ACCESS TO AND PROVIDER KNOWLEDGE AND PRACTICES ON ARTEMISININ-BASED COMBINATION THERAPY AND QUININE IN DRUG OUTLETS AND THEIR USE IN HOUSEHOLDS IN MALARIA ENDEMIC AREAS OF WESTERN KENYA

BY

WATSIERAH A. CARREN

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SCHOOL OF PUBLIC HEALTH AND COMMUNITY DEVELOPMENT

MASENO UNIVERSITY

ABSTRACT

Artemisinin-based Combination Therapy (ACT) was adopted as the most effective treatment option against malaria in Kenya. Artemether-Lumefantrine (AL) is the first-line ACT drug for treatment of uncomplicated malaria, while quinine is preferred for complicated and severe malaria. Information on access and knowledge and practices of providers prior to or during implementation of ACT and quinine is scanty. Moreover, the evaluation of how these factors influence the use of these drugs in households is rare. The results could be used as a guideline to step-up the activities to enhance malaria treatment and as a key bench-mark to evaluate the success of the implementation of the malaria treatment policy in Kenya and further evaluate the role of policy implementation in malaria burden in the study region. The study adopted World Health Organization (WHO) and Health Action International (HAI) standardized methodologies to evaluate access and provider knowledge and practices and use of these drugs. A cross-sectional survey using three-stage sampling was conducted in two *Plasmodium falciparum* endemic regions. Based on WHO and HAI methodologies, two main health facilities were selected. This was followed by additional selected of five district hospitals under each main facility and eight other facilities (health centres and dispensaries) under each district hospitals to give a total of 96 outlets (including 4% non-response). A matching number of private outlets were randomly selected. In addition, all (66) not-for-profit outlets and additional 30 public facilities within the study area were sampled to get the required sample size of 288. For every outlet targeted, one household was surveyed to give a total of 288 households. Results revealed that most private outlets, 27 (40.5%) did not stock the first-line anti-malarial. Quinine was the most available in private 45 (68.8%). AL was 1.88 times more expensive in private outlets relative to the government recommended price. Private sector had 50 (52.1%) who failed to state the correct anti-malarial for complicated and severe malaria. Only 15 (15.6%) of providers in private outlets had been trained on the use of ACT for malaria treatment. Those trained were 2-3 times more likely to provide the correct treatment regimen for uncomplicated (OR, 2.01; CI, 1.66-3.83; P=0.039) and severe malaria in children (OR, 2.66; CI, 1.88-5.44; P<0.0001) and in adults (OR, 2.01; CI, 1.88-4.25 P=0.002). Those who had gone through in-service training among the private providers were almost 4 times unlikely to sell partial packs of ACT (OR, 3.79; CI, 2.77-11.2; P<0.0001), were 3 times likely to request for written prescription (OR, 3.00; CI, 2.45-10.4; P=0.001) Anti-malarial price (OR, 2.88; CI, 1.99-4.31; P<0.0001), affordability (OR, 3.01; CI, 2.45-5.01; P=0.005) and knowledge of dosing regimen (OR, 2.67; CI, 2.02-4.33; P<0.0001), sale of partial packs (OR, 2.78; CI, 2.22-4.45; P<0.0001) and advice given by providers (OR, 1.24; CI, 1.10-2.67; P=0.004) were several folds likely to influence anti-malaria use in households. There is low accessibility to policy recommended anti-malarials (ACTs and quinine) in outlets. The government should ensure continuous availability of recommended drugs to the consumers in right package sizes, and at affordable prices in all outlet types and train stakeholders on new policies. It is essential to educate the consumers on the need to adhere to the correct treatment regimen and ensure that changes in treatment guidelines are accompanied by subsequent implementation activities involving all health sector players.

CHAPTER ONE: INTRODUCTION

1.1 Background

Artemisinin-based Combination Therapy (ACT) has been adopted as the most effective treatment option against malaria in 79 countries since 2011 (WHO, 2012). This is due to the widespread resistance by malaria parasite to the more affordable anti-malarial drugs such as chloroquine and sulphadoxine-pyrimethamine (SP). Kenya adopted Artemether-Lumefantrine (AL) as the first-line ACT drug for the treatment of uncomplicated malaria in the year 2004, while quinine is preferred for complicated and severe malaria (MoH, 2006). In the year 2000, the heads of state gathering in Abuja resolved that by 2010, sixty percent of people with malaria would be able to access "*affordable and appropriate treatment within 24 hours of the onset of symptoms*" (WHO, 2000). The target was later increased to eighty percent by the Roll Back Malaria initiative (WHO, 2005).

However, despite the strategies to increase access to effective anti-malarial drugs, in the year 2009, less than fifteen percent of children under-five years of age received ACT when they presented with fever in 11 of 13 African countries (WHO, 2010). In addition, most mortalities in children who are able to attend a health facility that is well staffed and with adequate supplies occurs within 24 hours after admission (WHO, 2000). Consequently, it is evident that most mortalities occurs as a result of delay in home management with effective drugs, thus underscoring the importance of early treatment for preventing such mortality (WHO, 2000). Many patients in Africa use the private sector as their primary source of medicines with 50% of febrile episodes reported to be treated in the private sector (WHO, 2006b). It is therefore critical to improve access to appropriate health care. One way of tackling this problem is to ensure access to treatment using effective anti-malarials like ACT and quinine, which could be given promptly even at primary health care facilities. The World Health Organization (WHO) highlights the need to ensure access to and rational use of ACTs to minimize parasitic resistance (WHO, 2000). Even with the efforts to increase case management against malaria, the success of policy implementation and effectiveness is measured by the availability of the recommended drugs at the point of care (Williams *et al.,* 2004). Studies in Kenya on availability to recommended ACT and quinine drugs in health care institutions are insufficient. As such, the current study evaluated the availability of ACT and quinine drugs at the point of care in Nyanza in western Kenya.

The marked-up manufacturer's selling prices and final patient prices of anti-malarials have been reported to range from 56 to 358% in private sector, making treatment unaffordable (Cameron *et al.,*

2009). On average, households in many malaria endemic countries spend up to 90% of their household expenditure on medicines, portraying high anti-malarial pricing as an important contributing factor to the lack of access to ACT (Goodman *et al.,* 2009). The high prices make the drugs to be more inaccessible to many households since the affordability depends not only in price but also on the cost of travelling and diagnostic procedures. Since no study has evaluated affordability in households in Nyanza region of western Kenya, the current study determined the affordability of ACT and quinine in drug outlets in malaria endemic areas of western Kenya.

To enhance ACT policy implementation, the Kenyan government has scaled up case management strategies as follows; 1) all public health institutions offer ACT free of charge and 2) introducing cheaper Artemether Lumefantrine (AL) in the year 2010 to be sold at Kenyan shillings 40 (USD 0.5) in retail drug outlets (DOMC, 2011). Despite the efforts to improve access, ACT remains registered as prescription-only drug recommended for formal sector providers (Amin *et al.,* 2007) making it more inaccessible to many households. In addition, the high cost of anti-malarial has been found to be an important contributing factor to the lack of access in a study done in Kenya. (Chuma *et al.,* 2009). Although the subsidy policy was rolled out in 2010 it is unknown whether ACT is truly available at these subsidized prices in all the outlet types in Kenya. The current study thus assessed the prices of ACT and quinine in drug outlets in malaria endemic areas of western Kenya.

While the new national treatment policy has been adopted, accessibility to these recommended anti-malarials remains a challenge. A few studies before the implementation of subsidy policy which have evaluated the access of ACT recorded various challenges in the public sector, households and community levels with the most common being frequent stock-outs of ACT, leading to the use of several inappropriate alternatives (KNBS, 2010; Watsierah *et al.,* 2010); Kangwana *et al.,* 2009; (Abuya *et al.,* 2007; Kangwana *et al.,* 2009).

Health workers' adherence to treatment guidelines is one of the critical aspects determining effective implementation of malaria case management policies (Whitty *et al.,* 2008). The implementation of a policy is a continuous process and involves many activities including but not limited to, in-service training to update the personnel already in the field with new knowledge and adoption of new practices which comes with the changes in treatment policy.

In Kenya and other malaria endemic countries, the government have put efforts on public sector to train its medical personnel on the use of combination therapy while such efforts have been minimal in the private sector despite the vital role they play in malaria treatment (Mugoyela and Minzi, 2011)

(Njogu et al., 2008). Sufficient knowledge on the use of a particular anti-malarial and its availability in the market are important factors in determining which anti-malarials are bought for use (Watsierah *et al.*, 2011).

Although ACT have been received with great hope as a major breakthrough in the treatment of malaria in many malaria endemic areas, the dosage regimens of most ACTs are rather more complicated in comparison to a single dose recommended for SP. The challenge for the successful outcome of the use of ACTs, therefore, is posed by the requirement for provision of proper knowledge for both the health care providers and the patients, who are the end users. Therefore, it is critical to assess the knowledge level of providers that are associated with treatment regimen especially in the dawn of a new policy in all the sector players.

Previous training of health workers have been shown to influence their practices when dispensing drugs (Marsh *et al.*, 1999; Marsh *et al.*, 2004). Most of the practices associated with anti-malaria use reported to have not adhered to policy recommendations include poor prescription habits, dispensing of non-recommended drugs and inadequate counseling and dispensing tasks (Zurovac *et al.*, 2008). It is therefore important to assess the providers' practices in using the new treatment policy. Research efforts have pinpointed the need to train drug retailers about appropriate doses and drug regimens, thus increasing adherence to national recommendations in the community (Marsh *et al.*, 2004). Other studies have used survey instruments to assess knowledge, attitudes and practices and to characterize actions taken by primary caregivers during malaria infection (Njama *et al.*, 2003). While other studies (Geissler *et al.*, 2000; Guyatt and Snow, 2004) have addressed the frequency of anti-malarial use in populations in specific settings, customers depend on the advice given by the health providers to sufficiently use the drugs correctly. It is therefore important to evaluate how access, knowledge and practice factors influence the use of anti-malarials in the households.

Nyanza region is a malaria endemic area where transmission is high and intense throughout the year with a *P. falciparum* malaria prevalence of $\geq$ 40% which causes the most severe form of the disease and accounts for 98% of all malaria-related infections (DOMC, 2009). Given the severity of the diseases, the population should therefore have access to recommended anti-malarials. It is on this background that the study evaluated access to national policy anti-malarials: ACT and quinine as defined by availability, price and affordability in the public, private and not-for-profit outlets in Nyanza region of western Kenya. In addition, the study investigated the provider knowledge and practices of treatment policy and dosing regimens of these anti-malarials and further examined the

influence of access and provider knowledge and practices on the use of these drugs in households in the study area.

1.2 Problem statement

Even though the government has introduced subsidy on ACT, their availability is supposed to be restricted to the public and formal private health sector. However, following the introduction of government subsidy on ACT (AL) in Kenya, it is unknown whether recommended anti-malarials are available in public, private and not-for-profit outlets, in the right packages, and at the recommended subsidized prices, consequently, whether or not the drugs are affordable to the households in malaria endemic regions such as in Nyanza in western Kenya. In addition, little is known on the provider's knowledge and practices on treatment policy and dosing regimens on the use of ACT since the policy change on malaria treatment. Furthermore, the evidence that access factors and provider knowledge and practices can influence the use of anti-malarials in households has not been documented. Therefore the current study evaluated access to effective anti-malarials: ACTs and quinine in the public, private and not-for-profit drug outlets, and additionally investigated the provider's knowledge and practices on treatment policy and dosing regimens of these anti-malarials in Nyanza in western Kenya. Further investigations were carried out to examine the influence of providers' knowledge and practices to the use of these drugs in households in malaria endemic region of western Kenya.

1.3 Objectives

1.3.1 General objective

To evaluate access to and assess the provider knowledge and practices on Artemisinin-based Combination Therapy (ACT) and quinine in drug outlets and their use in households in malaria endemic areas of western Kenya.

1.3.2 Specific objectives

1. To assess the availability of ACT and quinine in drug outlets in malaria endemic areas of western Kenya.
2. To assess the prices of ACT and quinine in drug outlets in malaria endemic areas of western Kenya.
3. To determine affordability of ACT and quinine in drug outlets in malaria endemic areas of western Kenya.
4. To evaluate the provider knowledge level of treatment policy and dosing regimens of ACT and quinine in malaria endemic areas of western Kenya.

5. To assess the provider practices of treatment policy and dosing regimens with ACT and quinine in malaria endemic areas of western Kenya.
6. To determine access factors and providers' knowledge and practices that influences the use of ACT and quinine in households in malaria endemic areas of western Kenya.

