PRESCRIPTION PATTERNS OF LICENSED CHEMICAL SELLERS SHOPS IN THE MANAGEMENT OF UNCOMPLICATED MALARIA ONE YEAR AFTER THE IMPLEMENTATION OF THE NATIONAL ANTI-MALARIA DRUG POLICY.

by

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DECLARATION

I, Anthony Amalba hereby declare that this submission is my own work towards the MSc and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any degree of the University, except where due acknowledgement has been made in the text.

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ABSTRACT

Introduction:

Malaria remains a leading cause of morbidity and mortality in pregnant women and children particularly in tropical Africa. Effective medicines and preventive measures are available. Globally, malaria control programme are threatened by the growing resistance of plasmodium falciparum to the conventional mono-therapy such as chloroquine, amodiaquine and sulphadoxine-pyrimethamine. However, these effective and relatively inexpensive medicines like Chloroquine have been rendered ineffective to the plasmodium falciparum parasite due to prescribers prescribing practices and other causes. This led to a policy change in the management of malaria. In 2005 the new anti-malaria policy was launched in the country with Artemisinin Combination Therapy for treatment of malaria.

Aim:

The aim of this study was to ascertain the knowledge level of Licensed Chemical Sellers (LCS) shops on the new anti-malaria drug policy on the management of malaria in Northern Ghana (Northern Region, Upper East and Upper West), one year after the introduction of the policy.

Method:

This research was a cross-sectional survey of Licensed Chemical Sellers (LCS) in the three northern regions of Ghana. Questionnaires were administered to a randomly selected Licensed Chemical Sellers in all the districts in the three northern regions (N/R, UE & UW).

Result:

The study revealed that although majority of LCS (76%) were aware of the new policy, a large majority (98%) of LCS shops were not knowledgeable about dosage, frequency of administration and duration of the new anti-malaria drug. For the reason for the change in policy 66% said Chloroquine was no longer effective and 34% were not sure of the reason. For prophylactic drug in pregnant women 51% will give Chloroquie as against 30% SP and 19% Daraprim**.**

Conclusion:

The treatment guidelines of Ghana Health Service (GHS) on malaria should be made available to all Licensed Chemical Sellers (LCS) to allow Pharmacy Council to monitor the implementation of the new anti-malaria drug policy at the facility level.

KEY WORDS: Anti-malaria drug policy, Licensed Chemical Sellers, Artesunate combination-based therapy.

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LCS- Licensed Chemical Sellers

NMCP- National Malaria Control Programme

PC- Pharmacy Council

GHS- Ghana Health Service

ACT-Artemisinin Combination Therapy

WHO- World Health Organisation

CDC- Centre for Disease Control

UDS- University for Development Studies

SMHS- School of Medicine and Health Sciences

IMCI- Integrated Management of Childhood Illness

NCID-National Centre for Infectious Disease

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Chapter one

1.1 Introduction

Malaria remains a leading cause of morbidity and mortality in pregnant women and children particularly in tropical Africa, where about 90% of the malaria deaths occur. Yet malaria is a curable disease and not an inevitable burden (WHO 2005).

Effective medicines and preventive measures are available. However, these effective and relatively inexpensive interventions reach only a small proportion of the populations in need, mainly because of insufficient financial resources (WHO 2005).

During the last decade, new medicines and approaches have been developed for malaria case management, for selective vector control and for epidemic detection and control

The primary purpose of anti-malarial therapy is to ensure prompt, effective and safe treatment of malaria. Dependent on the epidemiological and operational situations, "effective treatment" can be either clinical cure, i.e. clearance of clinical signs and symptoms and prevention of their recrudescence, or radical cure, i. e. clinical cure with the elimination of parasites. (WHO 2005)

Achieving effective antimalarial drug use over the short-to medium-term will require an appreciation of how drugs are currently used in the real world and development of innovative approaches to optimize that use.(WHO 1993)

Globally, malaria control programmes are threatened by the growing resistance of *Plasmodium falciparum* to the conventional mono-therapy such as chloroquine, amodiaquine.

Antimalarial drug resistance is forcing newly developed pharmaceuticals into widespread use at an accelerating pace. While other regions of the world may have greater problems with multi-drug resistant malaria, the public health threat of drug resistance is greatest in Africa, which bears the bulk of the burden of malaria.(WHO 1993)

Studies conducted by the National Control Programme in collaboration with the Noguchi Memorial Institute for Medical Research showed that there is now resistance of *Plasmodium falciparum* to chloroquine (MOH/GHS/NMCP/WHO 2004). The study indicated that the level of treatment failure could not be attributed to poor quality of chloroquine as tests performed on samples of chloroquine tablets used showed that the drugs were generally of good quality (MOH/GHS/NMCP/WHO 2004). This led to a policy change in the management of malaria. In 2005 the new anti-malaria policy was launched in the country with Artemisinin Combination Therapy for treatment of malaria. This was against the background that the malaria parasite is growing resistant to chloroquine which was the drug of choice in the treatment of malaria. In line with policy shift, efforts were made to train all prescribers (Doctors, Pharmacists, and Nurses etc), including Licensed Chemical Sellers (LCS) on the new drug combination. Despite the fact that the programme has been on going for sometime now, that is over a year there has been little follow-up studies to find out the knowledge and skills of these service providers especially the Licensed Chemical Sellers as to the use of this new anti-malaria drug. This research work seeks to find out the knowledge level of LCS shops with regards to their prescription patterns in relation to the new anti-malaria drug policy.

1.2 Theoretical Background.

Malaria is a protozoa disease transmitted by the Anopheles mosquito caused by minute parasitic protozoa of the *Genus Plasmodium*, which infect human and insect hosts alternatively. It is a very old disease and pre-historic man is thought to have suffered from malaria. It probably originated in Africa and accompanied human migration to the Mediterranean shores, India and South East Asia. In the past it used to be common in the marshy areas around Rome and the name is derived from the Italian, mal-aria meaning bad air. It was also known as Roman fever (MOH/GHS/NMCP/WHO 2005). Precisely, a hundred years ago the British Physician Ronald Ross proved that malaria was spread, not by air, or water, but by mosquitoes (MOH/GHS/NMCP/WHO 2005).

Fishermen and traders, long before British colonisation, probably introduced the disease into northern Australia and in the past malaria was not uncommon in the northern parts of the country. In Western Australia an explosive outbreak of falciparum malaria occurred at Fitzroy crossing in 1934 which was mistaken for influenza and resulted in 165 deaths. WHO declared Australia free of malaria in 1981. "Airport malaria" has become a problem in recent years. A publican working in an establishment close to London's Heathrow Airport became acutely ill and was found to be suffering from falciparum malaria; he had never been out of the country. A lady driving her car passing the same airport became ill with malaria although she too had never been out of the country (MOH/GHS/NMCP/WHO 2005).

Four workers unloading a cargo plane at Amsterdam Airport became infected with malaria. It is assumed that infected mosquitoes were carried on planes from Africa and released at the destination airport.

Malaria was among the most common reasons for hospitalization during the two world wars, each reporting more than 1.2 million cases between them.

The Vector

There are approximately, 3,500 species of mosquitoes grouped into 41 *Genera.* Human malaria is transmitted only by females of the *Genus Anopheles*. Of the approximately 430 Anopheles species, only 30-40 transmit malaria i.e. are vectors in nature. *Anopheles* are found world wide except Antarctica. Malaria is transmitted by different Anopheles species, depending on the region and the environment. *Anopheleses* that can transmit malaria are found not only in malaria – endemic areas, but also in areas where malaria has been eliminated. The latter areas are thus constantly at risk of re-introduction of the disease (MOH/GHS/NMCP/WHO 2005).

In Ghana, there are two main malaria vectors namely, *Anopheles, Gambiae sensu latum* (in the general sense) and *Anopheles tuneslus* (MOH/GHS/NMCP/WHO 2005).

The *Anopheles gambiae* is a complex species consisting of six siblings. The three important siblings for Ghana are *A gambiae setisu strictum* (ss) – in a restricted sense, *A melas* and *A arabiensia* (MOH/GHS/NMCP/WHO 2005)

A gambiae SS in found in the whole country, *A melas* is in the coastal swamps, whilst *A arabiensis* is found in the north. Of the three species, the important one is *A gambiae SS. Anopheles gambiae SS* is mainly indoor-biting and indoor-resting, whilst *A arabiensis* is mainly outdoor biting and outdoor-resting with peak biting period around 10:00pm. *A gambiae* breeds in temporary water collections and therefore its population increases after rain (MOH/GHS/NMCP/WHO 2005).

Anopheles funestus is found mainly in forest areas where streams abound. It is mainly indoor-feeding (endophasic) and indoor-resting (endophilic). It breeds in permanent water bodies and is therefore present throughout the year (MOH/GHS/NMCP/WHO 2005).

Life Stages

Like all mosquitoes, anophelines go through four stages in their life cycle egg, Larva, Pupa and adult.

The first three stages are aquatic and last 5-14 days, depending on the species and the ambient temperature. The adult stage is when the female Anopheles mosquito acts as malaria vector. The adult females can live up to a month (or more in captivity), but most probably do not live more then 1-2 weeks in nature (MOH/GHS/NMCP/WHO 2005).

Eggs

Adult females lay 50-200 eggs per oviposition. Eggs are laid singly directly on water and are unique in having floats on either side. Eggs are not resistant to drying and hatch within 2-3 days although hatching may take up to 2-3 weeks in colder climates.

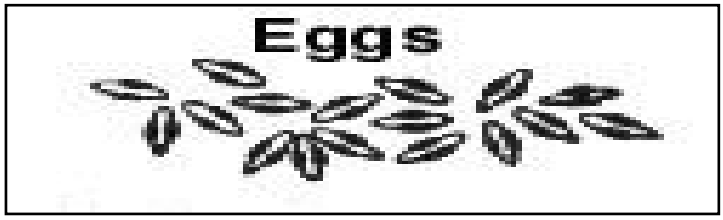

Fig.1.1 eggs stage

Larvae

Mosquito larvae have a well-developed head with mouth brushes used for feeding a large thorax and a segmented abdomen. They have no legs in contrast to other mosquitoes. Anopheles larvae lack a respiratory siphon and for this reason position themselves so that their body is parallel to the surface of the water. Larvae breathe through spirades located on the 8th abdominal segment and therefore must come to the surface frequently. The larvae spend most of their time feeding on algae, bacteria, and other micro-organisms in the surface micro-layer. They dive below the surface only when disturbed. Larvae swin either by jerky movements of the entire body or through propulsion with the mouth brushes. Larvae developed through four stages, or instars after which they metamorphose into pupae. At the end of each instar, the larvae molt, shedding their exoskeleton, or skin to allow for further growth. The larvae occur in a wide range of habitats but most species prefer clean unpolluted water. Larvae of Anopheles mosquitoes have been found in fresh or salt-water marshes, mangrove swamps, rice fields grassy ditches, the edges of streams and rivers and small temporary rain pools. Many species prefer habitats with vegetation. Others prefer habitats that have none. Some breeds in open sun-lit pools while others are found only in shaded breeding sites in forests. A few species breed in tree holes or the leaf axils of some plants.

