0 (0%)	32 (8.0%)	66 (16.5%)	98 (24.5%)
Total		302 (75.5%)	32 (8.0%)	66 (16.5%)	400 (100.0%)

CHAPTER FOUR

DISCUSSION, CONCLUSION, RECOMMENDATION.

4.1 DISCUSSION

4.1.1Management of Malaria in the Hospital

A total of 17 (seventeen) clinicians comprising 15 (Fifteen) medical doctors and two (2) medical assistants see and manage uncomplicated malaria in the hospital. An overview of the management of malaria in the hospital (Table 3.1) shows an adherence by clinicians to the Standard Treatment Guidelines in the management of uncomplicated malaria. Artesunate + Amodiaquine (AA), Artemether + Lumefantrine (AL) and Dihydroartemisinin + Piperaquine (AP) are the Antimalarial medicines used in the hospital for the management of malaria. Clearly from Table 3.1 AA is the most prescribed Antimalarial (51%), while AL constitutes 43% and AP 6% of prescriptions for malaria management in the hospital. The commonest factors considered by clinicians in prescribing Antimalarials (Table 3.2) are

- Side effects of medication
- Duration of treatment
- Frequency of administration
- Pill burden.

In managing the patients only 3% (12) of the total sample was involved in the decision of their prescription; this is woefully low. 97% (388) did not know what they were being managed for (Table 3.3). Also 45% of patients did not know the medications they were taking home. (Table 4.1 Appendix 4)

This kind of pharmaceutical care were patients are not involved in their care contributes to non adherence to treatment. Adherence to medical recommendations has been defined as the extent to which a person's behavior coincides with medical or health advice, such as taking medication regularly, returning to a doctor's office for follow-up appointments, and observing preventive and healthful lifestyle changes (Morisky, 2001).

To prevent nonadherence situations the consultation between patients and the health care team should be one of concordance. Concordance is fundamentally different from either compliance or adherence in two important areas: it focuses on the consultation process rather than on a specific patient behaviour, and it has an underlying ethos of a shared approach to decision-making rather than paternalism. (Weiss & Britten 2003). Concordance values the patient's perspective, acknowledging that the patient has expertise in his or her body's experience of illness and response to treatment (Weiss & Britten, 2003**)**. Further more a recent systematic review of the literature relevant to concordance found that two-way communication between patients and professionals about medicines led to improved satisfaction with care, knowledge of the condition and treatment, adherence, health outcomes and fewer medication-related problems. (Cox, 2003).

4.2 CLINICIANS' PERCEPTION OF ANTIMALARIA POLICY

4.2.1 Clinicians' Awareness and Knowledge of the New Policy

All 17 clinicians responded "yes" to knowledge of the policy. With the description of knowledge of the policy however two (12%) of them had no response (Table 4.2 Appendix 4). Three (18%) of them said it is the use of Artesunate+Amodiaquine, one (6%) said it is the use of Artesunate+Amodiaquine as first line treatment and the use of quinine tablets/intravenous in pregnant women. Eleven (64%) of them said it is the use of ACTs. Clearly, all the clinicians prescribe the three Antimalarial combinations in the hospital although their definition of the policy was skewed towards Artesunate + Amodiaquine. Clinicians and Health professionals were well informed about the new policy change in a study in a rural community in Ghana. Information was through periodic updates by the Pharmacy Council of Ghana and the District Health Directorate. (Asante et al, 2009).

4.2.2 Clinicians' perception of Efficacy

Out of the 17 clinicians, 94% (16) said that the combinations are effective and 6% said that they are not effective (Table 3.5). The most effective combination cited here was AA (53%). AP was not cited here at all and this is reflected in the general overview where prescriptions on AP scored 6%. On the question of whether the combination was the best policy to be adopted by Ghana, 82% of clinicians responded "yes" and 18% said "no". Out of the 18% who said "no" one (33.3%) had no reason for this response.

The other two (66.7%) attributed their response to adverse drug reactions and development of resistance stains. Ironically one of the benefits of using the combination therapies is to prevent the development of resistance strains of the plasmodium parasite; this reason is therefore unfounded. Side effect is however key among the factors considered when prescribing.

4.2.3 Clinicians' perception of Safety

On the safety of the combinations AA and AL have the same level of side effects (47%). Here 53% of clinicians said the combinations have mild and quite tolerable side effects whilst 41% said that they have serious side effects (Fig3.3). 6% did not respond. Overall clinicians are satisfied with the combinations. Their satisfaction with turnover rate on review of patient's shows that 59% are very satisfied, 35% are satisfied and 6% are fairly satisfied (Table 4.3 Appendix 4). Further on documentation of adverse reactions, 29% do not find the need to do so (Fig 3.7) possibly because they do not actually see these reactions; mention of them could then be a perception.

4.3 PATIENTS' PERCEPTION OF ANTIMALARIAL POLICY

Majority of patients barely know the preventive aspect of the new malaria policy. Only 1.9% of those who knew the policy could describe the medicine aspect of it.