1.3.3 Research questions

1. What is the availability of ACT and quinine in drug outlets in malaria endemic areas of western Kenya?
2. What are the prices of ACTs and quinine in drug outlets in malaria endemic areas of western Kenya?
3. What is the affordability to ACT and quinine in drug outlets in malaria endemic areas of western Kenya?
4. What is the provider knowledge level of treatment policy and dosing regimens of ACT and quinine in malaria endemic areas of western Kenya?
5. What are the provider practices of treatment policy and dosing regimens with ACT and quinine in malaria endemic areas of western Kenya?
6. What are access factors and providers' knowledge and practices that influence the use of ACT and quinine in households in malaria endemic areas of western Kenya?

1.4 Justification of the study

Beyond the difficulties of changing national treatment policies, a key bench-mark of successful policy implementation, and thus effectiveness, is that the recommended drugs are available at the point of care (Williams *et al.,* 2004). Prompt access to effective malaria treatment is central to the success of malaria control worldwide. The Roll Back Malaria (RBM) partnership had set 2010 as a target of ensuring that 80 percent of those suffering from malaria have prompt access to, and are able to correctly use, affordable and appropriate treatment within 24 hours of symptoms onset (WHO, 2005). Evaluating access to the recommended anti-malarials and further evaluating how access factors influence their use will give information on the extent to which the ACT treatment policy and quinine use have been implemented and the role it has played in addressing the malaria burden in western Kenya.

1.5 Significance of the study

The results of this study would be relevant and valuable to all stakeholders in health including health system developers, policy implementers, and more importantly to the drug providers who will benefit from the evaluation of their methods of dispensing drugs. The results would further be used as a key bench-mark to evaluate the success of the implementation of the WHO policy on malaria treatment in Kenya. It would also be used to inform the policy on procurement and distribution needs and lastly, to direct intervention efforts to improve effective use of anti-malarials in the households.

CHAPTER TWO: LITERATURE REVIEW

2.1 Availability of ACT and quinine

The key determinant of appropriate medication is the availability of appropriate drugs in the market. More often, public health facilities do not stock the recommended anti-malarials (Wasunna *et al.,* 2008). Lack of drugs in the formal sector contributes to people buying anti-malarials over the counter, where the quality of drugs is less controlled and information on dose is not often provided (WHO, 2000). In a study evaluating the policy paper on reducing user fees for primary health care in Kenya, health workers and community members reported that public health facilities suffered from chronic drug shortages due to delays in drug deliveries from the central level and the failure to adjust drug quantities to suit seasonal fluctuations in disease burden (Chuma *et al.,* 2009).

Studies in Kenya on the availability of the recommended ACT and quinine in health care institutions are insufficient. A nationally representative household survey carried out three years after the introduction of ACT not only showed wide availability of less efficacious anti-malarials in the markets, but also their extensive use along with ACT (Kangwana *et al.,* 2009). In another similar survey, 8.0% of children <5 years with fever took ACT or Amodiaquine, and 3.0% took SP, with chloroquine and quinine being taken in the same frequency (1.2%) and other anti-malarials constituted 2.6% (KNBS, 2010). Another household survey performed in peri-urban population from malaria holoendemic region of western Kenya not only revealed that SP (37.0%) was used in almost the same frequency as ACT (32.0%), but that the SP was also available in the markets, in addition to other non-recommended drugs, six years after the implementation of the ACT and change in anti-malarial drug policy. When asked what could have led to the extensive access to other anti-malarials apart from ACT, some of the reasons given in the study included their availability at the source, the previous knowledge on the use of a particular drug and lower prices per treatment course (Watsierah *et al.,* 2010).

In a baseline study undertaken prior to nationwide distribution of Artemether-Lumefantrine (AL) in Kenya, the recommended first-line treatment for uncomplicated malaria, AL (tablets) was found in all sectors and in all provinces, but in only 33% of the facilities. At the time of this survey, the deployment of AL as the first-line treatment was just starting, without a full country-wide scale-up. All formulations of quinine, for severe malaria were widely available in all formal sectors and provinces (MoH, 2007). Other studies show different results. For instance, two years after AL introduction, a cross-sectional survey in seven districts in Nyanza, Western, and Coast Provinces

(areas highly endemic for malaria), demonstrated that 25.6% facilities had none of the four AL weight-specific treatment packs in stock, while 75.0% of facilities were out of stock of at least one weight-specific AL pack. The most worrying revelation was that packs for the group most at risk of malaria mortality (children <5years), were absent in nearly two-thirds (61.0%) of facilities, leading health workers to prescribe a range of inappropriate alternatives (Kangwana *et al.*, 2009).

The more recent country-wide surveys in Kenya in 2010 on malaria case-management following change of policy to universal parasitological diagnosis and targeted artemisinin-based combination therapy reported that at least one AL pack was in stock at 94.3% of public facilities while the availability of weight-specific AL packs ranged from 79.3% for 18 tablets pack to 86.2% for 24 tablet pack. All the four AL packs were in stock at 64.9% of facilities. With respect to AL stock-out in 3 months prior to the surveys, stock-out of all the four AL tablet packs was 20.6% and for at least one AL pack was 52.3% (Nyandigisi *et al.*, 2011).

Most of the studies reporting ACT availability are based on country-wide surveys and were done before the roll-out of the subsidy policy in August 2010. Furthermore, the studies were concentrated on the public facilities rather than all the sector players including private facilities (which play a vital role in drug management and distribution). Currently, no data exists on the availability of ACT and quinine in different outlet types specific to western Kenya. It is in this context that the current study evaluated the availability of ACT and quinine in different outlet types in Nyanza region of western Kenya.

2.2 Cost of malaria treatment in households and affordability

Few studies in Kenya have estimated the costs of malaria treatment to households or to the health system, by considering various dimensions of expenses involved in malaria treatment. For instance, a cross-sectional survey in Kilifi district at the Kenyan coast in 2006 estimated the costs incurred by households following a self-reported fever, regardless of the timing and source of treatment. The mean spending for an acute malaria episode amounted to KES 232 with 80.0% comprising the drug cost while the mean direct costs amounted to 7.1%, with the poorest households spending 11% of their monthly income on treatment relative to the poor populations (3.4%) (Chuma *et al.*, 2007).

Another study on the use of formal and informal curative services in the management of paediatric fevers in four districts in Kenya estimated the costs of anti-malarials and transport for first actions. The median cost of anti-malarials for one treatment purchased in retail outlets in the four districts was KES 17, while the median cost of anti-malarials for one treatment from a private hospital was

KES 215 (Amin *et al.,* 2003). An exploratory study of community factors relevant for participatory malaria control on Rusinga Island, western Kenya found that the estimated median expenditure for treating sick children with malaria was KES 250 and further noted that 92% comprised cost of drugs (Opiyo *et al.,* 2007).

A previous study estimated the costs of anti-malarials purchased from the Kenyan retail sector. The average retail price of adult doses of SP and amodiaquine was KES 29.6 and KES 59.0, respectively. AL was found in less than 1% of the retailers at a median cost of KES 593, twenty times higher than SP (Amin *et al.,* 2007). In their exploratory study, Chuma and colleagues estimated a direct cash expenditure of KES 34 for fever treatment with the total estimate including indirect costs of KES 149 for uncomplicated fevers treated according to the national guidelines (i.e., prompt treatment with AL) (Chuma *et al.,* 2007). A recent study in western Kenya showed that the mean price for a course of AL was 2.73 USD. Prices for the subsidized brand of AL, Artefan, ranged from 0.5 USD to 2.5 USD while Coartem®, a brand name of AL, ranged between 0.63 USD to 7.5 USD in the private sector outlet (Smith *et al.,* 2011).

A recent survey of socio-economic status of households in Nyanza province showed that an average of sixty two percent of households are living in USD 0.875 in a daily basis when considering the daily disposable income as the economic indicator (IEMP, 2012). This results points out that most of the population in Nyanza region are actually struggling with meeting the basic needs of the day and therefore living in malaria endemic region makes it worse when the disease strikes and are forced to choose between buying the appropriate and full dose of drugs and providing for the basic needs.

The studies above however, showed that households spend a significant amount of money on malaria treatment before the subsidy policy on AL and even after the subsidy the private outlets still could not adhere to the recommended price. The studies on the cost and subsequent affordability of malaria treatment are focussed on the general factors including the cost of travelling and diagnosis. In addition, the past studies have treated the target population as homogeneous, using the daily wages of the lowest paid unskilled government worker as reference income level. This may not give a true reflection of the ability of households to afford the recommended anti-malarial drugs in the market in relationship to the economic context of the study population. Therefore, the current study assessed the prices of ACT and quinine in the drug outlets and further determined the affordability of these drugs by using the number of days households in lowest socio-economic level would have to work in order to afford the full dose of treatment course with ACT/quinine available in the outlet.

2.3 Provider Knowledge on anti-malarials

Studies in the region on knowledge have shown mixed results. For instance, in a study conducted in Tanzania within 6 months of the implementation of the ACT policy, to assess if dispensers in private pharmacies had received any training on the treatment policy changes from chloroquine to SP and from SP to AL had showed that none of the participants were either involved in the preparation of the guidelines or trained on their implementation (Minzi and Haule, 2008). In the same country in a separate study, when knowledge between health workers in public and private health care facilities on implementation of artemether-lumefantrine treatment policy for malaria was compared, the results indicated that only 18.8% of the interviewed health workers had received formal training on how to prescribe and/or dispense artemether-lumefantrine (Mugoyela and Minzi, 2011).

Another separate study in the region on rational dispensing and use of AL during pregnancy in Dar-es-salaam, only 17% of pregnant women were given information on the importance of taking food when using AL, but none of them was given information on the importance of fatty meals when using AL. In conclusion, the results show that most drug dispensers had inadequate knowledge about good dispensing practice of AL in pregnancy (Kamuhabwa and Jalal, 2011). Similar results were reported in a cross-sectional survey done in Malawi to assess the knowledge and perceptions of Malawian medical doctors and pharmacists on the use of ACT and the drivers of treatment choice and clinical treatment decisions. The results showed that 73.9% of participants had ever received information on ACT and only 31.5% had received training on management of malaria using ACT although there was high knowledge of treatment for complicated and severe malaria among the study participants (Kalilani-Phiri *et al.,* 2011). A Kenyan study done one year after the beginning of ACT implementation process reported that 46% of health providers in the public facilities as having been trained on the new combination therapy policy (Njogu *et al.,* 2008).

Experience has shown that good treatment policies and guidelines may be put in place and yet disappointing results are obtained due to wrong interpretation and implementation (Williams *et al.,* 2004). An active intervention process, ranging from provision of accurate information, education, sensitisation and community involvement is needed before any future drug policy change is effected in the country (Eriksen *et al.,* 2005); (Williams *et al.,* 2004). Until now, the studies on knowledge of drug providers in Kenya are solely focussed on the public sector and were mainly done before the ACT subsidy policy. Therefore, the current study assessed the provider knowledge on treatment policy and dosing regimen using ACTs and quinine in all outlet types in Nyanza region.

2.4 Provider Practices on the use of anti-malarials

The World Health Organization current policy on malaria treatment is combination therapy, which in this case, is the use of two or more anti-malarials with, at least one of them, containing a derivative of artemisinin (WHO, 2000). The WHO further recommends that the two drugs should have independent working mechanisms. The aim of this recommendation is to improve efficacy and delay the development of resistance of the malaria parasite against components of the combination drugs. Artemisinin-based Combination Therapy (ACT) is now generally considered to be the best option for the treatment of uncomplicated malaria in endemic areas (WHO, 2006a).

However, the WHO initiative to fight malaria using combination therapy could be thwarted by the practices of retail trade in monotherapies in rural communities. The types of provider accessed by the study populations also determine the pattern of use of anti-malarials. For example in a study in Mali, even though only 8% of respondents sought treatment at health centres, more than half of the remainder obtained their treatments through pharmacies or drug shops allied to health centres, where they were more likely to receive anti-malarials at the correct dose (Geissler *et al.,* 2000). This can also be compared to two previous studies carried out in Kenya (Marsh *et al.,* 1999; Marsh *et al.,* 2004), where the main source of anti-malarial were small general shops with untrained shopkeepers, and the type and duration of treatment was largely determined by the client's ability to pay, the practices that have not adhered to policy recommendations. In a survey in Uganda on malaria case-management under AL treatment policy, AL was prescribed for 60% and 16% of patients had no anti-malarial drug prescribed. AL was prescribed in the correct dose for 95% of patients. Only three out of seven AL counseling and dispensing tasks were performed for more than 50% of patients (Zurovac *et al.,* 2008).

In another study in Tanzanian Dar-es-salaam, various anti-malarials (17 monotherapies) were found to be displayed in formal outlets with inconsistent dosing instructions and inadequate internationally recommended doses (Kachur and Slutsker, 2006). In a study assessing the self-treatment of malaria in rural communities in Ethiopia, the use of the drugs for malaria was high (92%) including chloroquine tablets (73.5%) and SP tablets (60.6%) (Deressa *et al.,* 2003). Failure to prescribe the recommended medications has been shown in a recent study in Kenya exploring prescribing practices following the change of treatment policy from SP to AL. A low level of prescriptions of the nationally recommended drug was reported in the study. Only 26% of children that needed treatment with AL according to national guidelines received a prescription for this drug, 39% received amodiaquine, 4% received SP, 8% received other anti-malarials, while and 23% left the

facility without any anti-malarials prescribed, although their symptoms indicated the need for malaria treatment (Njogu *et al.,* 2008).