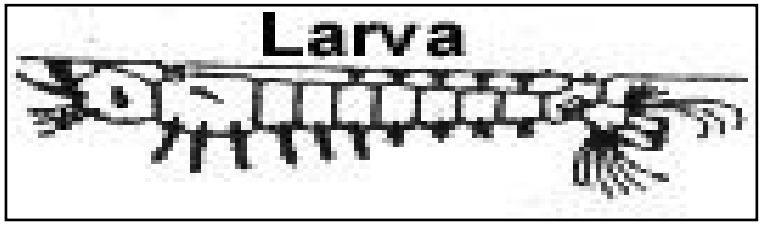

Fig.1.2 larva stage

Pupae

The pupa is comma shaped when viewed from the side. The head and thorax are merged into a cephato thorax with the abdomen curving around underneath. As with the larvae, pupae must come to the surface frequently to breathe, which they do through a pair of respiratory trumpets on the cephalothorax. After a few days as a pupa the dorsal surface of the cephalothorax splits and the adult mosquito emerges. The duration from egg to adult varies considerably among species and is strongly influenced by ambient temperature.

Fig.1.3 Pupa stage

The head also has an elongated forward projecting proboscis used for feeding and two sensory palps. The thorax is specialised for locomotion. Three pairs of legs and as pair of wings are attached to the thorax. The abdomen is specialised for food digesting and egg development. This segmented body part expands considerably when a female takes a blood meal. The blood is digested over time serving as a source of protein for the production of eggs, which gradually fill the abdomen.

Anopheles mosquitoes can be distinguished from other mosquitoes by the palps, which are as long as proboscis, and by the presence of discrete blocks of black and white scales on the wings. Adult Anopheles can also be identified by their typical resting position.

Male and female rest with their abdomens sticking up in the air rather than parallel to the surface on which they are resting. Adult mosquitoes usually mate within a few days after emerging from the pupal stage. In most species, the males form large swarms, usually around dusk, and the females fly into the swarms to mate.

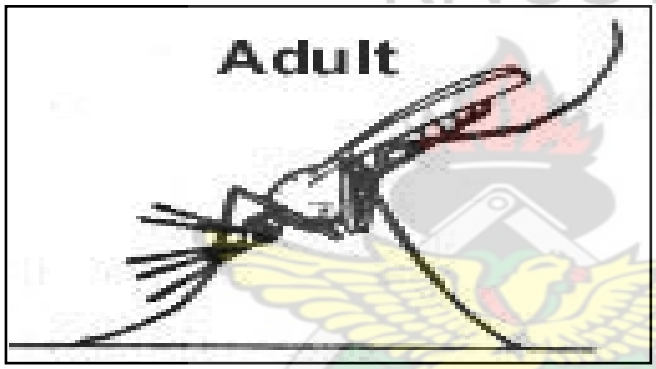

Fig.1.4 adult stage

Males live for about a week, feeding on nectar and other sources of sugar. Females will also feed on sugar sources for energy but usually require a blood meal for the development of eggs. After obtaining a full blood meal, the female will rest for a few days while the blood is digested and eggs are developed. This process depends on the temperature but usually takes 2-3 days on tropical conditions.

1.2.1 Pathophysiology of Malaria

All the typical clinical symptomology and severe disease pathology associated with malaria is caused by the asexual erythrocytic or blood stage parasites. When the parasite develops in the erythrocyte numerous known and unknown waste substances such as hemozoin pigment and other toxic factors accumulate in the infected red blood cell. These are dumped into the bloodstream when the infected cell lyse and release invasive merozoites. The hemozoin and other toxic factors such as glucose phosphate isomerase (GPI) stimulate macrophages and other cells to produce cytokines and other soluble factors which act to produce fever rigors and probably influence other server symptoms associated with malaria

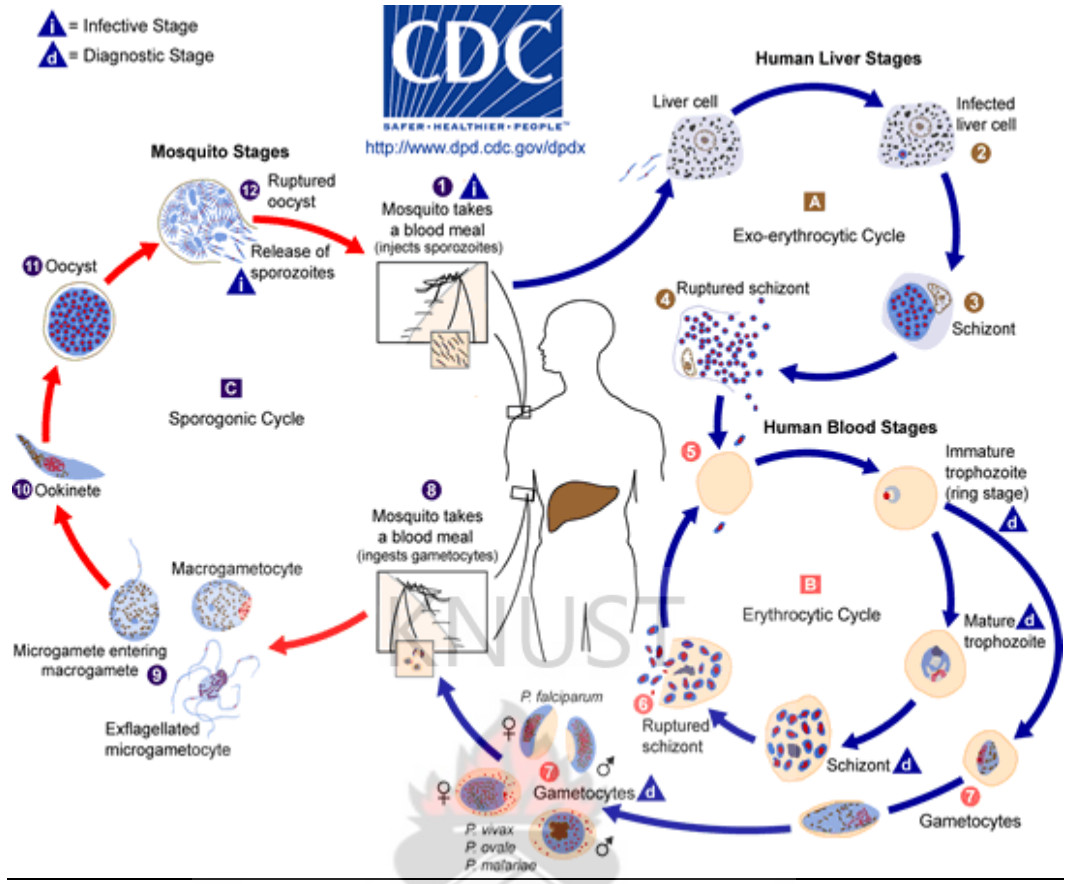

Fig.1.5 Life cycle of malaria parasite. Source: CDC

Schema of the Life Cycle of Malaria

The malaria parasite life cycle involves two hosts. During a blood meal, a malaria-infected female Anopheles *mosquito inoculates sporozoites into the human host* ❶. *Sporozoites infect liver cells* ❷ *and mature into schizonts* ❸, *which rupture and release merozoites* ❹. *(Of note, in* P. vivax *and* P. ovale *a dormant stage [hypnozoites] can persist in the liver and cause relapses by invading the bloodstream weeks, or even years later.) After this initial replication in the liver (exo-erythrocytic schizogony* Ⓐ*), the parasites undergo asexual multiplication in the erythrocytes (erythrocytic schizogony* Ⓑ*). Merozoites infect red blood cells* ❺. *The ring stage trophozoites mature into schizonts, which rupture releasing*

merozoites ❻. *Some parasites differentiate into sexual erythrocytic stages (gametocytes)* ❼. *Blood stage parasites are responsible for the clinical manifestations of the disease.*

The gametocytes, male (microgametocytes) and female (macrogametocytes), are ingested by an Anopheles *mosquito during a blood meal* ❽. *The parasites' multiplication in the mosquito is known as the sporogonic cycle* C. *While in the mosquito's stomach, the microgametes penetrate the macrogametes generating zygotes* ❾. *The zygotes in turn become motile and elongated (ookinetes)* ❿*which invade the midgut wall of the mosquito where they develop into oocysts* ⓫. *The oocysts grow, rupture, and release sporozoites* ⓬, *which make their way to the mosquito's salivary glands. Inoculation of the sporozoites* ❶*into a new human host perpetuates the malaria life cycle.*

Plasmodium falciparum causes more severe disease than other plasmodium species do. Some of the following factors account for the greater pathogenecity of *P. Falciparum*.

P. falciparum is able to infect red blood cells of any age, leading to high parasite burden and profound anaemia. The other species infect only new or old red blood cells which are a smaller fraction of the red blood cell pool (Kumar *et al.*, 2004).

P. Falciparum causes infected red blood cell to clump together (rosetting) and to stick to endothelial cells linning small blood vessels (sequentration), which block blood flow. Several proteins, including *P. falciparum* erythrocyte membrane protein 1 (PfEmP1), form knobs on the surface of red blood cells. PfEmP1 binds to ligands on endothelial cells, including CD36, thrombospondin, E-selectin etc. Ischemia due

to poor perfusion causes the manifestation of cerebral malaria which is the main cause of death due to malaria in children (Kumar *et al.,* 2004).

P. falciparum stimulates production of high levels of cytokines, including TNF, IFN-Y and IL-1, GPI-linked proteins, including merozoite surface antigens, are released from infected red blood cells and induce cytokine production by host cells by a mechanism that is not yet understood. These cytokines suppress production of red blood cells, increase fever, induce nitric oxide production leading to tissue damage, and induce expression of endothelial receptors for PfEmP1, increasing sequestration (Kumar *et al.*, 2004).