4.3.1 Patients' Awareness and Knowledge of the New Policy

Out of the total sample of 400 patients 65.5% (262) had knowledge of the

policy. 34.5% had no knowledge at all of the policy. This compares well with a study conducted by Eriksen et al (2005) to assess the diffusion of the change of first line antimalarial drug from chloroquine (CQ) to sulphadoxine/pyrimethamine (SP) at household level in a rural district of Tanzania less than a year after the policy implementation. Caretakers in 729 households were interviewed on knowledge of the new policy, home stocking of antimalarials, home-treatment practices of children younger than 5 years with fever, health-seeking behaviour and experience of SP. From the results about 51% of the population knew that SP was the first line antimalarial.

In another study by Asante et al (2009) 40% of care givers did not know about the policy change to Artesunate + Amodiaquine. The percentage who knew the policy could only talk about the prevention of malaria as shown in Table 3.9 and the main source of information is the mass media (Fig 3.7). The impact of patients' educational background is very significant in this study. Table 3.8 shows that education has a positive impact on knowledge of policy. The group with no formal education recorded the lowest percentage of 42.85% which is the percentage of the total number in this group who had knowledge of the policy. The percentage rose through the levels to the tertiary education which recorded the highest percentage of 90%.

4.3.2 Patients' Perception of Efficacy

Out of the 335 patients who have previously taken an ACT 86.87% (291) said they are efficacious and 13.13% (44) said they are not effective. Some patients who said

the combinations were not effective obviously kept a poor dosage schedule and were ready to take them again. Respondents in a study on community perceptions of malaria treatment and implications for ACTs in a rural community in Ghana shows that patients who had ever taken AA perceived it to be a good drug; although they mentioned they had experienced some side effects including headaches and body weakness. (Asante et al, 2009). With reassurance and information these patients would improve.

4.3.3 Patients' Perception of Safety

56.72% of all the patients who have taken an ACT (335) said the combinations are safe. A significant percentage of 41.19 said they have unbearable side effects. The commonest side effects cited were;

- Dizziness
- Weakness
- Abdominal pain
- Palpitation

(Table 4.4 Appendix 4)

Out of all who have taken ACTs 96.4% know about some simple precautions to observe whilst taking the medications, some of which are;

- To take medication after meals
- To complete treatment
- To take right dose

With another episode of malaria 90.4% of those who have had an encounter with an ACT would still want to take an ACT. Twenty-Six (6.5%) said they would take any other ACT apart from Artesunate + Amodiaquine.

4.4 CONCLUSION

Among the Artemisinin-Based combination therapies used for the management of uncomplicated malaria at the St. Dominic Hospital this study showed that Artesunate+Amodiaquine is the most commonly prescribed option. Other combination therapies used in the hospital are Artemether+Lumefantrine and Dihydroartemisinin+Piperaquine and dosage is based on patient's body weight.

Although clinicians see the side effects of the ACTs as key in prescribing them, they said that these side effects are mild and quite tolerable. The side effect profile was the same (47%) for AA and AL. AP was not sited for side effects. They are therefore satisfied with patient turnover rate on review. Their perception of safety and efficacy of ACTs is therefore a very positive (good) one and the policy was said to be a good one (82%). Current effort to eliminate malaria greatly depends on the perceptions of antimalarial interventions.

Eighty eight percent (88. %) of clinicians who see patients with malaria at the hospital have knowledge of the new Antimalaria policy and adhere to the standard treatment guidelines.

Among patients, there is very low knowledge of the policy. Those who responded

to having knowledge of the policy (65.5%) barely knew of the preventive aspect of the policy. Only 1.9% of those who knew the policy could state that the new malaria policy requires that no one uses monotherapy. Among patients, 86.87% of patients who have used ACTs said they are safe and efficacious.

34% of patients said the ACTs have side effects that are unbearable although 75.5% are ready to take them with another episode of malaria. It is clear from this relationship that there is some perception among patients that ACTs are intolerable possibly based on what they hear others say. 97.0% of patients were not involved in issues concerning their prescription with the clinician. Only 3% were told what their ailment was and the management thereof.

4.5 LIMITATIONS

Due to constraint of time the sample was collected over a period of only one month and this could have an impact on the findings as this period could not be representative of the whole year. Financial constraint limited the sample size for the study. Larger samples could be studied in future if a budget is approved.

4.6 RECOMMENDATION

Education of both health care professionals and the public is still important; very little is known about the Antimalaria policy by the public. There is the need to package information in such manner that the public would appreciate the combination therapies of the new malaria policy. The public's mind should be disabused of the negative perceptions of the ACTs. The area of policy on treatment options for malaria requires emphasis. Health care planners of the hospital therefore need to integrate this into the programmes outlined for the hospital.

It is also important that clinicians involve patients in their health management when they see them. This will enable patients take better care of themselves in managing malaria especially in the area of compliance to medication regime. Adverse drug reactions could be life threatening, therefore it is imperative that clinicians do documentation on this as and when required. This, when done promotes pharmacovigilance and provides information for malaria research.

Pharmacy staff need to do more on patient education since a good number of patients (45% in this study) do not know the medications they are given.

Further study is also required on patient and health professional perceptions and attitude concerning the use of ACTs in malaria since not much has been done in this area.

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