The findings of a study in 2004 on predictors of the quality of health worker treatment practices for uncomplicated malaria at government health facilities in Kenya showed that in cases where AL was prescribed, doses were more likely to be correct compared to the more common drugs of amodiaquine and SP. A follow-up study exploring why health workers did not prescribe AL, despite the drug being in stock at the health facilities identified various reasons for non-adherence to the treatment guidelines, most of which were related to health workers responding to general health system weaknesses (Wasunna *et al.,* 2008).

The practices reported by the 2004 study on predictors of the quality of health worker included failure of health workers to prescribe AL to all deserving cases due to insufficient supply of AL, which further raised fears of stock-outs and patients' preferences for SP over AL because of its simple dose. In the same study, health workers assessed which cases deserved AL since it was considered expensive on the side of the government expenditure, although the drug was provided for free to the consumers. Other practices included prescription of available drugs like amodiaquine since they were continuously supplied to the health facilities despite the policy change to ACT (Wasunna *et al.,* 2008). Three years later health workers' adherence to malaria diagnosis and treatment recommendations was evaluated in public facilities. Artemether 20mg Lumefantrine 120mg was prescribed for 63.6% of children aged <5 years and for 65.0% of patients aged ≥5 years and 58.0% of patients without test performed (Juma and Zurovac, 2011).

Currently, literature on the provider's practices on treatment policy and dosing regimens on the use of ACT since the policy change and subsequent subsidy is dwindling not only in the public sector, but also in the private sector. Furthermore, despite the use of quinine for decades, no study has been carried out to evaluate the providers' practices on its use on malaria treatment in Kenya. It is on this background that the current study evaluated the provider's practices of treatment policy and dosing regimens with ACT and quinine in the public, private and not-for-profit drug outlets.

2.5 Use of anti-malarials in households

Quinine is one of the oldest known anti-malarial drugs with its use dating 400 years ago. Studies on quinine use in Kenya are hard to come by, despite WHO recently offering guidelines recommending a combination of quinine plus some antibiotics such as doxycycline, clindamycin and tetracycline among others, as second-line treatment for uncomplicated malaria (to be used when the first-line

drug fails or is not available) and for treatment of malaria in the first trimester of pregnancy (WHO, 2010).

However, in most African countries, quinine is still used as a monotherapy, contrary to the WHO recommendations. The reason for this practice may be due to the higher costs of quinine-antibiotic combinations (WHO, 2010). However, quinine continues to play a significant role in the management of malaria in sub-Saharan Africa and other malaria endemic areas, and its use in routine practice may not be restricted to the stated WHO recommendations. In Cameroon, even one year after the introduction of ACT, quinine continued to be used as first-line therapy, with 45% of adults receiving oral quinine for uncomplicated malaria (Sayang *et al.*, 2009). Recent surveillance data from sentinel sites in Uganda showed that quinine was prescribed for up to 90% of children < 5 years with uncomplicated malaria (MoH, 2010). Using quinine as a first-line anti-malarial may have implication on the treatment of malaria on population at the Kenya-Uganda border where cross-border migration is common although this may require further evaluation. A survey carried out in Kenyan households in malaria endemic regions in western Kenya demonstrated that higher proportions of households that used quinine had the correct doses (89.3%) and durations (92.9%) observed primarily because its main source was government facility where its administration was entirely supervised by trained health personnel (Watsierah *et al.*, 2011).

Despite the recommendations by WHO for countries in malaria endemic areas to adopt the combination therapy (WHO, 2000), many countries still trade in monotherapies. In a survey in Dar-es-salaam, various anti-malarials, seventeen monotherapies were found to be displayed in chemical shops with inconsistent dosing instructions and inadequate internationally recommended dose. Thus, in spite of the call by the WHO for the voluntary withdrawal of these monotherapies from the market, these drugs are likely to coexist with the recommended combination therapies (Kachur and Slutsker, 2006). For example, in the study of self-treatment of malaria in rural communities in Ethiopia, the use of modern drugs at the time for malaria was high (92%), CQ (73.5%) and SP (60.6%) tablets (Deressa *et al.*, 2003).

Previous studies have tried to find out the prevalence of adherence to anti-malarial drugs in the community. For example, in Cambodia, two community-based studies were conducted, the first in 1998 when the recommended treatment was 7 days of quinine (3 doses/day) and tetracycline (2 doses/day). Only 1–10% of those who bought quinine and tetracycline used the full course (Denis, 1998). In another study in 2002, of those who took the new recommended first-line therapy of blister packaged artesunate and mefloquine, over 77% were adherent (i.e., completed the blister

package over 3 days). However, less than 10% of the respondents actually received the recommended therapy in the first place and artesunate monotherapy in inadequate doses was one of the more popular options at 67% (Yeung and White, 2005). While in the Ghanaian study, 163 (77%) of the 213 patients who had used anti-malarial drugs prior to attending the health facilities used the drugs inappropriately (Buabeng *et al.,* 2007).

In a study in Uganda, adherence to a 3-day course of co-formulated artemether-lumefantrine (Co-artem) was reported to be higher at 90–93%, even though twice daily dosing was required (Fogg *et al.,* 2004). A study in Kenya (Marsh *et al.,* 1999) found that in a recommended one-dose regime of CQ, only 29% reportedly took the right dose. Overdosing rates were similar to those in the clinic-based studies. For instance, a study of anti-malarial use in a highland area of low seasonal malaria transmission in Kenya described excess of over-paediatrics use as 24% of adult and 14% of child users purchased an anti-malarial drug (Guyatt and Snow, 2004). High use of anti-malarial drugs has also been described for older school children in Kenya (Geissler *et al.,* 2000).

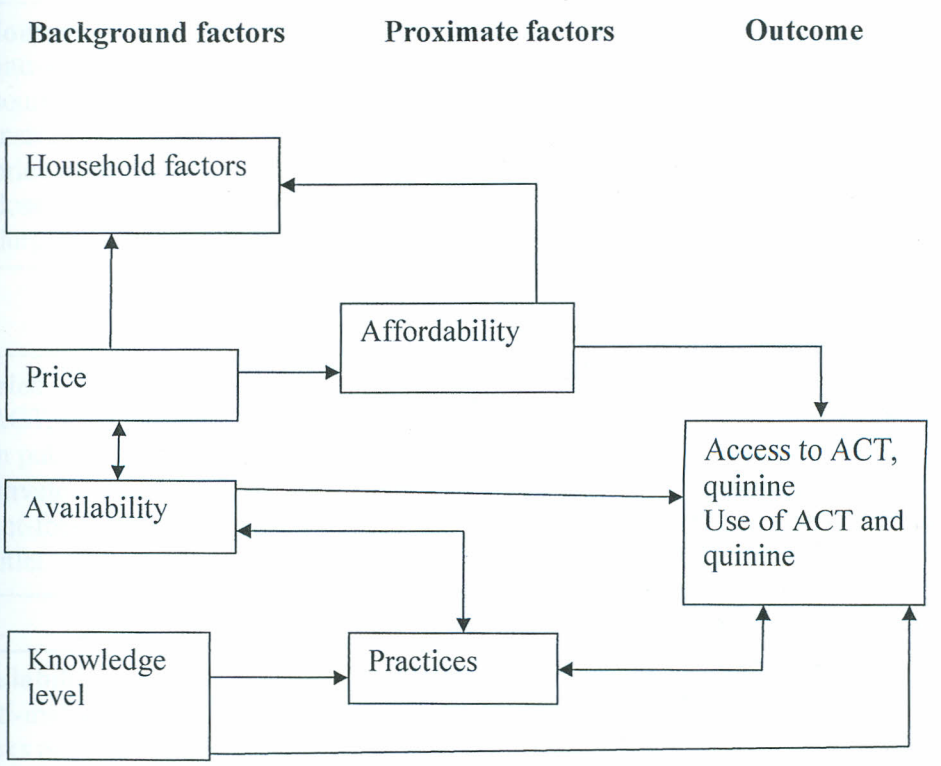
A study done in Kenya on use of over-the-counter malaria medicines in children and adults in three districts found that the two most commonly used types of over the counter (OTC) anti-malarials were the Ministry of Health first and second line recommended medicines at that time, SP and AQ, together accounting for 83.3% and 86.4%, respectively of all anti-malarial used in children and adults. The remaining 19.9% of anti-malarial used in children included CQ (16.6%), combinations of AQ and SP (2.1%) and others (1.3%). Among the adults, the remaining 13.6% of anti-malarial included chloroquine (10.0%), combinations of AQ and SP (2.8%), and others (0.6%) (Abuya *et al.,* 2007).

In Kenya, most malarial fevers and convulsions occur at home. Prompt and effective management of malaria cases is, therefore, important for malaria control across all the epidemiological zones of the country. The target for case management of malaria is for 60 percent of fever cases to receive appropriate malaria treatment within 24 hours of onset of fever (MoH, 2006). In the last demographic survey, it was reported that among children under five with fever, only 23% took anti-malarial drugs compared with 27 percent in 2003 (KNBS, 2010). Despite all the studies in the anti-malarial use in Kenya, the influence of access factors and knowledge and practices of health providers on the use of ACT and quinine drugs in households in Kenya has not been reported. Therefore, the current study determined the influence of providers' knowledge and practices on the use of these drugs in households in Nyanza region.

2.6 Conceptual framework

In the current study, access comprises of three main dimensions namely: (1) availability, which refers to the presence of anti-malarials in the outlet, (2) affordability, which includes the cost of treatment in relation to peoples' income, and; (3) the price which refers to the cost of a full dose of an anti-malarial drugs. It is appreciable that all elements of access should be considered comprehensively in order to understand the concept and to draw concrete and actionable policy recommendations.

Although availability and price of drugs may act independently to determine access, price will also determine whether drugs are affordable, in the process further affecting access (Figure 2.1). Knowledge of drug providers on the other hand determines the actions of providers when dispensing drugs to their customers. For example, the provider having knowledge on the first-line treatment with ACT will prescribe the drug; give the correct advice for its use and hence help the patient access and use the correct medication for malaria as recommended by the policy. Availability, price and affordability play significant roles in obtaining anti-malarials for use. These factors in turn, lead to the outcome as correct dose or correct duration of treatment in the patient. On the other hand, use of anti-malarial drugs in the household can be influenced by factors which affect the household like their level of income; it is also likely to be affected by sources of such drugs, as well as the knowledge about drugs available in the community. These factors have been summarised in Figure 2.1.



Associative conceptual diagram (Starfield, 2002) adopted with modifications.

Figure 2.1: Conceptual framework

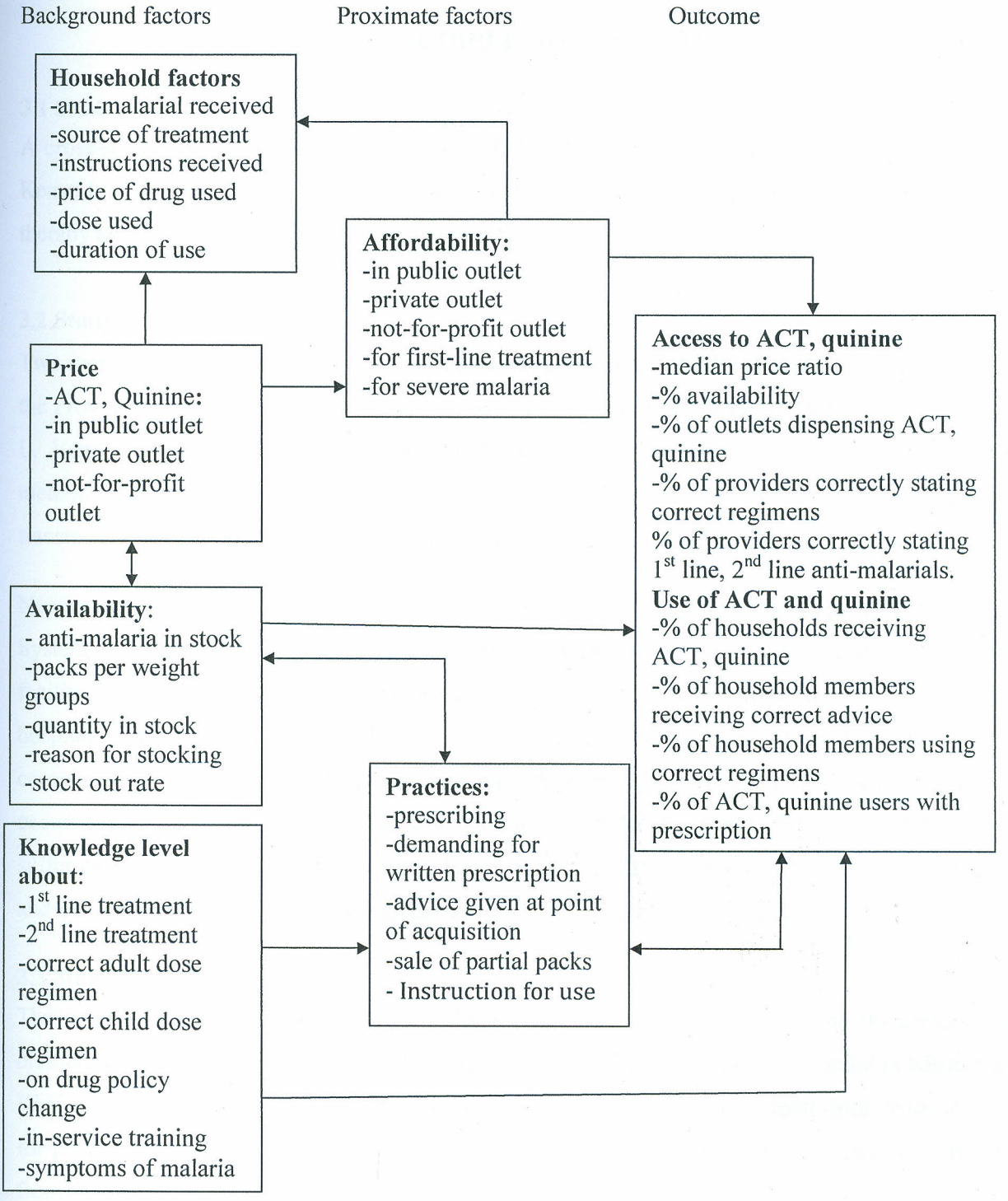


Figure 2.2: Operational framework with variables that were measured in the current study.