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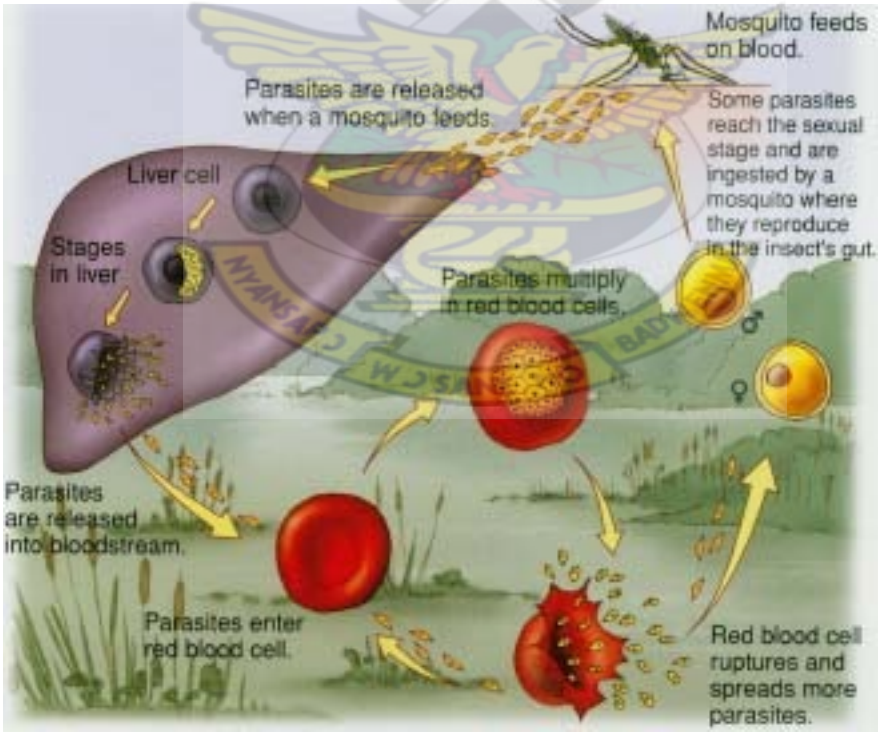


Fig.1.6 Source: CD

1.2.2 HOST RESISTANCE TO PLASMODIUM

There are two general mechanisms of host resistance to *Plasmodium.* First, inherited (Genetic factors) alteration in red blood cells make people resistant to *Plasmodium*, several common mutations in haemoglobin genes confer resistance to malaria. People who are heterozygous for the sickle cell trait (Hbs) become infected with *P. falciparum*, but are less likely to die from infection (Kumar *et al.*, 2004).

The Hbs trait causes the parasite to grow poorly or die at low oxygen contraction, perhaps because of low potassium levels caused by potassium efflux from red blood cells on haemoglobin sickling (Kumar *et al*., 2004).

In general, the prevalence of haemoglobin, the thalassemias and G6PD deficiency are more prevalent in malaria endemic areas and are thought to provide protection from malaria disease.

People can also be resistant to malaria due to the absence of proteins to which the parasites bind. *P. vivax* enters the red blood cells by binding to the Duffy blood group antigen. Most of the people in West Africa and much of East Africa do not have this receptor and they are protected from *P. vivax* infection (Kumar *et al.*, 2004).

Secondly, repeated or prolonged exposure to the plasmodium species stimulates an immune response that reduces the severity of the illness caused by malaria. Individual living where plasmodim is endemic often gain partial immune-mediated resistance to malaria, evidenced by reduced illness despite infection.

Antibodies and T-lymplocytes specific for plasmodium reduce disease manifestation although the parasite has developed strategies to evade the host immune response (Kumar *et al.*, 2004).

It is significant to note the immunity acquired against malaria is that the maintenance of this non-sterile state of immune protection requires continued exposure to malaria infection and a functioning spleen. Splenectomy makes an otherwise immune protected human fully susceptible again to infection and disease. Likewise, when immune individuals leave a malaria endemic area and reside for several years in a malaria-free area often become susceptible to infection and clinical symptoms when they return to a malaria area. Malaria parasites infect different targets such as liver and erythrocytes and therefore different immune resources are elicited by infection with malaria parasites. These immune responses include antibodies lymphocytes, monocytes, macrophages, natural killer (NK) cells, and neutrophils .

Experimental studies have shown that antibodies, cells and cellular factors can mediate protection in malaria as well as disease. Antibodies can mediate their protective effect by multiple mechanisms. Antibodies developed against parasites can neutralise the parasites, retard parasite development and prevent them from entering target cells and help macrophages to efficiently engulf the parasites and infected cells. Antibodies developed against gametocytes (sexual stage parasites) can prevent development of sexual stage parasites in mosquitoes when taken up along with the blood meal. This type of immune protection is often referred to as transmission-blocking immunity. Some research conducted by Center for Disease Control (CDC) scientists focuses on how humans acquire protective antibodies after natural exposure to malaria parasites and how it helps them to control malaria parasites and prevent diseases. NK cells and neutrophils are first line defences against malaria and they can attack malaria parasites in several ways (Kumar *et al.*, 2004).

Macrophages are responsible for eventual clearance of parasites from the blood. These cells engulf malaria parasites and parasitized erythrocytes and kill them. Cellular immunity involving cytotoxic T-cells are particularly effective in attacking malaria parasites during the liver stage development. Cytokines (cellular factors) released from lymphocytes enhance this process. Cytokines secreted by different leucocytes populations may also play a direct role in protection. For example, interferon-gamma has been shown to work against liver stage parasites development and activates macrophages to attack blood stage parasites (Kumar *et al.,* 2004).

Cytokines are also responsible for the severity of disease. A cytokine known as tumor necrosis factor (TNF) alpha is one factor responsible for high fever observed in malaria patients.

The severity of disease may vary depending upon the level and the type of cytokines produced after malaria parasite infection. For example, only about 2/3 of the patient who develops the clinical syndrome known as cerebral malaria survives after curative and supportive treatment. It is not known; though why still about 20% to 30% of patients die despite treatment (Kumar *et al.,* 2004).

Understanding the host immune pathways may help to improve treatment for cerebral malaria. Similar studies will also help in understanding why some women deliver prematurely after malaria and why some women deliver low birth weight babies. Each of the developmental forms (liver stages, asexual blood stages, gametocytes, sporozoites) of the malaria parasites presents a different group of targets antigens) to the immune system of the infected host. In addition to this diversity of targets malaria parasites mutate rapidly generating different variant forms such that individual antigens may differ within the same species of parasite. This ability to generate different forms and a diversity of polymorphism within the

antigenic targets of the host's immune system help the parasites to evade malaria immunity. Characterisation of parasite diversity is critical for developing suitable targets for vaccine development.

1.2.3 Malaria Diagnosis

1.2.3.1 The Clinical presentation of malaria

Malaria is an illness usually characterised by fever but its clinical presentation may mimic other diseases, which often makes diagnosis difficult. A comprehensive presentation of the clinical features of malaria has been made by Harinasuta and Bunnag (Harinasuta *et al.*, 1988). Malaria can be confused with viral infections like influenza and hepatitis and bacterial infections, such as meningitis in comatose patients, and respiratory and urinary infections. In addition, the clinical manifestation of malaria may be modified by partial immunity acquired by a previous infection and/or subcurative treatment with antimalaria drugs. In spite of this, the diagnosis of malaria must be addressed as a matter of urgency since the predominant parasite. *P. falciparum*, may rapidly lead to death (Harinasuta *et al.*, 1988).

Clinical identification of cases is the first essential step in the management of malaria in all settings. The diagnosis of malaria is suggested by the clinical features, presented by the patient, and confirmed by the demonstration of parasitaemia by laboratory examinations. In malaria-endemic countries, doctors, nurses and health assistants are all confronted with the non-specific nature of the clinical presentation of malaria, the absence of laboratory support in peripheral health services, and the need for urgent management of a rapidly killing disease. Time constraints often lead

to inadequate assessment of fever with the consequence of over-treatment of malaria and lack of treatment of other major diseases (Giles H.M., 1988).

Clinical assessment, however, is the only feasible approach to the diagnosis of malaria, and will probably continue to be the basis for the management of malaria for the near future (Giles H.M., 1988). Moreover, in highly endemic areas the laboratory confirmation has a limited role in the diagnosis of malaria because of the high prevalence of asymptomatic parasitaemias. In such areas, the rational used of the microscopic examination should be for identifying and confirming treatment failures and severe malaria, as well as to support the diagnosis of uncomplicated clinical attacks during the low transmission season (Giles H.M., 1988).

Current WHO recommendation emphasizes the assessment of fever or history of recent fever for the diagnosis and treatment of malaria (WHO, 1992). These guidelines aim to maximize sensitivity to ensure that most cases with a true malaria attack receive antimalaria treatment. However, fever alone may have a very low specificity for the diagnosis of malaria (Armstrong-Schellenberg *et al.,* 1994). This may limit investigation of other causes of fever, which then will be left untreated (Redd *et al.,* 1992).

In areas with low malaria risk, including the low transmission period in areas with seasonal variations of malaria, presumptive treatment with anti-malarial drugs of uncomplicated fever may result in a potentially high proportion of mis-diagnoses and consequently mis-treatments (Schapira A., 1994). For example, malaria diagnosis based on fever alone was confirmed by parasitological examination in 61.9% of children under 5 years of age during the rainy season in Niamey, Niger, but only 5.4% had evidence of infection during the dry season (Oliver *et al.,* 1991).

In areas with low malaria transmission and no laboratory support, the need for improved criteria for the clinical assessment of fever is well recognized.

The clinical diagnosis of malaria is defined on the presence, or recent history of fever, after exclusion of other major causes of fever. This definition is included in the standard WHO training manuals on malaria control for district health workers in Africa (WHO, 1992).

1.2.3.2 The Role of Laboratory Diagnosis

The role of laboratory diagnosis is primarily to support clinical care. Laboratory support is desirable, for diagnosing treatment failures and severe disease in all situations, as well as for detecting uncomplicated disease in areas of unstable or low transmission. It is particularly important where both *P. falciparum* and *P. vivax* occur and where the recommended therapies of the two infections are different (WHO. 1993).