CHAPTER THREE: METHODOLOGY

3.1 Study design

A cross-sectional survey was conducted from February to May 2012 in Nyanza region in western Kenya to evaluate access to and provider knowledge and practices on artemisinin-based combination therapy and quinine in drug outlets and their use in households.

3.2 Study area

Two regions, endemic for *P. falciparum* transmission, but with different levels of risk for malaria in the Province were targeted: the lowlands of the Province (Kisumu, Siaya and Bondo regions) around L. Victoria experiencing a holoendemic and stable *P. falciparum* transmission (altitude 0-1300 meters) and Kisii highlands (Kisii, Gucha and Nyamira regions), experiencing an epidemic transmission (>1300-1750 meters) (Latitude 0.50°S Longitude 34.50°E) (Appendix 1).

Nyanza region reports high levels of malaria cases. Data from Health Management Information System in Jaramogi Oginga Odinga Teaching and Referral Hospital (the largest referral health facility in Nyanza region) shows that malaria accounts for 40% of out-patient visits and 40% of hospital in-patient admissions with between 10-15 paediatric cases of severe malaria often complicated with anaemia and malnutrition, in a daily basis (IRIN, 2009). Malaria transmission occurs all year round, peaking in the rainy season months of April and May. The highlands areas suffer epidemic levels, where temperature increases and rainfall variation impacts on vector breeding and malaria transmission with some areas experiencing prevalence of up to 20% (DOMC, 2009).

3.3 Study population

The survey was carried out at public medical health facilities: dispensaries, health centers, sub-district/district hospitals and Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu and Kisii Level 5 hospital in Kisii (Appendix 2), private: pharmacies and licensed drug shops and not-for-profit outlets: NGO and mission health facilities. In addition data was collected in households from the survey areas.

3.3.1 Inclusion criteria

All public drug outlets, private and not-for-profit outlets in the study area were recruited for the study. In addition, households with individual(s) who had used anti-malarials or other drugs viewed by them as anti-malarials within the last two weeks.

3.3.2 Exclusion criteria

Outlets that did not have ACTs or quinine on the day of survey and had not stocked ACTs or quinine in the last three months were excluded in the study. If more than one person in the household had used an anti-malarial within the period given, focus was on the most recent episode. This was done to minimize errors due to problems with recall.

3.4 Sample size determination

The study adopted World Health Organization (WHO) and Health Action International (HAI) standardized methodologies for surveying drug prices, availability, and affordability (WHO, 2008). According to the above methodology, a small sample of facilities is selected in at least 6 geographical areas: a country's main urban centre and at least five other administrative areas (survey areas). In each survey area, a sample of drug outlets is examined from the public sector (e.g. primary health-care centres and hospitals) and the private sector (e.g. licensed pharmacies and licensed drug stores). Up to two 'not-for-profit' sectors where drugs are commonly sold can also be surveyed, such as the mission hospitals, NGO hospitals and dispensing doctors. In each survey area, data is collected in at least five drug outlets per sector. For a total of five outlets, multiplied by six survey areas = 30 outlets per sector.

Adopting the above methodology, first, from each of the two selected study regions, the main public hospital was selected, and then five hospitals under the main one were randomly sampled. Lastly, eight other public outlets that were falling under each of the hospitals were surveyed, to total to 92 (Table 3.1). In addition, failure rates of 4% (WHO, 2008), was added to total to 96. Matching number of private outlets was randomly selected. All (66) not-for-profit outlets and additional thirty public facilities were sampled to get the required sample size of 288. For every outlet targeted, one household was surveyed to make a total of 288 households.

Table 3.1 Sample size calculations

Facilities	Required number	Number selected
Main Health facility	1 per region	2
District hospitals	5 per region	10
Health centres and dispensaries	8 for each district hospital	80
Total		**92**

Non response rates at 4%= 92×4÷100=3.68

92+4=96

=96 outlets × 3 outlet types=288 outlets.

3.4 Sampling design

Multi-stage sampling approach was used to survey drug outlets and households. Nyanza region was divided into two regions; Kisii highlands and the lowlands around the shores of L. Victoria. For each region, a list of public medical facilities was compiled using a database obtained from the Ministry of Health (www.ehealth.or.ke/facilities-3/5/2011, 1230hrs). Adopting WHO's methodology for surveying drugs (WHO, 2008) a three-stage sampling approach was used to select the public medical facilities. First, from each of the two selected survey areas, the main public hospital was selected (Jaramogi Oginga Odinga Teaching and Referral Provincial hospital in Kisumu and Kisii Level 5 hospital). Secondly, for each main public facility, five randomly selected district hospitals were sampled. Lastly, eight other public facilities (Sub-district hospitals, Health centres and Dispensaries) that were falling under the district hospitals were surveyed. Matching numbers of private (pharmacies and chemical shops) and not-for-profit outlets (NGO, mission facilities) were targeted for the survey.

Households around the sampled drug outlet were targeted for the survey. One household was randomly chosen for every outlet surveyed. The design was tested by recruited study team in thirty outlets and thirty households in the same study region. Each area selected for pre-test represented levels of risk for malaria transmission as in the study areas and was similar in environmental conditions to that of the survey area. However, these data sets generated from the pre-tests were not used in the final analyses.

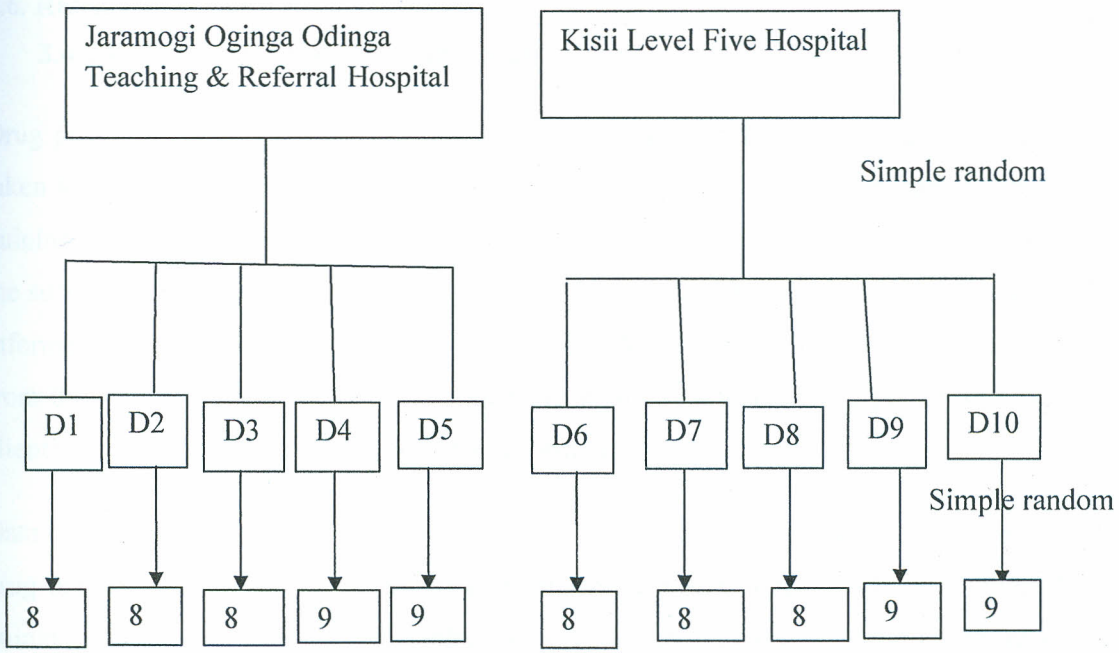


Figure 3.1: Multi-stage sampling in 3 stages

Legend: D, district hospital. For every public outlet surveyed, private and not-for-profit outlets and one household geographically placed nearest, was surveyed.

3.5. Data collection tools

Audit sheet (Appendix 3) and provider questionnaire (Appendix 4) was administered at each outlet, while household interview guide was administered at the household (Appendix 5). Audit sheet documented information about the anti-malarials (ACTs and quinine) available at each outlet. This information was used to determine the availability, the price, the frequency of stock-out and the affordability of the ACT and quinine for treatment of malaria. The provider questionnaire was used to assess provider knowledge and training related to malaria treatment, government treatment policy, and dosing regimens with ACT and quinine. Furthermore, the questionnaire was used to quantify the typical practices of providers:-practices of treatment policy and different instructions when dispensing ACT and quinine. The household interview guide captured the information on where the drugs were accessed, anti-malarial used, instructions given by the provider, dose used and duration for use.

3.6. Research procedure

3.6.1 Data collection at the drug outlets

Drug providers were recruited to participate in the survey. Those who agreed to participate were taken through two screening questions to determine whether (1) the outlet had stocked ACTs and or quinine within the previous three months, and (2) ACTs and or quinine were available on the day of the survey. All providers answering "yes" to at least one of these questions were recruited and gave information about the subsidized ACT (AL), other ACTs and or quinine after consent was obtained from them (Appendix 6). In outlets with more than one attendant, the person that was serving the clients at that particular time provided the information.

Data collectors, who had received standardized training, including data collection pilot tests, visited drug outlets in pairs and recorded information on each subsidized ACT (AL), other ACTs and or quinine found at the outlets. The information collected included, generic name, retail price, dose form, and packs per weight group, as well as information on the drug package size. The frequency of stock-outs was also recorded in various outlets. The price of anti-malarials was originally collected in Kenya Shillings (KES), and then later converted to US dollars (USD) for international standardization in costs. In addition, data on provider practices on the use of subsidized ACT (AL), other ACTs and quinine and their knowledge regarding national anti-malarial treatment guidelines was collected.

3.6.2 Data collection at the household

The quantitative data was collected from 288 households. The interview was performed using semi-structured questions which were administered to the particular household member who had used the anti-malarial drugs in the last two weeks prior to the study. However, in cases of children below the age of 13 years, mothers or caretakers provided the information. Particular emphasis was on the most recent episode of treatment of malaria due to self/presumptive or laboratory diagnosis within the last two weeks. Data on source of treatment, anti-malarial received, price of anti-malarial bought, the instructions received from the drug provider, dose and duration used was collected.

3.7 Data processing and analysis

3.7.1 Data processing

Data collected was checked on the field and cleaned at the end of each day to ensure completeness, consistency, credibility and eligibility. This was done to correct errors or to fill in missing information before another day of data collection.

3.7.2 Data analysis

Analysis adopted WHO and HAI standardized methodologies for availability, prices and affordability of drugs. Data from the outlets were grouped into three categories and analysed separately into: 1) public outlets, 2) private outlets and 3) not-for-profit outlets. Furthermore, anti-malarials were stratified as government subsidized ACT (AL), other ACTs and lastly quinine. Using the mean and median, drug access (price, availability and affordability) was established. For the availability analysis, different dose strengths of the same drug were combined to calculate the overall availability of that particular anti-malarial on the day of the survey.

The mean prices of anti-malarials were calculated for less than four drugs identified for each anti-malarial category, if not, median prices were computed. For comparison, the median price ratios (MPR) of the ACT median price to the current government recommended price for a single treatment course with subsidized ACT (AL) was computed in private and not-for-profit outlets at USD 0.5 (KES 40). For quinine, the MPR of private to not-for-profit outlets was calculated since there was no government subsidized price at the moment.

Affordability was expressed as the number of days households with lowest daily disposable income level at KES 150, USD 1.875 (IEMP, 2012) would need to work in order to pay for the full dose of treatment course with subsidized ACT (AL), other ACTs and quinine available in the outlet. In addition, open-ended questions were asked to test for knowledge and practices of treatment policy and dosing regimen. The respondents' description was recorded and later coded for easy entry into SPSS software.

Logistic regression analysis was used to establish how knowledge of the providers influenced their practices and how access factors including knowledge and practices of health providers influences the use of anti-malarials in households. For variables with two possible outcomes (anti-malarial availability, provider knowledge of treatment policy, provider knowledge on dosing regimen, request for written prescription, prescription of AL, sale of partial packs and affordability) a binary logistic

regression was used while for variables with more than two possibilities (provider awareness on currently banned drugs, training of staff, advice given when dispensing drugs), a multinomial logistic regression was used to establish the association between the variables and the outcome. Chi-square analyses were used for proportionality. Statistical significance was assessed at a $p \leq 0.05$.

3.8 Ethical considerations

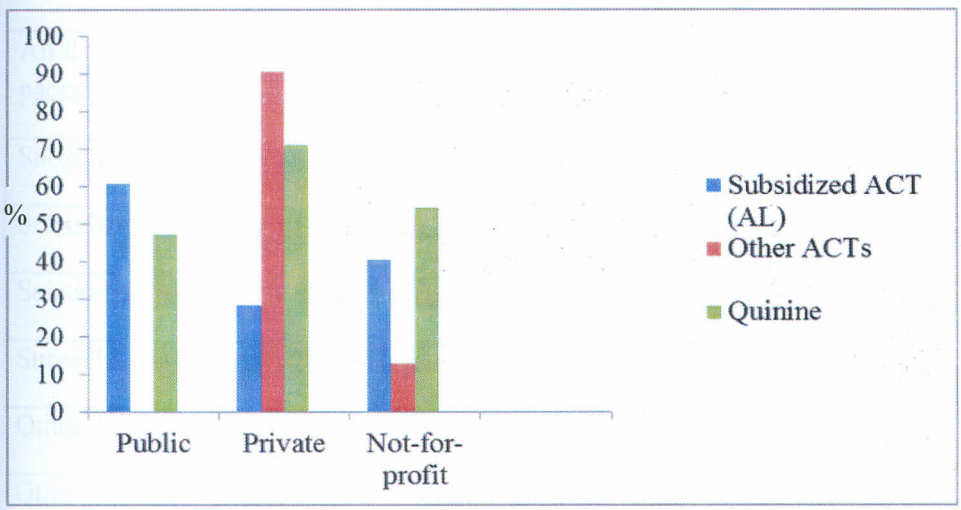
The study was approved by the School of Graduate Studies (SGS) of Maseno University. Ethical approval was obtained from Maseno University Ethics Review Committee (MUERC). The aim and purpose of all components of the study was discussed and agreed on before legal consent was obtained from the authorities. Consent and approval was obtained from Ministry of Medical Services through Nyanza Provincial Director of Medical Services (PDMS). The researcher always briefed the respondents about the nature of the research, its purpose, and implications in order to encourage informed consent and the respondents were required to voluntarily sign the consent form (see Appendix 6), of which a copy was retained by the respondent. Confidentiality of the information given was assured before starting each interview.

CHAPTER FOUR: RESULTS

A total of 288 outlets and equal number of households across the two geographical regions of Nyanza region were sampled and information about ACTs and quinine collected. The sampled population included 126 (44%) public facilities, 96 (33%) private outlets and 66 (23%) not-for-profit facilities.

4.1 Availability of anti-malarials

All outlets stocked more than one category of anti-malarial. More public 76 (60.7%) and not-for-profit outlets 27 (40.5%) surveyed stocked the subsidized ACT (AL), the recommended first-line treatment for uncomplicated malaria. However, less than a third of the private outlets 27 (28.4%) had stocked subsidized ACT (Figure 4.1). Other ACTs were stocked mostly by private outlets 87 (90.6%) and less by not-for profit 9 (12.9%), while public outlets did not stock other ACTs. All outlets stocked both first-line subsidized ACT (AL) and second-line (quinine) anti-malarials in varied proportions (Figure 4.1).



Legend: ACT, artemisinin-based combination therapy, AL, artemether-lumefantrine

Figure 4.1: Availability of anti-malarials by outlet type

4.1.1 Availability of packs per weight group

All the outlets had stocked more than one class of anti-malarials. All the four weight-specific subsidized ACT (AL) was available in less than half of the total outlets 88 (30.6%), while other ACTs were available in a total of 104 (36.1%) and quinine in 137 (47.6%) outlets. Other ACTs were widely available for both children 93 (96.9%) and adults 82 (85.0%) in private outlets. The availability varied with the outlet type as shown in Table 4.1. Availability of packs for different

weight groups was also evaluated in the three outlet types. The six tablet pack was in stock in more public outlets 47 (37.3%) than in private 21 (21.9%) and not-for profit 16 (24.2%) outlets (Table 4.1).

Table 4.1: Availability of anti-malarials in different packs per group weight by class and outlet type

	Class of anti-malarials		
	Subsidized ACT (AL)	Other ACTs	Quinine
Overall availability	88 (30.6%)	104 (36.1%)	137 (47.6%)
	Outlet type		
	Public (n=126) (%)	Private (n=96) (%)	Not-for-profit (n=66) (%)
Availability of packs per weight group			
All the four subsidized ACT (AL) weight specific packs	53 (42.1)	23 (23.9)	12 (18.2)
Subsidized ACT (AL) 6 tablet pack for 5-14kg	47 (37.3)	21 (21.9)	16 (24.2)
Subsidized ACT (AL) 12 tablet pack for15-24kg	62 (49.2)	25 (26.0)	12 (18.1)
Subsidized ACT (AL) 18 tablet pack for 25-34kg	66 (52.4)	12 (12.5)	33 (50.0)
Subsidized ACT (AL) 24 tablet pack for ≥35kg	111 (88.1)	42 (43.8)	46 (69.7)
Other ACTs for children	0	93 (96.9)	8 (12.1)
Other ACTs for adults	0	82 (85.0)	9 (13.6)
Quinine (any formulation)	58 (46.0)	45 (68.8)	34 (53.0)

Legend: ACT, Artemisinin-based Combination Therapy, AL, Artemether-Lumefantrine.

4.1.2 Stock-out of anti-malarials

Stock-out in the past three months was defined as absence of drugs from stock for at least seven consecutive days (WHO, 2008). The stock-out rates in public outlets was most frequent in the last three months with 106 (84%) outlets reporting three times or more stock-outs. On the other hand,

private sector suffered stock-outs once in the past three months in 70 (73%) outlets while in not-for-profit outlets, there was no stock-out in 57 (87%) in the past three months (Table 4.2).

The government recommendation guided decision for restocking in both public in 125 (99.5%) and not-for-profit in 51 (76.7%) outlets while private outlets restocked depending on most the profitable in 57 (59.2%) and consumer demand in 25 (26.3%) among other reasons (Table 4.2).

Table 4.2: Stock out of anti-malarials by outlet type

	Outlet Type		
	Public (n=126) (%)	**Private (n=96) (%)**	**Not-for-profit (n=66) (%)**
Stock out rates			
None	0 (0.0%)	17 (17.7%)	57 (86.4%)
Ones	3 (2.4%)	70 (73.3%)	6 (9.1%)
Twice	17 (13.5%)	9 (0.9%)	3 (4.5%)
Thrice or more	106 (84.1%)	0 (0.0%)	0 (0.0%)
TOTAL	126 (100%)	96 (100%)	66 (100%)
Decision for restocking			
Most profitable	0 (0.0%)	57 (59.2%)	0 (0.0%)
Recommended by government	125 (99.5%)	9 (9.4%)	51 (76.7%)
Lowest priced	0 (0.0%)	0 (0.0%)	0 (0.0%)
Drug company influence	0 (0.0%)	3 (3.1%)	0 (0.0%)
Consumer demand	0 (0.0%)	25 (26.3%)	12 (18.8%)
Easily available	0 (0.0%)	1 (1.5%)	2 (3.0%)
Prescribed most often by doctors	0 (0.0%)	1 (1.5%)	0 (0.0%)
Other reasons	1 (0.5%)	0 (0.0%)	1 (1.5%)
TOTAL	**126 (100%)**	**96 (100%)**	**66 (100%)**

4.2 The prices of anti-malarials

Anti-malarials in the public outlets were provided for free and were not included in the price analysis. Prices of anti-malarials with same generic names and the price range (R) were recorded and then median prices (MP) were computed. The overall median prices for subsidized ACT (AL), other ACTs and quinine were USD 0.94 (R=0.63-1.25), USD 5.63 (R=1.88-8.13) and USD 1.25 (R=0.75-1.25), respectively. The median price for all anti-malarials categories was much higher in private outlets than in not-for-profit outlets as shown in Table 4.3. Other ACTs were highly priced than the subsidized ACT (AL) and quinine.

The median price ratios (MPR) for other ACTs were computed using the government subsidized price of ACT (AL) of USD 0.5. The private outlets had higher MPR for other ACTs compared to their not-for-profit counter parts (Table 4.3). Although subsidized ACT (AL) was available in all the outlet types, the government recommended price of USD 0.5 did not apply and the ACTs were sold at median price of USD 0.94 (R=0.63-1.25) and USD 0.75 (R=0.63-1.0) in private and not-for-profit outlets, respectively. Other ACTs were averagely 12 times higher in price than the subsidized ACT (AL) in private outlets and 5 times higher in not-for-profit outlets (Table 4.3).

Table 4.3: Median prices and Median Price Ratios of anti-malarials being sold in private and not-for-profit outlets

	Outlet type				
Anti-malarials	Private		Not-for-profit		
	Median price-MP (range) USD	Median price ratio (MPR)	MP (range) USD	MPR	Overall MP
Subsidized** ACT (AL)	0.94 (0.63-1.25)	1.88	0.75 (0.63-1.00)	1.5	0.94 (R=0.63-1.25)
Other ACTs**	6.0 (1.88-10.63)	12	2.5 (1.88-3.13)	5	5.63 (R=1.88-10.63)
Quinine*	1.0 (0.75-1.25)	1.33	0.75 (0.63-1.13)	1	1.25 (R=0.75-1.25)

Legend: USD, United States Dollars; ACT, artemisinin-based combination therapy; AL, artemether-lumefantrine. **Median price ratio was calculated as anti-malarial median price to the government recommended price of subsidized ACT (AL) (KES 40, USD 0.5). *Median price ratio was calculated using median price of quinine in not-for-profit as reference since there is no government subsidized price.

4.3 Affordability of anti-malarials

Affordability which included the amount paid for anti-malarial drug in relation to households' level of disposable income was expressed as the number of days households in lowest socio-economic level would have to work in order to afford the full dose of treatment course with ACT and quinine available in the outlet. From previous survey done in Nyanza region in January 2012, it was reported that 62% of households earn an average maximum of Ksh. 4500 monthly which translate to Ksh 150, USD 1.875 per day (IEMP, 2012).

All the anti-malarials were more affordable in not-for-profit outlets than private outlets. The quinine purchased within not-for-profit outlets was most affordable to household with lowest disposable income levels (Table 4.4). Other ACTs were least affordable and would cost up to 3.20 days of disposable income in private outlets.

Table 4.4: Number of days of disposable income to afford anti-malarials by outlet type.

	Outlet type	
	Private	Not-for-profit
Anti-malarials		
Subsidized ACT (AL)	0.50	0.40
Other ACTs	3.20	1.34
Quinine	0.54	0.40

Legend: AL, artemether-lumefantrine; ACT, artemisinin-based combination therapy. Affordability was expressed as median price (numerator) against lowest daily disposable income level (at KES 150, USD 1.875= denominator).

4.4 Provider knowledge of treatment policy and dosing regimen

Prior to determining the provider's knowledge of treatment policy and dosing regimen, their professions and training was determined.

4.4.1 Professions of drug providers

The professions of the drug providers varied with the outlet type (Table 4.5). Overall, the majority reported to be pharmacists 148 (51.4%), with the other major group comprising of nurses 52 (18.1%). Counselors were 23 (8.0%), midwives 16 (6.0%), laboratory technicians 9 (3.1%), and

clinical officers, relatives and shop assistants each comprised of <5 (2.0%). Other trainings not mentioned in the questionnaire comprised of 30 (10.4%) and included community health workers, nurse aids and nutritionists, who were mainly dispensing in private outlets (Table 4.5).