Diagnosis by light microscopy

Giemsa-stained thick blood smears are the basis for microscopic diagnosis (Dowling *et al.,* 1966). The standard examination of a thick film is 100 microscope fields, examined at a magnification of 600-700 times which is equivalent to approximately 0.25 ul/blood (Dowling *et al.,* 1966). The limit of detection is approximately 10-20 parasites/ul blood, which corresponds to approximately o.004% parasitaemia. Parasite numbers are normally counted as either the number of parasistes per microscope fields or per white blood cells. If the latter is used, considering an average leucocyte count or 8000/ul, the parasite density count can be expressed as:

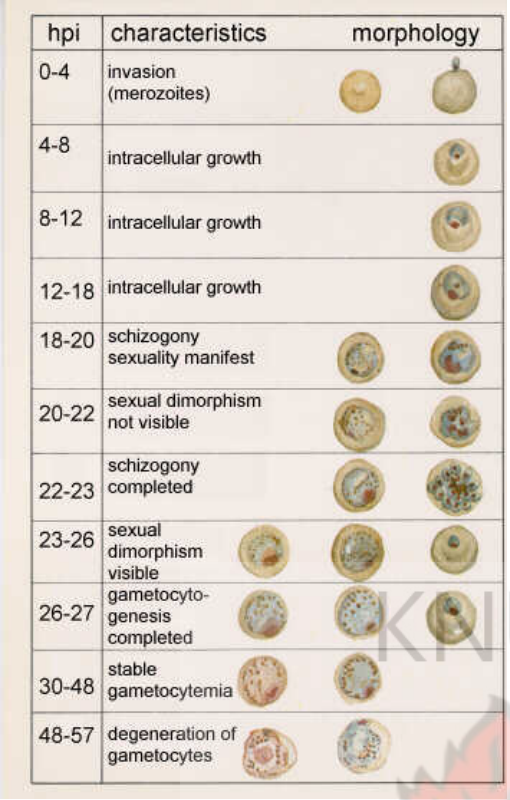


Fig.1.7 Morphology of the different stages

Parasites /1 blood = no. of parasites counted x 8 000

No. of leucocytes counted

The following semi-quantitative method, expressed as one to four "pluses", is often used for designation of parasite counts:

\+ = 1 – 10 parasites per 100 thick films fields

++ = 11 – 100 parasites per 100 thick films fields

+++ = 1 – 10 parasites per one thick film field

++++= more than 10 per one thick film field

A number of methods to detect malaria parasites without the use of the microscope have been developed. These assays were designed to detect parasites with limits of detection equal to, or better than, those provided by light microscopy. In all cases, these methods rely on the detection of parasite-derived proteins or nucleic acids.

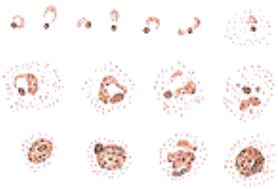
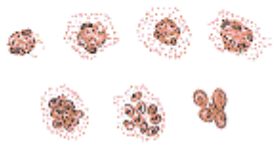
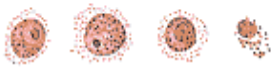
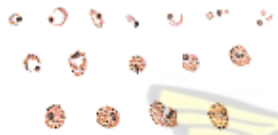
 *Size:* may be smaller than *P. vivax*; *number:* usually few; *shape:* ring to rounded, compact forms; *chromatin:* single, prominent; *cytoplasm:* fairly regular, fleshy; *pigment:* scattered, coarse.	 *Size:* rather like *P. malariae*; *number:* few; *mature forms:* 4–12 merozoites, usually 8, in loose cluster; *pigment:* concentrated mass.	 Immature forms difficult to distinguish from mature trophozoites. *Mature forms:* round, may be smaller than *P. vivax*; *chromatin:* single, well defined; *pigment:* scattered, coarse. Eroded forms with only chromatin and pigment present.	All stages seen; prominent Schuffner's stippling in 'ghost' of host red cells, especially at film edge.	*P. ovale*
 *Size:* small; *number:* usually few; *shape:* ring to rounded, compact forms; *chromatin:* single, large; *cytoplasm:* regular, dense; *pigment:* scattered, abundant, with yellow tinge in older forms.	 *Size:* small, compact; *number:* usually few; *mature forms:* 6–12 merozoites, usually 8, in loose cluster; some apparently without cytoplasm; *pigment:* concentrated.	 Immature and certain mature forms difficult to distinguish from mature trophozoites. *Mature forms:* round, compact; *chromatin:* single, well defined; *pigment:* scattered, coarse, may be peripherally distributed. Eroded forms with only chromatin and pigment present.	All stages seen.	*P. malariae*

Fig.1.8. WHO guidelines for morphology

1.2.3.3 Distinguishing between uncomplicated and severe disease

The primary goal of the evaluation of a patient with malaria or suspected malaria is to identify person with severe disease and those who are at risk of complicated malaria, and to determine appropriate diagnostic and therapeutic actions (WHO. 1993). The core information required included a basic clinical examination, an assessment of whether the patient can take oral medications, and a determination of whether the patient has received previous treatment for malaria. This information

can be used to identify patients who can be treated in an outpatient setting and those who should be referred to a higher level facility. Specific considerations for each of these points are outlined below:

- presence of respiratory distress, may indicate malaria illness, severe anaemia, or coexisting pneumonia.
- Hydration status, dehydration may be caused by hyperpyrexia, vomiting, diarrhoea, and anorexia. An algorithm for detecting and classifying dehydration among children has been developed by the Diarrhoea Diseases Control Programme of WHO (WHO. 1993).
- Presence of hyperpyrexia, by temperature measurement.
- Presence of anaemia, either by laboratory testing or by clinical signs. If laboratory facilities are not available then the presence of anaemia may be assessed by clinical signs. Palm or nailbed pallor has been demonstrated in several study sites to give a greater sensitivity for the detection of severe or moderate anaemia in children than conjunctival pallor alone (Dowling *et al.,* 1966).

1.2.4 Objectives of therapy

The primary purpose of antimalarial therapy is to ensure prompt, effective and safe treatment of malaria. Depending on the epidemiological and operational situations, "effective treatment" can be either clinical cure, i.e. clearance of clinical signs and symptoms and prevention of their recrudescence, or radical cure, i. e. clinical cure with the elimination of parasites. In areas of intense transmission, infected persons with high levels of immunity are often asymptomatic, but if symptomatic infections

are rare in areas of low transmission and low population immunity, and clinical cure is not achieved without parasite elimination. Thus, the objectives of malaria chemotherapy should be defined for different epidemiological and operational situations and be a part of the national antimalarial drug policy (WHO. 1994).

All treatment recommendations should include counselling of the parent/guardian and/or the patient about proper drug dosage and administration, and about the need to return at any time if the condition is not improving or is worsening, or if new symptoms develop.

No antimalarial drug is devoid of side-effects. Patients who develop serious adverse reactions should be advised to stop taking the drug and the condition reported immediately. This applies particularly to any allergic reaction as well as neurological or psychological disturbances after mefloquine and to skin reactions after treatment with sulphur-derived antimalarias. If necessary, an appropriate alternative antimalarial should be given.

The main conditions which may require additional measures for optimal management of uncomplicated malaria include dehydration, hyperpyrexia, and anaemia. Accessory treatments indicated for persons diagnosed with severe malaria, including the management of hypoglycaemia, severe anaemia, and seizures, should be considered differently (WHO.1990).

The ability to take oral medication is needed to determine the route of administration of antimalarial medications. Oral formulation of antimalarial drugs should always be administered with copious amounts of liquids. Vomiting of antimalarials is probably less likely if fever is first lowered with antipyretics. Patients who vomit less than 30 min after receiving the drug should receive a second full dose. If vomiting occurs 30-60 min after a dose, an additional half-dose should be given.

Vomiting together with diarrhoea may lead to treatment failure due to poor drug absorption.

1.2.5 **ANTI-MALARIAL DRUG RESISTANCE**.

Antimalarial drug resistance has been defined as the "ability of a parasite strain to survive and/or multiply despite the administration and absorption of a drug given in doses equal to or higher than those usually recommended but within tolerance of the subject". This definition was later modified to specify that the drug in question must "gain access to the parasite or the infected red blood cell for the duration of the time necessary for its normal action" (Bruce-Chwatt et al., 1986).

Many factors can contribute to treatment failure including incorrect dosing, non-compliance with duration of dosing regimen, poor drug quality, drug interactions, poor or erratic absorption, and misdiagnosis. Probably all of these factors, while causing treatment failure (or apparent treatment failure) in the individual, may also contribute to the development and intensification of true drug resistance by increasing the likelihood of exposure of parasites
to suboptimal drug levels (WHO 2001).

Achieving effective anti-malarial drug deployment over the short-to-medium term will require an appreciation of how drugs are currently used in the real world and development of innovative approaches to optimize that use. Over the long term, however, effectively responding to anti-malarial drug resistance will come to a choice between maintaining business as usual (which would include an on-going need for rapidly developing and deploying new malaria treatments in order to keep up with, if not stay ahead of, developing drug resistance) or making fundamental

changes in how drugs against malaria are used in practice, in order to sustain their useful life spans as long as possible (NCID, 2004).

As is true with many different drugs in practically all cultures, it is recognized that anti-malarial drugs are often taken in incorrect or incomplete doses. For years, chloroquine was highly efficacious, so incomplete dosing was still likely to reduce the parasite load, if not eliminate it.

The reports suggest that while most of the newer malaria treatment currently recommended do offer much-improved parasitologic efficacy over failing treatment like chloroquine and sulphadoxine-pyrimethamine, that increased efficacy typically comes at a cost, both an increased economic cost and a cost of increasing complexity (NCID, 2004). Newer treatments tend to be much more expensive and are more difficult to administer. Furthermore, their safety is relatively unproven, especially among the highest risk groups for malaria in sub-Saharan Africa, young children and pregnant women. In some countries, these newer pharmaceuticals are about to be deployed on a relatively large scale long before the country's medical community has gained any practical experience with them. For the most part, few countries have considered how the introduction of newer treatment regimens might affect the delivery system. While the drug names and dosing schedules may change, the environment in which they are deployed is expected to remain unchanged (NCID, 2004).

This situation (comparatively high drug cost, complex regimen, uncertain safety, poor diagnosis, heightened concern over resistance) argues strongly in favour of a fundamental change in the way that anti-malarial drugs are deployed and used. Such fundamental changes would require a new vision of malaria treatment policy and

practice and substantial investments into health infrastructure within both the public and private sectors (NCID, 2004).

The first paradigm opts for sensitivity in case finding over specificity and maintains that the best approach to reduce malaria morbidity and mortality is to make effective treatment widely and freely available down to the most peripheral level, the household. Essentially, anyone with even a small chance of being infected receives treatment (even in situations where as few as 5% of febrile patients are actually infected (WHO, 1997). This approach is a fundamental part of the Global Strategy for Malaria Control and Roll Back Malaria, and is a major component of related strategies, such as the ~Abuja Declaration goals, and the Integrated Management of Childhood Illnesses (IMCI) program, such as emphasis on deploying efficacious malaria treatment as widely as possible is supported by observations that, under experimental conditions, it can reduce severe malaria-related morbidity and overall mortality among young children (Bloland, 2001).

The alternative paradigm, which favours specificity over sensitivity, maintains that a primary objective of malaria therapy should be to limit the advent and spread of drug resistance. Because drug pressure is a leading contributor to intensification of resistance, this paradigm stresses that access to treatment should be controlled sufficiently to ensure that only those with confirmed diagnosis receive treatment. This approach recognizes, even emphasizes, the existence of a very limited anti-malaria armamentarium, and a slow and costly process involved in developing new anti-malarial drugs (NCID, 2004).