Table 4.5: Drug providers' professions by outlet type

	Outlet types			
Providers' Professions	Public	Private	Not-for-profit	Total
	n=126 (%)	n=96 (%)	n=66 (%)	N=288 (100%)
Reported Pharmacists	76 (60.3)	52 (54.2)	20 (30.3)	148 (51.4%)
Midwives	13 (10.3)	-	3 (4.5)	16 (6.0%)
Clinical officers	4 (3.2)	-	-	4 (1.4%)
Nurses	23 (18.3)	1 (1.0)	28 (42.4)	52 (18.1%)
Laboratory Technicians*	-	3 (3.1)	6 (9.0)	9 (3.1%)
Counsellors*	6 (4.7)	17 (13.5)	-	23 (8.0%)
Shop Assistants*	-	4 (4.2)	-	4 (1.4%)
Relatives*	-	2 (2.7)	-	2 (0.6%)
Others*	4 (3.2)	17 (13.5)	9 (13.6)	30 (10.4%)

Legend: * Professions without clinical training.

4.4.2 Training of providers

Table 4.6 presents the proportions of staff receiving in-service training in the last two years by outlet type. Results revealed that less than half of respondents (142; 49.3%) had received in-service training on the use of ACT as a first-line treatment of malaria within two years prior to the current study. The training was mainly performed by non-governmental organizations (NGO's; 72%) although the government personnel offered health briefs regularly in the public facilities. There was significant difference on the training of drug providers in all the three outlet types ($P<0.0001$) (Table 4.6).

Table 4.6: Training of staff by outlet type

	Outlet type			
	Public	Private	Not-for-profit	***P*-value**
Training within last 2 years	n=126 (%)	n=96 (%)	n=66 (%)	
Yes	**91 (72.2)**	**15 (15.6)**	36 (54.5)	<0.0001
No	20 (15.9)	74 (77.0)	27 (40.9)	
Do not know	16 (12.7)	7 (7.3)	3 (4.5)	

Legend: Analyses performed by Chi-square tests. *Statistically significant at $P \leq 0.05$ for public verses private outlets.

4.4.3 Provider knowledge level of treatment policy

In order to establish the provider's knowledge level of treatment policy with subsidized ACT (AL) and quinine, an open-ended question was asked and responses of provider were captured. Providers were categorised as having high knowledge level when the response constituted the following: correct treatment policy, by mentioning ACT as first-line treatment for uncomplicated malaria and quinine as second line treatment for complicated and severe malaria. Other responses were categorised as having low knowledge level of treatment policy. A proportionality distribution of provider's knowledge level against drug outlets was performed. Results revealed that the proportions of providers with knowledge of treatment policy were at its maximum in public outlets 126 (100%) and almost all 65 (98.4%) in not-for-profit relative to private 49 (51.0%). These proportions were able to mention ACT as first-line treatment as recommended by the government for uncomplicated malaria.

Similarly, those who were able to name quinine correctly as the treatment for severe malaria were 121 (96.0%) in public, 55 (83.3%) in not-for-profit and 46 (47.9%) in private outlets. There was a significant difference in proportion of those who had knowledge versus those who did not have any knowledge on the use of ACT as the first-line anti-malarial among the three outlet types ($P<0.0001$) as well as knowledge of quinine as second line anti-malarial ($P<0.0001$) as shown in Table 4.7.

Table 4.7: Provider knowledge level of treatment policy by outlet type

		Outlet type			*P*-value
Treatment policy		Public n=126 (%)	Private n=96 (%)	Not-for-profit n=66 (%)	
First-line treatment with ACT	Correctly	125 (99.2)	49 (51.0)	65 (98.4)	<0.0001
	Incorrectly	1 (0.8)	**47 (49.0)**	1 (1.6)	
Second-line treatment with quinine	Correctly	121 (96.0)	46 (47.9)	55 (83.3)	<0.0001
	Incorrectly	5 (4.0)	50 (52.1)	11 (16.7)	

Legend: ACT, artemisinin-based combination therapy. Analyses performed by Chi-square tests. *Statistically significant at $P \leq 0.05$ for public verses private outlets.

4.4.4 Provider knowledge level of dosing regimens

In order to establish the provider's knowledge level on dosing regimen with subsidized ACT (AL) and quinine, an open-ended question was asked and response of provider was captured. Providers were categorised as having high knowledge level when the response constituted the following: the correct dose and duration for adults of specific weights and correct dose and duration for children of specific weights. Other responses were categorized as having low knowledge of dosing regimen. A proportionality distribution of provider's knowledge level against drug outlets was performed. High knowledge of subsidized ACT (AL) dosing regimen in children was demonstrated by providers in public in 119 (94.4%) in comparison with those in private 75 (78.1%), and not-for-profit 58 (78.8%) outlets. Knowledge level of dosing regimen in adults weighing 45kg also showed the same trend with 116 (92.0%) providers in public outlets able to state correctly the recommended doses with subsidized ACT (AL) as compared with 55 (57.3%) and 58 (78.8%) in private and not-for-profit outlets, respectively. There was a significant difference in proportion of those who had knowledge versus those who did not have any knowledge on the dosing regimen among the three outlet types ($P<0.0001$). Similar disparity was recorded with quinine regimen for adults and children as shown in Table 4.8.

Table 4.8: Provider knowledge of dosing regimens with subsidized ACT (AL) and quinine by outlet type

Weight groups		Outlet type			
		Public n=126 (%)	Private n=96 (%)	Not-for-profit n=66 (%)	*P*-value
Children 9kg	Correct subsidized ACT (AL) dose	119 (94.4)	75 (78.1)	58 (78.8)	<0.0001
	Incorrect subsidized ACT (AL) dose	7 (5.6)	21(21.9)	8 (21.2)	
	Correct quinine dose	111 (88.1)	50 (52.1)	37 (56.0)	<0.0001
	Incorrect quinine dose	15 (11.9)	**46 (47.9)**	29 (44.0)	
Adults 45kg	Correct subsidized ACT (AL) dose	116 (92.0)	55 (57.3)	58 (78.8)	<0.0001
	Incorrect subsidized ACT (AL) dose	10 (8.0)	**41 (42.7)**	8 (21.2)	
	Correct quinine dose	112 (88.8)	31 (32.3)	43 (65.2)	<0.0001
	Incorrect quinine dose	14 (11.2)	**65 (67.7)**	23 (34.8)	

Legend: AL, artemether-lumefantrine; ACT, artemisinin-based combination therapy. Analyses performed by Chi-square tests. *Statistically significant at $P \leq 0.05$ for public verses private outlets.

4.4.5 Provider awareness on currently banned drugs

More than half 164 (56.9%) of all the providers were aware of the most recent government ban on some anti-malarials and correctly named Sulphadoxine-pyrimethamine (SP) as the drugs under ban for the treatment of uncomplicated malaria. The reason for ban was mentioned as malaria drug resistance by 108 (37.5%) providers, although 83 (28.8%) could not give any reason, while 97 (33.7%) gave other reasons which comprised of drug side effects, the high cost and lack of it in the market. Table 4.9 shows the provider awareness on recent government ban by outlet type.

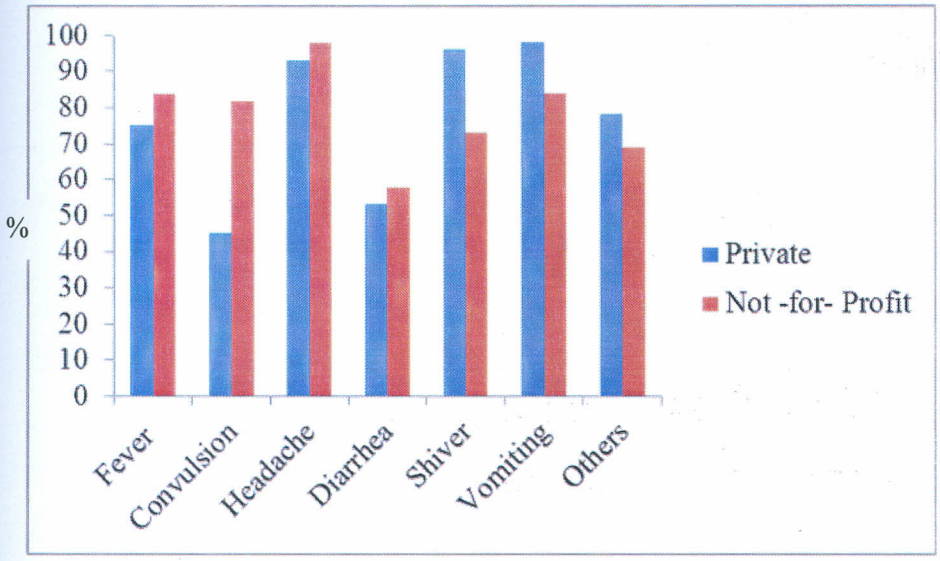
Table 4.9: Provider awareness on currently banned drugs by outlet type

Awareness on most currently banned anti-malarials	Outlet type				*P*-value
	Public n=126 (%)	Private n=96 (%)	Not-for-profit n=66 (%)	Totals N=288 (%)	
Correctly naming SP	108 (85.7)	29 (30.2)	27 (41.0)	164 (56.9)	<0.0001
Naming other drugs	15 (11.9)	43 (44.8)	27 (41.0)	85 (29.6)	<0.0001
Do not know about the ban	3 (2.4)	24 (25.0)	12 (18.0)	39 (13.5)	<0.0001

Legend: SP, Sulphadoxine-Pyrimethamine. Analyses were performed by Chi-square tests.
*Statistically significant at $P \leq 0.05$ for public verses private outlets.

4.4.6 Provider knowledge on symptoms of malaria

Providers in private (n=96) and not-for-profit (n=66) outlets were requested to name the symptoms of malaria that would make them prescribe an anti-malarial drug. All providers mentioned more than 3 symptoms and they included: headache 156 (96%), vomiting 147 (91%), fever 130 (80%), shivering 137 (85%), convulsions 102 (63%) and diarrhoea 91 (56%) and 'other' symptoms which comprised of joint pains, paroxysm and sweating were mentioned by 120 (74%). The knowledge on symptoms of malaria varied with outlet type as shown in Figure 4.2.



Legend: Other symptoms included joint pains, paroxysm and sweating.

Figure 4.2: Provider knowledge on symptoms of malaria by outlet type

4.4.7 Influence of in-service training on knowledge

Additionally, binary logistic regression analysis was performed to identify knowledge variables that were associated with in-service training of staff. In-service training was treated as independent variable while outcome variables comprised of drug recommended for treatment of uncomplicated malaria, treatment regimen for uncomplicated malaria in a child weighing 9 kg, treatment regimen for uncomplicated malaria in an adult weighing 45 kg, drug for treatment of severe malaria, treatment regimen for severe malaria in a child weighing 9 kg, treatment regimen for severe malaria in an adult weighing 45 kg and awareness on recent anti-malarial ban. Results revealed that the providers who had undergone in-service training were between 1-2 times more likely to mention the correct drug recommended by the government for treatment of uncomplicated malaria (OR; 1.07, 95% CI, 1.03-2.44, P=0.040), were 2 times more likely to mention the correct treatment regimen for uncomplicated malaria in children (OR; 2.01, 95% CI, 1.66-3.83, P=0.039) and in adults (OR; 2.03, 95% CI, 1.68-3.80, P=0.039), and treatment regimen for severe malaria in children (OR; 2.66, 95% CI, 1.88-5.44, P<0.0001) and in adults (OR; 2.01, 95% CI, 1.88-4.25, P=0.002) were positively influenced by in-service training of the providers (Table 4.10).

Table 4.10: Influence of in-service training on knowledge

	OR	95% CI	*P*-value
Drug recommended for treatment of uncomplicated malaria	1.07	1.03-2.44	**0.040**
Treatment regimen for uncomplicated malaria in a child weighing 9 kg	2.01	1.66-3.83	**0.039**
Treatment regimen for uncomplicated malaria in an adult weighing 45 kg	2.03	1.68-3.80	**0.039**
Drug for treatment of severe malaria	1.44	0.78-1.99	0.142
Treatment regimen for severe malaria in a child weighing 9 kg	2.66	1.88-5.44	**<0.0001**
Treatment regimen for severe malaria in an adult weighing 45 kg	2.01	1.88-4.25	**0.002**
Awareness of recent ban	1.51	0.65-2.01	0.158

Legend: Binary logistic regression analysis was performed between independent (In-service training) and dependent variables (Knowledge factors) to identify knowledge variables significantly associated with in-service training of staff. The *P*-values in bold were statistically significant at $P \leq 0.05$; OR = Odd Ratios. 95% CI = 95% Confidence Interval. UM, Uncomplicated Malaria; SM, Severe Malaria.

4.5 Provider practices on treatment policy

Providers in private outlets who did not give advice when dispensing AL were 35 (36.5%) and only 22 (22.8%) requested for written prescription from their customers before dispensing AL, while in public and private outlets were 109 (86.3%) and 52 (79.1%), respectively. Selling of partial packs of anti-malaria was most common in private outlets in 79 (82.3%). Only one provider in public outlet advised on the need to take 1st dose of AL immediately while 21 (21.8%) and 53 (81.1%) providers in private and not-for-profit outlets, respectively, gave advice on the need for timing during treatment course. Providers verbally described the treatment course to their customers in 50 (39.7%) of public outlets, 11 (8.7%) in these outlets mentioned the possible side effects of the drug while 45 (35.7%) mentioned the importance of adherence to treatment course. None of the providers mentioned the need to take AL with a lot of fluids or foods while 35 (36.5%) in private outlet did not give any advice (Table 4.11).

Table 4.11: Provider Practices on treatment policy by outlet type

Practices		Outlet type		
		Public (n=126) (%)	Private (n=96) (%)	Not-for-profit (n=66) (%)
Request for written prescription	Yes	109 (86.3)	22 (22.8)	52 (79.1)
	No	17 (13.7)	**74 (77.2)**	14 (21.2)
Prescribes AL	Yes	86 (67.9)	13 (37.6)	19 (29.1)
	No	40 (31.6)	**83 (72.4)**	47 (70.9)
Sale of partial packs of AL	Yes	1 (1.0)	**79 (82.3)**	8 (12.1)
	No	125 (99.0)	17 (17.7)	58 (87.9)
Advice given when dispensing AL				
Take 1st dose immediately		1(1.0)	5 (5.2)	1 (1.0)
Need for adherence to timing		9 (7.1%)	21 (21.8)	53 (81.1)
Verbal description of treatment course		50 (39.7)	8 (8.0)	7 (11.2)
Side effects		11 (8.7)	10 (10.4)	-
Drug interactions		-	-	1 (1.0)
Importance of adherence to treatment course		45 (35.7)	3 (3.0)	3 (4.9)
Taking with a lot of fluids/food		**0 (0.0)**	**0 (0.0)**	**0 (0.0)**
Others		2 (1.6)	15 (15.6)	-
None given		7 (5.6)	35 (36.5)	1 (1.9)

Legend: AL, artemether-lumefantrine; ACT, artemisinin-based combination therapy.

4.5.1 Influence of in-service training on provider practices

Further logistic regression analyses were performed to determine the practices associated with in-service training. In-service training was treated as independent variable while outcome variables

comprised of request for written prescription, prescription of AL, selling partial packs of AL and advice given when dispensing AL. Results demonstrated that those who had gone through in-service training were 3 times more likely to request for written prescription (OR, 3.00; 95% CI, 2.45-10.4; $P = 0.001$), were 4 times more likely to prescribe AL (OR, 4.03; 95% CI, 2.99-14.7; $P < 0.0001$), and were almost 4 times unlikely to sell partial packs (OR, 3.79; 95% CI, 2.77-11.2; $P < 0.0001$) (Table 4.12).

Table 4.12: Influence of in-service training on provider practices

Provider's practices	**OR**	**95% CI**	***P*-value**
Request for written prescription	3.00	2.45-10.4	**0.001**
Prescription of AL	4.03	2.99-14.7	**<0.0001**
Selling partial packs of AL	3.79	2.77-11.2	**<0.0001**
Advice given when dispensing AL	1.50	0.77-2.06	0.208

Legend: Binary logistic regression analysis performed on request for prescription, prescription of AL and selling of partial packs while multinomial logistics regression analysis performed on advice given when dispensing drugs. Independent variable was in-service training while dependent variables were practices. The *P*-values in bold were statistically significant at $P \leq 0.05$; AL, artemether lumefantrine. OR = Odd Ratios. 95% CI = 95% Confidence Interval.

4.6 Use of anti-malarials in households

Use of anti-malarials was assessed by inquiring about which anti-malarials were used, where the drug was accessed, instructions given at the point of access, the duration of use and the dose/frequency of use. Other drugs viewed by respondents as anti-malarials were reported by 24 (8.3%) households and were not included in the analysis for use. Slightly more than half (142-54%) of the household members who used recommended anti-malarials used subsidized ACT (AL), while 89 (34%) and 33 (12%) used other ACTs and quinine respectively.

The number of households that accessed anti-malarials from public outlets were 104 (39.5%), private 124 (46.9%) and not-for-profit 36 (13.6%). Individuals in households reported to have received more than one instruction on how to use anti-malarials and these included taking 1st dose of subsidized ACT (AL) immediately and 2nd dose after 8 hours in 17 (6.4%) households, need for adherence to timing 85 (32.2%), verbal description of treatment course 169 (64.0%), side effects of anti-malarial accessed 15 (5.7%), importance of adherence to treatment course 58 (22%), other instructions 38 (14.4%) and no instructions given to 49 (18.6%) individuals. However, none of the

individuals had been advised on the need to take ACT with a lot of fluids/food or on drug interactions. Assessment of correctness of dose used revealed that 178 (67.4%) of household members who used recommended anti-malarials used the right doses. Specifically, the proportion of individuals who took the correct anti-malarial doses of the drugs were: quinine 29 (87.9%), other ACTs 76 (85.4%) and subsidized ACT (AL) 73 (51.4 %).

Furthermore, valuation of correctness of duration of use revealed that 175 (46.2%) took drugs within the specified duration. Considering the proportion of correctness of duration for each drug, the results show that quinine was 31 (93.9%), other ACTs 64 (71.9%) and subsidized ACT (AL) 80 (56.3%).

4.6.1 Influence of access factors, knowledge and practices on the use of anti-malarials in the households

In order to determine factors influencing use of anti-malarials in households, a logistic regression analysis was performed. The independent variables included access factors at the outlets (availability, price, affordability of anti-malarials, provider knowledge of treatment policy, provider knowledge of dosing regimen, awareness of recent anti-malarial ban, prescription of AL, sale of partial packs and advice given while dispensing), while the dependant variables included anti-malarial used, dose used and duration used in the households.

Results revealed that anti-malarial use was more likely to be influenced by the availability of anti-malarial drugs (OR, 1.00; 95% CI, 1.01-1.55; P=0.050), 3 times influenced by its price (OR, 2.88; 95% CI, 1.99-4.31; P<0.0001) and almost 1.5 times more likely to be influenced by provider knowledge of treatment policy (OR, 1.03; 95% CI, 1.01-1.82; P=0.049). Knowledge of dosing regimen was almost 3 times likely to influence the dose used (OR, 2.67; 95% CI, 2.02-4.33; P<0.0001) and almost 1.5 more likely to influence duration of use (OR, 1.13; 95% CI, 1.02-2.40; P=0.006). In addition, sale of partial packs was almost 3 times likely to influence the dose used (OR, 2.78; 95% CI, 2.22-4.45; P<0.0001) and almost 1.5 times likely to influence the duration of use (OR, 1.24; 95% CI, 1.10-2.66; P=0.004) of anti-malarial. Finally, the advice given while dispensing anti-malarial was almost 1.5 likely to influence the dose used by the providers (OR, 1.24; 95% CI, 1.10-2.67; P=0.004) (Table 4.13).

Table 4.13: Influence of access factors, knowledge and practices **on the use of anti-malarials**

Use of anti-malarials in households									
	Anti-malarial used			**Dose used**			**Duration used**		
	OR	**95% CI**	***P-value***	**OR**	**95% CI**	***P-value***	**OR**	**95% CI**	***P-value***
Availability	1.00	1.01-1.55	**0.050**	0.63	0.34-1.35	0.101	0.78	0.54-2.03	0.486
Price	2.88	1.99-4.31	**<0.0001**	0.88	0.65-2.01	0.726	0.71	0.45-2.00	0.841
Affordability	3.01	2.45-5.01	**0.005**	0.73	0.41-1.99	0.873	0.67	0.39-1.45	0.279
Provider knowledge of treatment policy	1.03	1.01-1.82	**0.049**	0.75	0.43-170	0.341	0.74	0.41-1.99	0.872
Provider knowledge of dosing regimen	0.81	0.43-2.00	0.828	2.67	2.02-4.33	**<0.0001**	1.13	1.02-2.40	**0.006**
Awareness of recent anti-malarial ban	0.86	0.36-2.01	0.965	0.69	0.43-1.47	0.252	0.77	0.45-1.52	0.235
Prescription of AL	3.01	2.77-5.33	**0.016**	0.89	0.65-2.01	0.722	0.73	0.57-2.23	0.596
Sale of partial packs of AL	0.85	0.67-2.03	0.698	2.78	2.22-4.45	**<0.0001**	1.24	1.10-2.66	**0.004**
Advice given while dispensing	0.69	0.44-1.47	0.293	1.24	1.10-2.67	**0.004**	0.65	0.33-1.39	0.104

Legend: Logistic regression analysis between independent and dependent variables was used to identify influence of access factors and provider knowledge and practices on the use of anti-malarials. The *P*-values in bold were statistically significant at $P \leq 0.05$; AL, artemether-lumefantrine. OR = Odd Ratios. 95% CI = 95% Confidence Interval.

CHAPTER FIVE: DISCUSSION

This survey was carried out six years after the government of Kenya had implemented the policy on combination therapy for treatment of malaria. The findings showed that many private outlets did not stock the first-line anti-malarial. Subsidized ACT was 1.88 times expensive in private outlets relative to the government recommended price of USD 0.5 and needed up to 0.5 days of work among the poor households to afford full course of treatment. Most private outlets sold partial packs of anti-malarials. Providers who had received training on the new policy had high knowledge and better practices on the use of the anti-malarials. Anti-malarial availability, price and affordability and provider knowledge and practices were highly associated with and positively influenced anti-malarial use in households. The results could be used as a guideline to step-up the activities to enhance malaria treatment and as a key bench-mark to evaluate the success of the implementation of the malaria treatment policy in Kenya and further evaluate the role of policy implementation in malaria burden in the study region.

5.1 Availability of anti-malarials

Findings revealed that the government-recommended anti-malarials were available in all outlet types with public outlets providing only the two recommended anti-malarials; subsidized ACT (AL) and quinine. The private outlets on the other hand stocked various other ACTs in addition to the policy recommended anti-malarials. Stocking other ACTs in private outlets could be due to the fact that selling subsidized ACT would be unprofitable, since it is highly subsidized by the government and people get them at a cheaper price in public outlets. Previous studies from this malaria endemic region showed that private sectors prefer stocking drugs which can retail at competitive prices (Amuasi *et al.,* 2011). This is a matter of concern given that many households in the current study bought drugs from private outlets, where anti-malarials were sold at higher prices.

Low availability of all the four weight-specific packs of subsidized ACT (AL) is of more concern, and worse still, the low availability of the 6 Tablet Pack meant for the treatment of under-fives, which is the most vulnerable group to malaria infections. Coupled with the higher frequency of stock-outs recorded in this study, the calculation of appropriate regimen may not be guaranteed when the right package size is lacking, especially in the currently observed low knowledge of providers on the AL regimen in the private outlets. For example, giving 4 packets of the 6 tablet pack for treatment of malaria in patients who need 24 tablet pack or splitting the blister pack of 12 tablet pack

into half for a child weighing 9kg might result into a lot of confusion and needs better knowledge of the drug regimen.

A previous study carried out in Uganda showed that patients' adherence was high when they received AL blister packs with a weight-specific number of tablets and including pictorial instructions on how to use it (Fogg *et al.*, 2004). This observation was also recorded in a study done at the coastal region of Kenya where simplicity of drug regimen was associated with treatment adherence (Marsh *et al.*, 2004). The current study findings, consistent with previous ones (Chuma *et al.*, 2009) observed that lack of drugs in the formal sector contributes to people buying drugs from non-formal outlets, where the quality is less controlled and information on dose is not often provided. Yet in another study about a third of individuals who sought care from public health facilities did not get drugs from the hospital pharmacy because they were out of stock (Chuma *et al.*, 2010).

5.2 Price and Affordability of anti-malarials

The prices of subsidized ACT (AL) remained lower than other anti-malarials in all the outlets. The lower median price in not-for-profit outlets was as a result of this sector being supplied with subsidized ACTs by the government and had a tendency to adhere to the subsidy policy, although the anti-malarials were not free as in the public outlets. The not-for-profit outlets had additional service charge, further raising the price of the drugs. Lower prices of subsidized ACT (AL) are highly commendable although it is not affordable to people who are of lowest economic levels. For instance, buying a full course of subsidized ACT (AL) would cost USD 0.94 in private and USD 0.75 in not-for-profit outlets and this would need up to 0.5 and 0.4 days of disposable household income, respectively. These results indicate lower prices of a first-line drug compared to results found in a study in Democratic Republic of Congo where recommended first-line anti-malarial (artesunate-amodiaquine) was USD 3.20 as at 2008 (ACT, 2008), conversely, the price of first-line treatment in the current study is higher than the price of first-line treatment in Burundi which was USD 0.16 as at 2011 (Amuasi *et al.*, 2011).