Greater emphasis on the influence of cultural beliefs, treatment-seeking behaviour, household economics, actual behaviours and practices, among others, have all contributed to a more comprehensive concept of anti-malarial treatment.

Combining antimalarial drugs, especially when one of the components is an artemisinin compound, offers, increased efficacy and the potential for inhibition of development of resistance and reductions in overall transmission, at least in some environments. Use of drugs in combination (especially artemisinin-containing combinations or ACTs) is currently the World Health Organization's recommended strategy for coping with drug resistance globally (WHO, 2001).

Unfortunately, as is true for any drug (whether in combination or not, whether co-formulated or co-administered), the mere existence of a new treatment does not guarantee that the treatment will have any public health impact. Literature suggests that these therapies must not only exist, but must be affordable, accessible and acceptable to the end user. Additionally, the end-user must be able to take them in correct quantities and for correct amounts of time. They must be sufficiently safe, especially among users in the highest risk groups. Finally, they must be robust enough in terms of their ability to withstand the misuse that is likely to occur and the selective pressure that this misuse will place on the parasite (Bloland et al, 2000).

Most African countries including Ghana have moved to the use of Artemisin Combination Therapy (ACT) for the treatment of malaria as recommended by World Health Organisation (WHO). The primary purpose of anti-malarial therapy is to ensure prompt, effective and safe treatment of malaria as recommended by the Roll Back Malaria launched by WHO. How successful is this policy change in Ghana is so far as the introduction of the new anti-malaria drug policy is concern because similar policy change in Nigeria (Oshikoya, 2006) showed that chloroquine and sulphadoxine-Pyrimethamine use is still high despite the national policy change to the use of ACT.

1.3 Research Question

What are the prescription patterns of Licensed Chemical Sellers' (LCS) shops in the management of uncomplicated Malaria one year after the implementation of the new anti-malaria drug policy?

1.4 Aim

The aim of this study was to ascertain the knowledge level of LCS shops on the new anti-malaria drug policy on the management of malaria in Northern Ghana (Northern Region, Upper East and Upper West), one year after the introduction of the policy.

1.5 Objectives

1. |To ascertain the awareness level and understanding of the new anti-malarial drug policy by LCS shops;
2. To find out if they understand the reasons for the policy change;
3. To assess their knowledge of the current anti-malarial drug(s) used in Management of Malaria in northern Ghana
4. To assess how they manage patients with the new anti-malaria drug in terms of appropriate dosage and length of time of treatment.
5. To assess the awareness level among LCS shops in the northern zone of the current anti-malaria drug used for the prevention of malaria in pregnant women.

Chapter two

2.1 Research Design and Methodology

This research was a cross-sectional survey of Licensed Chemical Sellers (LCS) shops in the three northern regions of Ghana. A questionnaire was developed and this was pre-tested among 10 Licensed Chemical Sellers shops in Tamale Municipality. This was done with aim of ensuring that there were no ambiguities in the understanding of the questions. Where there were doubts in the understanding of a particular question it was either reframed or deleted from the entire questionnaire. The questionnaires were then administered to a randomly selected Licensed Chemical Sellers shops in the three northern regions. Those Licensed Chemical Sellers shops who were involved in the pre-test pilot phase did not take part in the main survey. Interviews were held with anyone who was dispensing drugs at the shop at the time of the visit. Interviewers were aware that in some cases caretakers interviewed might not be the shop owners who were originally licensed and trained to provide service.

The research was conducted in February, 2006 by trained research assistants and together with the lead researcher forms the research team.

The data in this study were collected in a survey in all the Districts of the three Northern Regions of Ghana. The study area is predominantly an agricultural area. A simple random sample of 160 (37.6%) was drawn from the list of 425 registered Licensed Chemical Sellers' shops in the region. A total of 158 (98.75%) out of 160 (2 of the facilities were closed at the time of the visit) LCSs shops in the sample were visited and an interview was held with the one delivering service at the time of visit. Of the eligible responds located, none refused to be interviewed. Completed interviews therefore numbered 158 respondents in all.

2.2 Population

The population of this study was all Licensed Chemical Sellers shops registered by the Pharmacy Council of Ghana and are located in the three northern regions of Ghana which are upper East, Upper West and Northern regions. At the time of this study the total number of Licensed Chemical Sellers shops in the three northern regions was 425. The break down was as follows: 255 (60%) Licensed Chemical Sellers shops were located in the Northern region; 106 (25%) in the Upper East region and 64 (15%) were located in the Upper West region

2.3 Sampling method

A total of 160 representing 37.6% of the total number of Licensed Chemical Sellers' shops in the three northern regions were targeted. These were randomly selected, taking into account the distribution ratio of the Licensed Chemical Sellers' shops in the three northern regions. Within the regions the selection of the Licensed Chemical Sellers' shops was done so as to cover all districts and sometimes the sub-districts in the region.

2.4 Sample size

For this study a sample size of 160 Licensed Chemical Sellers' shops representing a cross-section of all LCS shops in the three northern regions was used.

2.5 Instrument

The instrument used was a questionnaire that was developed to address the problem of this study. This is not a validated instrument.

Chapter three

3.1 Results

In line with the objectives of this study, efforts were made to visit a total of 160 Licensed Chemical Sellers' (LCSs) shops randomly selected from the list of 425 LCS shops registered in the 3 northern regions. In all 158 out 160 facilities were visited representing 98.75%. Interviews were held with anyone at the time of the visit. This is irrespective of whether the person is the licensed Chemical Seller or an employee/care taker. This approach was deemed important to enable the research team find out the caliber of people actually providing the services. The Pharmacy Council provides training for Chemical Sellers because they are first level service providers. It may be important to find out whether the trained people are actually providing the service on the ground (Figure 3.9).

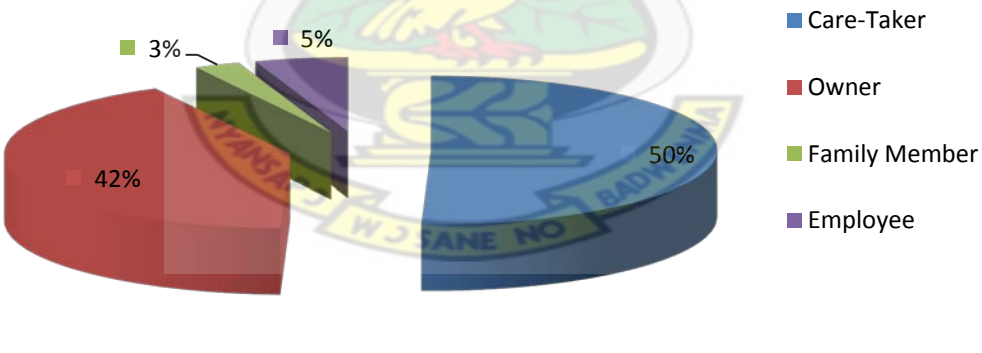


FIGURE 3.9: DESIGNATION OF RESPONDENTS

Owner is the person officially registered by Pharmacy Council and owns the facility

Caretaker is one who helps the owner of the facility in his/her absence.

Employee is a person employed to work in the facility and earns a salary

Family member is spouse, children of the owner of the facility.

Figure 3.9 shows that majority (58%) of all Chemical shops visited for this study were manned by either Care Takers 50% (79), family members including spouse or children 5% (8) or employee 3% (5).

The research team met only 42% (66) of registered Service Providers at post. The findings that majority 58% (92) of Chemical shops visited were manned by untrained personnel register the need for a stronger enforcement of the laws.

Figure 3.10 gives a summary of the sex of respondents for the study.

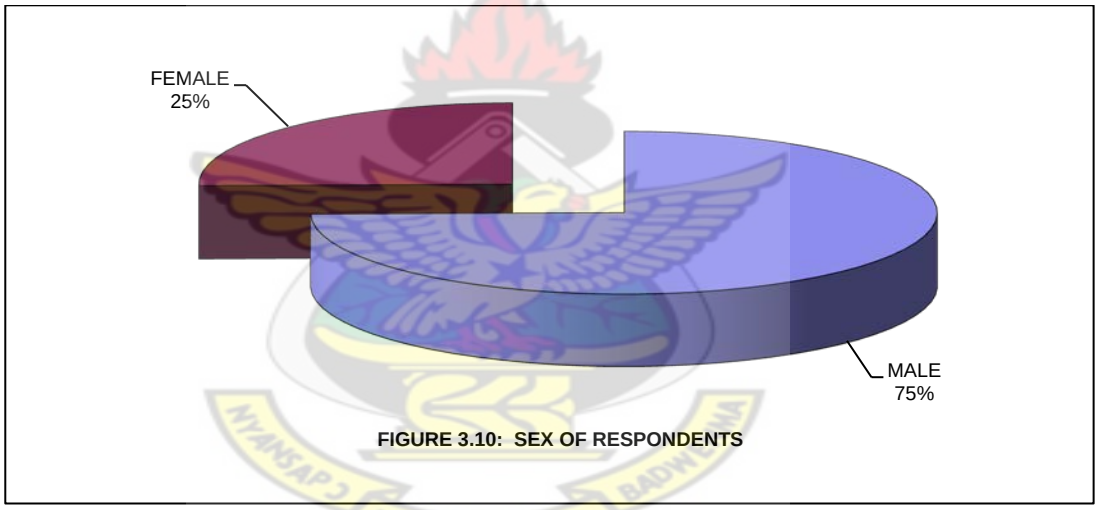


FIGURE 3.10: SEX OF RESPONDENTS

Figure 3.10 shows that the far majority 75% (118) of service providers (Licensed Chemical Sellers) met at post at the time of the visit were males. Even though this data may not reflect the true situation on the ground, it suggests the need to factor in gender considerations when considering applicants for selection as Chemical Sellers.

Figure 3.11 gives a summary of the ages of the respondents.

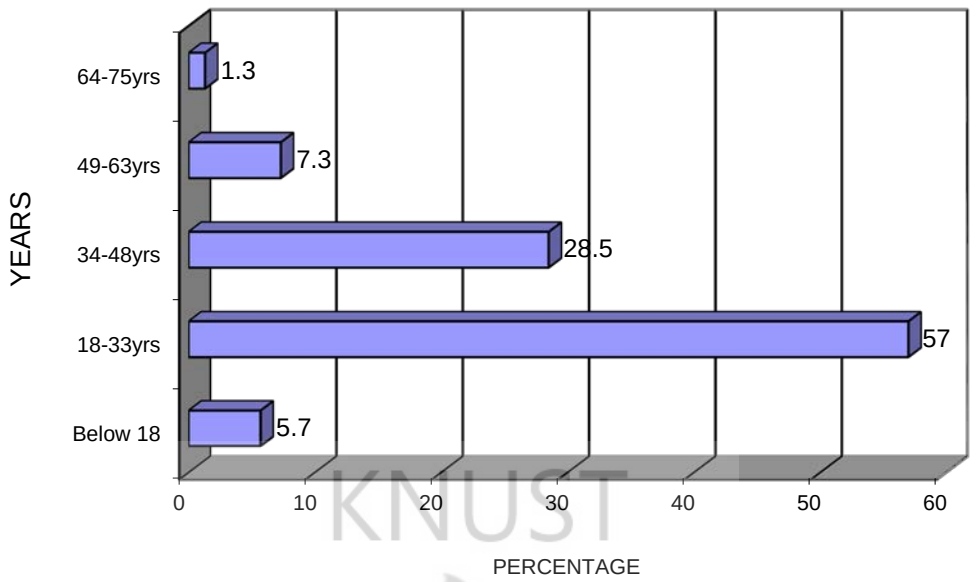


FIGURE 3.11. AGE OF RESPONDENTS

Figure 3.11 show that overwhelming majority 91.3% (144) of people providing the service at the Chemical Shop on the day of the interview were aged (18- 63 years). It is important to note that about 6% (9) of service providers at the time of the survey were minors (Below 18 years).

Efforts were also made in this study to find out the educational background of respondents. Figure 3.12 provides a summary of the findings.

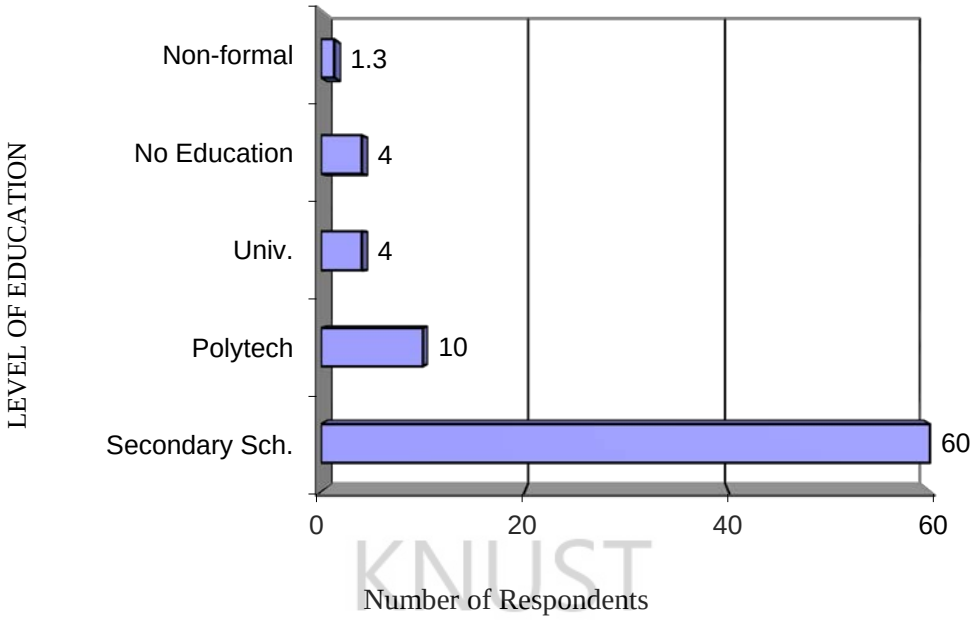


Figure 3.12: Educational Background of Respondents

Figure 3.12 show that majority 95% (150) of people at post in the facilities at the time of this survey have had at least basic formal education. Seventy-four percent (74%) of respondents were either graduates of tertiary institutions (University, or Polytechnic) or were of the secondary level (Secondary education or Technical school). Over five percent (5.3%) have either been through non-formal education ie an illiterate trained by the non-formal education programme by government (1.3%) or have never been to school at all (4%).

SIGNS AND SYMPTOMS

An important component of this study was to find out the level of knowledge of respondents on malaria. To ascertain the depth of knowledge of respondents, they were asked to indicate the signs and symptoms of malaria in children less than 5 years. Table 3.1 gives a summary of the findings.

Table 3.1: Knowledge about the signs and symptoms of uncomplicated/simple Malaria in Children under five Years

Signs/Symptoms	Frequency	Percentage %
Fever	103	65.2
Vomiting	101	63.9
Headache	83	52.5
Fatigue	36	22.8
Loss of Appetite	35	22.2
Diarrhea	34	21.5
Coldness of body	29	18.4
Convulsion/Fits	14	8.9
Body Shaking	11	7.0
Cough	7	4.4
Sweating	4	2.5
Thirst	3	1.9
Anaemia	3	1.9

Table 3.1 shows that a sizeable proportion of service providers interviewed did not know the common signs and symptoms of uncomplicated/simple Malaria in

Children under five years. A follow up question sought to find out knowledge of respondents about signs and symptoms that should trigger referrals to higher levels. This is important because as part of their role, Chemical Sellers as Level 'A' Providers in the Primary Health Care Scheme are to make prompt referrals where some danger signs are seen. Among other things, knowledge about these basic danger signs could have an effect on effective referrals and therefore on infant mortality and morbidity. Table 3.2 gives a summary of the findings.

Table 3.2: Signs and symptoms of malaria in children that will trigger referral by the chemical seller to the clinic/hospital

SIGNS AND SYMTOMS	Frequency	Percebtage (%)
Body Weakness	78	51
Diarrhea	64	41.6
Vomiting	62	39.2
Fever	56	35.4
Body shaking	36	22.8
Convulsion/Fits	36	22.8
Dizziness	30	19
Headache	26	16.5
Fatigue	20	13
Pale eyes	20	13
Anaemia	15	9.5
Loss of Appetite	15	9.5
No improvement after first	10	6.3
Cough	8	5.2
Coldness of Body	5	3.2
Sweating	2	1.3
Thirst	1	0.6

Multiple responses possible

The Table above shows that the major signs and symptoms that would trigger referral by Chemical Sellers' shops include; Body weakness (51%), Diarrhea (42%), vomiting (39%), and Fever (35%). It is interesting that only 6.3% of respondents would refer a patient whose condition did not improve after first aid. A further question sought to find out from respondents the type of drugs they give "for uncomplicated/simple malaria in children under 5 years as well as for adults"

Table 3.3 Results showing types of drugs, dosage, frequency of administration and duration

Drug	**No.of respondents**	**Correct Dosage**	**Frequency Adm.**	**Duration (No. of days)**
Malafan tab (syr)	32 (10)*	1	0	0
Amodiaquine tab (syr)	10 (15)	0	0	0
Artemos tab	12	0	0	2
Artesunate tab (syr)	11 (5)	2	1	3
Artesunate+Amodiaquine tab (syr)	2 (0)	2	0	2
Chloroquine tab (syr)	37 (25)	10	-	5
Paracetamol tab (syr)	16 (24)	5	-	-
Others -Alaxin tab(Syr)	4 (5)	0	-	-
TOTAL	**124 (85)**	**30**		

*Figures in brackets respresent the number of children who were given syrup.

On the issue of knowledge about the new drug, findings show that majority of respondents (98%) did not prescribed the new malaria drug at all.That is two respondents out of one hundred and twenty-four (124) gave artesunate-Amodiaquine. It is also clear that majority of respondents 98% were not knowledgeable about dosage. In all, only about 2% of respondents were knowledgeable about the frequency of administration of the drug and the duration ie the number of days as spelt out in the standards and protocols of the Ghana Health Service (GHS).

The table shows that the most common drugs on prescription for malaria in the Chemical shops surveyed were Malafan and chloroquine. Thus it is clear that majority of Chemical shops surveyed are not providing the approved drugs for malaria treatment for both children and adults.

Another important element of quality of care is whether patients are given counseling at the facility before the administration of drugs. Chemical Sellers are supposed to provide counseling and also give directions on dosage in both writing (on the packages of drugs) and verbally to ensure effective use of the drug. Figure 3.13 provides a summary of the findings.

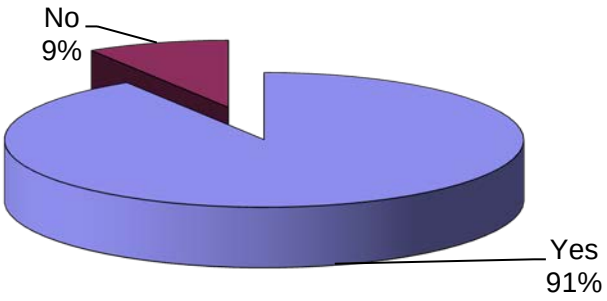


Figure 3.13: DO CHEMICAL SELLERS PROVIDE COUNSELLING TO PATIENTS?

The figure shows that the overwhelming majority of respondents (91%) provide some form of counseling before administering drugs over the counter. A follow up question sought to find out the area of emphasis given in such counseling efforts (Table 3.4).

Table 3.4: Issues on which counseling is given

ISSUE	Frequency	Percentage (%)
Clean Environment	39	27.1
Time and Dosage of the drug	50	34.7
Need for early treatment	20	13.9
Need to buy mosquito net	10	6.9
General Health Education	25	17.4
Total	**144**	**100**

Counseling on dosage is a very important aspect of quality of care. It is surprising therefore that majority of respondents 65.3% (94) did not counsel patients on when to take the drug, and dosage. Counseling on timing and dosage is certainly principal information to be given by all service providers to patients.

Prior to this survey, a national campaign to educate people on the new anti malaria drug policy of the GHS had been on going for some time using the mass media. As principal stakeholders, LCSs were supposed to acquire knowledge about this new policy because in the scheme of things, LCSs are key stakeholders supposed to be part of the first line advocates and providers of the service. In line with this, efforts were made in this study to find out whether respondents were aware of the policy, the most popular source of information on the policy, what they thought was responsible for the change in policy, knowledge about the proposed new drug, and its dosage.

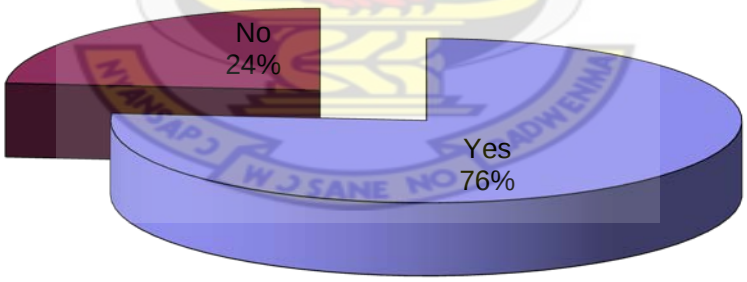


Figure 3.14 : AWARENESS ABOUT THE NEW POLICY

Figure 3.14 gives a summary of the awareness of respondents about the new policy. It is encouraging that the large majority of respondents 76% (120) have heard about the new anti malaria policy. A further question was to find out the most common source of information on the new policy (Figure 3.15).

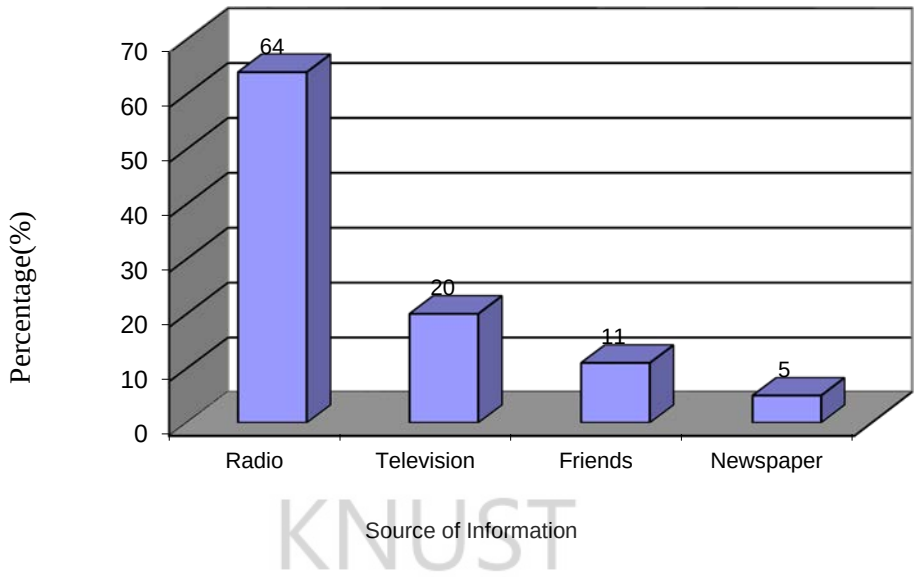


Figure 3.15: SOURCE OF INFORMATION ON THE NEW POLICY

Fifure 3.15 shows that the Radio 64% (101) and TV 20% (32) were the most common source of information on the new policy.

Further questions show that even though majority of respondents 64% (101) were aware of the new policy, knowledge on what the policy was about was low.

In all, only 36% (49) of respondents knew that the policy is about a new drug for the treatment of malaria. The rest of the respondents 64% (86) either did not know 22% (30) or were not sure about what the policy was all about 42% (57).

On the issue of "*why the need for a change in policy"* Table 3.5 gives a summary of the findings.

Table 3.5: knowledge about the main reason for the new policy

RESPONSE	Frequency	Percentage (%)
Chloroquine is not effective	49	36.8
Unpleasant Side effects	38	28.6
Because the new drug is more effective than chloroquine	24	18.0
Resistance to Chloroquine	15	11.3
To improve treatment for malaria	7	5.3
TOTAL	**133**	**100**

Findings suggest that majority of respondents 66.1% (88) were aware of the main reason for the change in policy by indicating that chloroquine was no longer effective. In all, 33.9% (45) of respondents were not sure of the reason for the change in policy.

It is interesting that a sizeable proportion of respondents (41%) were however recommending the drug even though it was clear that their knowledge about the drug was low. For those who said they have been recommending the new drug, a further question sought to find out the feedback from patients (Table 3.6).

Table 3.6: feedback from patients about the new drug

Response	Frequency	Percentage (%)
Patient feels bad (unpleasant reactions)	17	27
Drowsiness/Sleepiness	15	23
Expensive	2	3
It is good	30	47
TOTAL	**64**	**100**

From the report from a total of 64 LCSs who have sold the new drug, half (50%) said the feedback from patients about the drug is quite negative.

Patients reportedly complained about unpleasant side effects of the new drug including itchy body, and dizziness (27%), and also drowsiness (23%). Only 2 respondents said their patients complained about the cost of the new drug. A sizeable proportion (47%) however said "it is good".

In a follow up question, effort was made to find out reasons why despite the new Policy some LCSs shops were not selling the recommended drug for malaria (Table 3. 7).

Table 3.7: reasons why some chemical sellers are reluctant to sell the new malaria drug (prescribed by policy) to patients

Response	Frequency	Percentage (%)
Unpleasant side effects/Patients complain	39	41.5
Don't Know/Don't understand the new policy	24	25.5
No access	15	16.0
Expensive	14	15
Doubtful efficacy	2	2.1
TOTAL	**94**	**100**

The Table suggests that of the total of 158 Chemical sellers interviewed for this study, the majority (about 60%) were reluctant to sell the new malaria drug (prescribed by policy) to patients. Forty-two percent (42%) of those who do not sell the new drug said it was because of the complaints of side effects of the drug. It is important to note that about 26% do not sell the drug prescribed by policy because they do not know or do not understand the new policy; 18% have no access to supplies of the new drug; 15% said it is comparatively more expensive and 2% doubt the efficacy of the new drug.

Another major concern for this study is to find out anti-malaria drugs given by Chemical Sellers as prophylaxis to pregnant women (Figure 3.16).

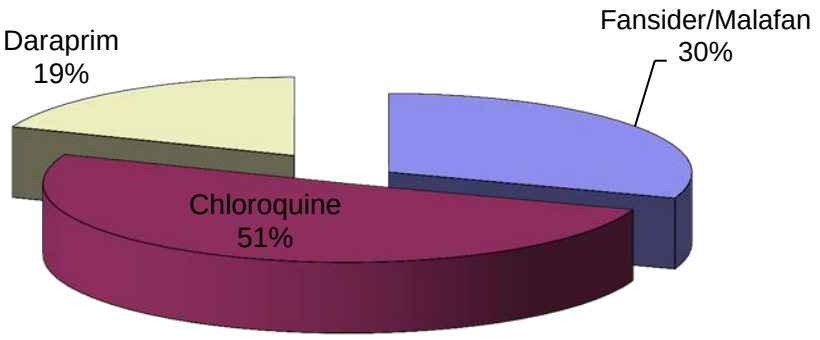


Figure 3.16: ANTI-MALARIA DRUGS GIVEN BY CHEMICAL SELLERS TO PREGNANT WOMEN FOR PROPHYLAXIS

The figure shows that for pregnant women, slightly more than half of Chemical Sellers' shops surveyed 51% (81) would give Chloroquine as against SP for the prophylaxis of malaria in pregnant women. This is contrary to the policy document which spelt out clearly the use of SP as the drug of choice for the prevention of malaria in pregnant women. In a follow up question respondents were asked to indicate what else they would do for a pregnant woman with malaria (Figure 3.17).

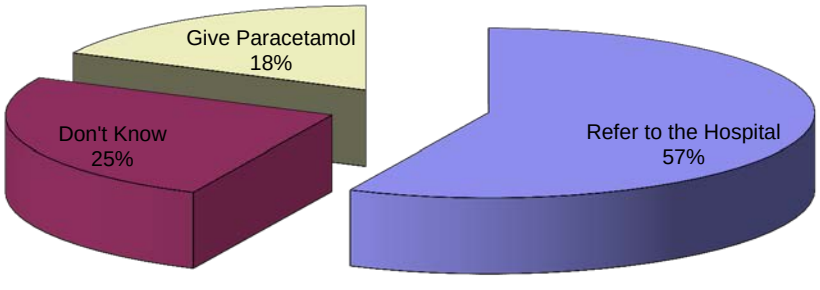


Figure 3.17: WHAT ELSE COULD BE DONE FOR PREVENTION OF MALARIA IN PREGNANT WOMEN

Majority of our respondents (57%) would refer pregnant women to the hospital. However it is important to note that quite a significant proportion of Chemical Sellers interviewed (43%) either would still give just a pain-killer (18%) or do not know what to do at all.

Chapter four

4.1 Discussion

The main objectives of this study were to identify:

1. The awareness level and the understanding of the new anti-malarial drug policy by LCS.
2. Find out if they understand the reasons for the policy change.
3. assess their knowledge of the current anti-malarial drug(s) used in Management of Malaria in northern Ghana,
4. assess how they manage patients with the new anti-malaria drug in terms of appropriate dosage and length of time of treatment
5. and finally assess the awareness level among LCS shops of the current anti-malaria drug used for the prevention (prophylaxis) of malaria in pregnant women.

Before the introduction of the new anti-malaria policy a lot of education on the policy had taken place in the country to educate all citizens about the reasons for the change.

This was necessary because malaria is ranked as number one on the list of ten most common diseases outlined by the Ministry of Health. Most health personnel in both the public and private sector including civil society all participated in a series of workshops that were organized and also public awareness campaign on the electronic and print media. Among the service providers in the pharmaceutical sector who play a key role in the provision of pharmaceutical services especially in the deprived areas are the Licensed Chemical Sellers. Therefore an attempt was made to ascertain the awareness level of the LCS in respect of this new policy.

From the results of the study, it was very encouraging to note that the large majority of the Licensed Chemical Sellers (LCS) shops (76%) had heard about the new anti-malaria policy. When the sources of information regarding the policy was investigated, it was realized that about 64% of LCS shops had heard of the new policy on radio, since a good majority of Licensed Chemical Sellers (LCS) is located in the rural areas where radios are very common and 20% on television. The study also revealed that although majority of LCS shops (76%) were aware of the new policy, knowledge on what the policy was about was low. Maybe the policy was not clear enough for the understanding of the LCS where the majority of them had as their highest level of education at the secondary level or below. Again LCSs are a large group of health service providers especially at the rural areas and they possess a formidable political force and influence and should have been part of information dissemination of the new anti-malaria policy. Clarity of policy guidelines, strong evidence, adequate funding of policy guidelines and support by opinion leaders especially professional bodies are some of the factors that positively influence the use of clinical guidelines (Sheldon et al., 2004). Therefore, the need to involve opinion leaders like LCS in policy implementation is very crucial to its acceptance and adherence especially in the rural areas where majority of them operate. Their involvement will result in an in-depth information dissemination by the leaders of LCS at the rural areas.. In all only 36% of respondents knew that the policy was about a new drug for the treatment of malaria. The rest of the respondents (64%) either did not know (22%) or were not sure about what the policy was all about (42%).

On the reasons for the change in policy, the study revealed that the majority of respondents (66.1%) were aware of the main reason for the policy change. In all, 66.1% (85) of respondents noted that the principal reason for change in policy was because chloroquine was no longer effective. However, 33.9% were unable to assign reasons for the change in policy. Ignorance of the policy will lead to its poor implementation. It was also observed during the survey that of the total number of 158 Chemical sellers interviewed for this study, the majority i.e.94 (about 60%) were reluctant to sell the new anti-malaria drug (prescribed by policy) to patients. About Forty-two (42%) percent of those who did not sell the new drug said it was because of the complaints people gave of the side effects of the drug. It is important to note that about 26% did not sell the drug prescribed by policy because they do not know or do not understand the new policy; 18% have no access to supplies of the new drug; 15% said it is comparatively more expensive and 2% doubt the efficacy of the new drug

On the identification of signs and symptoms of malaria, findings showed that about 35 % did not mention fever, 36% did not know vomiting as a sign, 48% did not mention headache, and nearly all respondents (98%) were not aware that those signs might indicate malaria infection that requires prompt treatment or immediate referral.

The findings suggest that even though some respondents have some knowledge, a significant number of service providers lack the basic knowledge for effective diagnosis and treatment of malaria in children.

Findings showed that majority of respondents cannot identify the new malaria drug at all and still use Chloroquine and sulphadoxine+pyrimethamine when it

was clear from the policy that resistance to chloroquine has been reported in six geo-political zones of Ghana (MOH,2007) A similar study in Nigeria (Oshikoya, 2006) also showed that despite the change in the national guidelines for malaria treatment chloroquine and sulphadoxine-pyrimethamine was high on prescription in one Teaching Hospital in Nigeria. In Ghana, most malaria cases are managed at the household level. Help is usually sought from the community pharmacist or licensed chemical seller (registered suppliers of specified over-the-counter-medicines) after the initial therapy has failed. There is concern that community and household management of malaria is often inadequate, inappropriate and ineffective. This was confirmed in a study (Buabeng et al., 2007) which showed a majority of patients who obtained their medication from LCS shops use the medicines inappropriately. The study also indicated that inappropriate use of anti-malarial drugs was highest among patients who obtained their drugs from LCS shops. This study further confirms that a large majority (98%) of respondents (LCS) were not knowledgeable about dosage. This is supported by a similar study conducted by Buabene et al (2007). In all, only about 2% of respondents were knowledgeable about the frequency of administration of the drug and the duration ie the number of days.

On correct dosage, findings show that majority of LCSs shops interviewed (98%) were not knowledgeable about the correct dosage of the new anti-malaria drug currently in use for the treatment of malaria as spelt out in the standards treatment guidelines and protocols of the Ghana Health Service (GHS). The standards treatments guidelines and protocols of the Ghana Health Service are not available at LCS facilities in the rural areas for their study and compliance to national guidelines on the treatment of malaria. This may be a factor in the

incorrect dosages of anti-malarial drugs. This was also found in a similar study in Kenya (Abuya et al., 2007). Lack of adherence to malaria treatment guidelines was associated with inappropriate prescribing practices in rural Kenya (Philips-Howard *et al*., 2003). Poor Drug use practices like use of sub-therapeutic doses or failure to complete prescribed doses are among factors that could lead to emergence of and spread of mutant strains of Plasmodium falciparum (White *et al*., 1996).

In Ghana, the recommended ACT is artesunate-amodiaquine as recommended by WHO. This has huge economic implications for most poor patients in Ghana and sub-Saharan Africa as a whole, since the ACTs are comparatively more expensive. There are several legitimate concerns about the sustainability of this policy but the change is necessary for effective management of malaria in Ghana, due to the widespread multidrug resistant strains of malaria parasites in the West African sub-region and Ghana in particular (Buabeng et al., 2007). Effective and pragmatic strategies must be adopted to enhance public health education on safe and effective use of anti-malaria drugs in the community. In particular it is strongly recommended that appropriate training be provided for staff in the pharmacies, licensed chemical shops (Buabeng et al., 2007). Results of an audit conducted by Amalba A. 2005 unpublished,- on LCS shops before the implementation of the new anti-malaria drug policy concluded that if LCS in the rural areas are not adequately trained to have a better knowledge on: what malaria really is; how to identify the symptoms of malaria (especially in children under five years) and appropriately manage the condition, the introduction of a new drug to replace chloroquine will be an illusion, the malaria parasite will sooner than later develop resistance to the new malaria drug (Amalba, 2005 unpublished)

Objective 5: Another major concern for this study was to find out the anti-malaria drug given by Chemical Sellers as prophylaxis against malaria in pregnant women. The study showed that for pregnant women, slightly more than half of Chemical Sellers shops surveyed (51%) would give Chloroquine as against SP as prescribed by policy. In a follow up question, respondents were asked to indicate what else they would do for a pregnant woman with malaria, slightly more than half the respondance said they will refer to the hospitals or Clinics. Malaria in pregnancy is very serious and therefore first line service providers like Licensed Chemical sellers should refer such cases to the hospital since their knowledge on the use of prophylactic drugs against malaria in pregnant women with malaria is highly inadequate, unless they are properly trained/educated in this direction.

4.2 Conclusion

Most people with malaria will first seek medical attention from either Pharmacies or Licensed Chemical Shops before going to the hospital only after the initial therapy has failed. The result of this study and other similar studies indicate that the prescription patterns of LCS shops in the management of uncomplicated malaria is still poor. Though with the implementation of the new anti-malaria drug policy in Ghana a lot of education on the policy in both the public and private sectors was conducted, information on the policy especially on the current management of malaria as stipulated on the GHS treatment guidelines and protocols has not gone down well to the grassroots especially the LCS shops who are the majority service providers in the rural communities. The situation were only a limited number (6.3%) actually referred complicated cases to the hospital suggests that by far the overwhelming majority of Chemical Sellers surveyed do not know their limits and would rather continue with *"trial-and-error approach"* to the treatment of malaria in children. This is certainly not an encouraging situation. According to the Service Delivery Guidelines/Document from the Pharmacy Council, LCSs should refer patients with the following signs/symptoms in malaria to a clinic/hospital level: Anaemia, convulsion, difficulty in breathing, dark or cola-coloured urine etc.

Results of an audit conducted by Amalba A. 2005 unpublished,- on LCS before the implementation of the new anti-malaria drug policy concluded that if LCS in the rural areas are not adequately trained to have a better knowledge on: what malaria really is; how to identify the symptoms of malaria (especially in children under five years) and appropriately manage the condition, the introduction of a new drug to replace chloroquine will be an illusion, the malaria parasite will sooner than later

develop resistance to the new malaria drug (Amalba, 2005 unpublished). This seems to be the case here as shown by this study.

4.3 Recommendation

It is recommended that all first line service providers (LCS) at this primary level are adequately informed on current trends of malaria prevention and managements. Issues of appropriate counseling and training in the management of uncomplicated malaria must feature prominently in the Pharmacy Council's training for LCS. Training impact assessment must be given the requisite priority to guarantee quality of care in the services of LCS. This may lead to the effective management of uncomplicated malaria by LCS and thus also contribute to halting the malaria parasite building resistant against the new anti-malaria drug currently in use in Ghana. The policy on malaria treatment should not be limited only to change in guidelines but should also include continuous surveillance by Pharmacy Council etc to Licensed Chemical Facilities to monitor the rational prescription of these drugs. The treatment guidelines of GHS on malaria should be made available to all LCS shops to allow Pharmacy Council (PC) to monitor the implementation of these guidelines at the facility level. Further research should be conducted in other parts of the country on the prescription patterns of Licensed Chemical Sellers to see the trend of adherence to the anti-malaria drug policy.

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Appendix. 1

QUESTIONNAIRE

start time: **_____**

My name is _____ I am working for an organization that is trying to develop ways to improve Community Health. I am talking to Licensed Chemical Sellers who provide pharmaceutical service in rural, suburban and urban communities on the management of malaria especially in children under five years old. The purpose of the study is for academy work. You are NOT required to provide your name on the questionnaire and all answers provided will be kept confidential except for the academic work that is meant for.
May I ask you a few questions?
Thank you for understanding and answering the questions.

(Do not prompt respondent)

1.Location _____ 2. District: _____

3. Region: _____ 4. Designation of Respondent_____

5.What are the signs and symptoms of uncomplicated/simple malaria in children under five years.)?

Vomiting☐ Thirst☐ Fever ☐ Sweating☐

Headache ☐ `Cough☐ Fatigue☐ Convulsion/Fits☐

Loss of Appetite ☐ Body shaking☐ Coldness of body☐

Diarrhoea ☐ Anaemia ☐ Others (specify) _____

6. What signs and symptoms of malaria will make you refer a patient to the clinic/hospital?

Vomiting☐ Thirst☐ Fever ☐ Sweating☐

Headache ☐ `Cough☐ Fatigue☐ Convulsion/Fits☐
Loss of Appetite ☐ Body shaking☐ Coldness of body☐
Diarrhoea ☐ Anaemia ☐ Others (specify) _____

7. What drugs do you give for uncomplicated/simple malaria in children under five years and adults?

Drug	Dosage		Frequency of Adm.	Duration
	Adult Child			
	Adult Child			
	Adult Child			
	Adult Child			
	Adult Child			

8. Did you give any counselling to the patient? Yes ☐ No. ☐

11. If yes, what counselling did you give to the patient?

i. Uncomplicated malaria_____

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9. Has any patient reported of any side effects of the drugs you gave?
a) Yes b) No

10. If yes, what did she or he report on _____

11. Did the patient take any drug before reporting to your facility?
a) Yes b) No

12. If yes what drug

13. Have you heard of the new anti-malaria drug policy?
a) Yes b) No

14. If yes where?

Radio ☐ Television ☐ News papers ☐

Friends/relatives ☐ Others (Specify) _____

15.What is the policy about?

16. Why the change of policy?

17. What is the new drug used in the treatment of uncomplicated/simple malaria?

New Drug	**Dosage**		**Frequency of Adm.**	**Duration**
Artesunate/ Amodiaquine	Adult Child			
Chloroquine	Adult Child			
Amodiaquine	Adult Child			
Artesunate	Adult Child			
SP. (Fansidar/Malafan	Adult Child			
Artemos	Adult Child			
Others (specify)	Adult Child			

18. Have you started using the new drug? A) Yes b)No

19. If yes , what are the feedback from the patients? _____

20. If no, why are you not using the new drug? _____

---

21. What is the current anti-malaria drug used for prevention of malaria in pregnant women?

SP (Fansidar, Malafan) ☐ Chloroquine ☐ ☐ Daraprim

Others
(Specify)_____

PERSONAL DATA

1. Age: 2. Sex: Male Female

Level of education:
a. Middle school
b. Secondary school
c. Technical school
d. Polytechnic
e. University
f. Non-formal education

Name of Interviewer: _____

Date of interview: _____

End time: _____

THANK YOU