Higher prices than recommended in private outlets indicate lack of regulations and price control. This lack of control affects public health in the society, especially those most vulnerable to malaria-related morbidity and mortality due to poverty (WHO, 2003) . However, the price differences between the private and not-for-profit outlets for both subsidized ACT and quinine need to be reconsidered. Given the 3.2-fold price differences of other ACTs in the private outlets as compared

to the not-for-profit outlets, there is need to make the pricing of other ACTs in the private outlets comparable to that in other outlets. The reasons for reconciling and regulating prices may range from the fact that many households bought anti-malarials from private outlets due to frequent stock-outs in public outlets. Secondly, the private outlets are more accessible in terms of distance which has been found to influence the type of anti-malarials bought for use in this region (Watsierah *et al.*, 2010). Considering the two reasons which show evidence of the role played by private sector in providing treatment for patients in western Kenya, it is important to effectively increase other ACTs affordability and accessibility in these outlets. This would further increase adherence to treatment regimen since the affected population would be able to afford the full course of anti-malarials. The end results would be among other reasons, preventing the irrational use of drugs hence slow development of resistance by the malarial parasite. The WHO echoes that when health systems are not able to provide ACTs at little or no cost, consumers may have to purchase them in the private sector (WHO, 2010).

5.3 Knowledge of the providers on the malaria treatment policy

Access to anti-malarials is not only influenced by availability, price and affordability but is also subjective to the training and knowledge of the providers on the malaria treatment policy. Such trainings can be done through in-service and health briefs. The results of the current study revealed that 44.8% of the drug providers in the private sector lack clinical training which is critical in determining correctness of dispensing of any drug. Lack of proper training of health providers have been reported in other studies as well (Stensen *et al.*, 2001; Ongore, 1996). Furthermore, there were more in-service trained personnel in the past two years dispensing drugs in public outlets (72.2%) which had surpassed the target 60% set up by the Ministry of Health (Amin *et al.*, 2007; MoH, 2006). This figure was far much higher than 46% in another study conducted one year after the start of policy implementation in Kenya (Njogu *et al.*, 2008).

The expansion of the in-service training coverage in public facilities is encouraging even though the private sector still lags behind in training of its drug providers. Furthermore, a considerable bulk 43 (45%) of private outlet staff dispensing drugs did not have any clinical training. This confirms findings of other studies done previously in Kenya and Democratic Republic of Congo (Ongore, 1996; Stensen *et al.*, 2001) indicating that majority of staff dispensing drugs were untrained. The private sector qualification has been a staggering issue for a very long time in developing countries despite the significant role they play in medication management and provision of relevant information to patients (WHO, 2010).

The fact that more not-for-profit outlets were compliant with drug dispensing policies may be attributed to the mission hospitals which fall in this category that receive government support, and tend to effect policies enacted by the government. The 36 (55%) health providers who received training in this sector is nevertheless inadequate and may have been contributed to by the recent mushrooming of non-governmental interventions in Nyanza region, and most of these interventions targets integrated management of HIV and AIDS and malaria. The training of providers in this sub-sector has not yet been evaluated. Of importance and worth noting is the fact that about half (49%) of providers in private outlets could not mention ACT as first-line treatment for uncomplicated malaria and fewer (48%) could not mention quinine correctly for treatment of severe malaria in children. This was despite the fact that quinine has been used widely in Kenya for a long time, and notwithstanding the fact that it was being stocked by private outlets, although in less quantities as compared to other anti-malarials.

The observation further gives additional evidence of inadequate knowledge and skills on the treatment policy. The reason behind low knowledge of quinine could be attributed to it being less frequently stocked by the private sector due to reasons such as: Quinine is mostly prescribed as second line and therefore most customers would only ask for it after the failure of other drugs. Quinine is also less publicized in the media or not at all, decreasing awareness about it, as compared to first-line AL. Private providers tend to stock the drugs which are frequently requested by the consumers, as awareness on the type of anti-malarial in the market was found to influence the type of drug bought for use in a study in the region (Watsierah *et al.,* 2011).

Dosing regimen with subsidized ACT and quinine was inquired for particular weights (children 9kg and adults 45kg) for uniformity and easy recording. Disparity was observed in knowledge of dosing regimen with the two anti-malarials in public, private and not-for-profit outlets. The current study reports that a higher level of knowledge of dosing regimen in public and not-for-profit outlets was influenced by in-service training, further creating an indication of need for training. Although there was quinine being sold in private outlets in different formulations, many providers in this sector could not mention the correct doses in adults (67.7%) and further 42.7% could not state the correct AL dose for adults. Other studies similar to the current study reported that interventions improved formal provider behaviour and that in-service training delivered higher effectiveness (Denis, 1998; Greer *et al.,* 2004; Tavrow *et al.,* 2003), although in a different study, the interventions did not result in change of behaviour, probably because it involved short duration and didactic style of training,

with focus on rational drug use as per the national treatment guidelines (Ofori-Adjei and Arhinful, 1996).

Some studies related to prescription of AL reported that incorrect weight-specific prescriptions of AL were sporadic and that the packaging would have influenced dosing regimen (Njogu *et al.*, 2008). One such study carried out in Tanzania, consistent with the current findings, confirms that most dispensers in private pharmacies could not state the dosing schedules of AL without referring to the package leaflets (Minzi and Haule, 2008). Higher knowledge of treatment regimen with quinine for severe malaria in public outlets reported in the current study was also influenced by in-service training. These results contradicts a study in Democratic Republic of Congo which demonstrated that training of the providers did not improve the knowledge of the dosing schedule with quinine among the village health volunteers and pharmacy owners (Mayxay *et al.*, 2007). In addition, the differences on awareness level on the most recent ban on anti-malarials being observed in the outlets were not attributed to in-service training.

The question on knowledge of symptoms of malaria focused on respondents in private and not-for-profit outlets and excluded the public sector since most (92%) of the drug providers in public outlets had clinical training. The providers knew more than three symptoms, a good indication for subsequent prescription, even though the malaria treatment guidelines still confine ACT and quinine prescription to registered pharmacies and should only be provided to confirmed cases of malaria. It is important to mention that although the guidelines insist on laboratory tests before selling the recommended drugs to customers, the practice of providers in private outlets selling anti-malarials without prescription was observed in various outlets in the study region and the practice was influenced by in-service training. Providers' knowledge of treatment policy was associated with in-service training. For instance, in-service trained providers highly predicted correct stating of treatment regimen for severe malaria in children and in adults and the correct regimen for uncomplicated malaria in children and in adults. These observations are highly indicative of the need for such in-service trainings in the implementation of new treatment guidelines.

5.4 Provider practices on the malaria treatment policy

The providers at the drug outlets are charged with the responsibility of advising their customers on all matters relating to better adherence to treatment schedule and for proper use of drugs. These practices to be enhanced by the providers in ACT policy includes request for written prescription, sale of full doses of drugs, and even advising the patient to take the first dose immediately and the

second dose eight hours later in case of AL. Additionally, the staff should educate the customers on the need for adherence to timing, the possible side effects as well as the need to take more fluids/food during the treatment with ACT and finally verbally describe the treatment course and the importance to adhere to the treatment course. The discrepancy in the practices by the providers in private outlets is worrying. The sale of partial packs observed in private outlets (82.3%) of ACT shows lack of commitment to positive change by the providers even in the face of combination therapy. The practice further influenced the use of anti-malarials in the households, particularly three times likely to influence the dose used and almost 1.5 times likely to influence the duration of use of anti-malarial. This is a serious issue in the contribution to under treatment with recommended drugs which might eventually contribute to malaria parasite developing drug resistant. In addition, it is largely known that the type and duration of treatment in private outlets is determined by the client's ability to pay (Marsh *et al.,* 1999) the practices that have not adhered to policy recommendations. The low prescription of subsidized ACT in private and not-for-profit outlets could be attributed to the in-service training. The training influenced the prescription practice with better prescription seen in the public sector. Other observation showed that 77.2% of providers in private outlets never requested for prescription chit from their customers despite the government call on the implementation of universal parasitological diagnosis and targeted treatment with AL aiming by 2013 at universal coverage and adherence to the recommendations (Nyandigisi *et al.,* 2011).

Prescription practices have been reported in a study exploring why health workers did not prescribe AL, despite the drug being in stock at the public health facilities. The previous study identified various reasons for non-adherence to the treatment guidelines, most of which were related to health workers responding to general health system weaknesses (Wasunna *et al.,* 2008). A low level of prescriptions of the nationally recommended drug was reported in yet another study where only 26% of children who needed treatment with ACT received a prescription for this drug according to national guidelines (Njogu *et al.,* 2008).

The deviation from the guidelines in the current study shows inadequate skills and knowledge in preparation for implementation of the new policy in private sector. It is eminent that differences in outcome were as a result of lack of in-service training in readiness for the on-going implementation process. There is critical need to find an intervention which could address this discrepancy, owing to the importance of this sector in health provision and because absence of training in ACT policy has been reported to be a factor influencing ACT prescribing practice in Kenya (Njogu *et al.,* 2008). One way of increasing coverage can be through training of trainers from the same sector who will

further train their counterparts. This was seen to improve malaria treatment in private drug outlets in Bungoma District in western Kenya before the policy change (Tavrow *et al.,* 2003). Another approach may be to train the drug dispensers directly in organized workshops, give information, sensitization and education on the new policy and health briefs on quinine regimen, although this method might be more expensive for the government compared to the former. Previously, a study reported improvement on health worker performance in care and treatment of patients after conducting educative seminars and training of health workers (Yeung and White, 2005).

Focus on public sector to implement policy change was reported in a study performed in Kenya a year after the beginning of implementation process of the new malaria policy, in which health workers were trained in a cascade manner (Njogu *et al.,* 2008). The tendency to focus more on public sector to implement changes in the new guidelines downplay the previous call of WHO to include the private sector in malaria treatment due to their significant role in pharmaceutical management and provision of relevant information to patients, thus enhancing the improvement of rational drug use (WHO, 1988).

Formulation of good policies may not be a guarantee for proper interpretation of knowledge and practice. It must be accompanied by sensitization for the achievement of the outcome. In a previous study in neighbouring Tanzania, positive results in achieving policy change was reported in a targeted community that was sensitized before the implementation process (Eriksen *et al.,* 2005). Some studies found that targeted training in the private sector appeared to produce much better improvements in provider practice, achieving correct anti-malarial sales in 73–100% of intervention shops, an increase from lower baseline levels. The two studies focused on more participatory approach of interventions, in which the input of the drug vendors themselves was considered (Greer et al., 2004). Vendor-to-vendor education programme also showed improvements in provider practice in yet another study, although of a smaller magnitude (Tavrow *et al.,* 2003).

5.5 Use of anti-malarials in the households

The study has shown that factors which determine access and providers knowledge and practices influences how the drugs are used in the households with dose and duration for use highly dependent on the sale of either full or partial packs and advice given by the provider. Furthermore, the knowledge of providers on the dosing regimen greatly determine adherence in the households. In a study carried out in Cambodia, and consistent with the current findings, it was reported that when patients were given free drugs at the correct dose by a trained health provider, levels of adherence

were much higher, especially if careful verbal instructions had been given (Yeung and White, 2005). Health providers can be constantly reminded through briefing and media communication on the importance of giving instructions.

Many households accessed their anti-malarials from private outlets despite the fact that the public outlets offered anti-malarials for free. The choice for private outlets as the best option has been linked to many reasons, for instance, studies have shown that the public outlets are fairly not reachable by many households (Abuya *et al.,* 2007; Cameron *et al.,* 2009). Furthermore, consumers tend to avoid incurring other costs like for travelling and of laboratory diagnosis. At the public outlets, the long queues which translate to the long waiting time further discourage many from accessing these facilities (Chuma *et al.,* 2007). Therefore this observation provides enough evidence to target the private outlets to benefit from the activities of implementation process of a new policy.

Higher proportions of households had the correct doses and durations observed with quinine usage in the current study as in the previous study in the same area (Watsierah *et al.,* 2010), primarily because its main source was government facility where its administration was entirely supervised by trained health personnel (that is, many cases involving quinine are supervised within the health facility). This is contrary to a previous review which showed poor adherence with a seven-day regimen of quinine (Yeung and White, 2005). In a similar study in Uganda, it was found that giving detailed verbal explanation with the drug, with clear instructions on how to take the medication improved adherence (Okonkwo *et al.,* 2001). Conversely, in another study in the current region, feeling better was a reason for some patients to miss doses during the treatment course (Watsierah *et al.,* 2010) as was the case in almost half of the missed doses in a Ugandan study (Fogg *et al.,* 2004). These observations on the determinants of adherence to malarial treatment regimens in the households as currently reported clearly shows the need to create awareness on the importance of adherence to treatment regimen not only to the providers, but also to the end users of these drugs.

The needs of training providers about appropriate doses and duration have been pin-pointed as one of the viable intervention to increase adherence to national recommendations in the community (Marsh *et al.,* 2004). Current behaviour patterns in the use of anti-malarials by consumers must be taken into account when considering treatment policies. The affordability and prices of drugs is also directly related to the ways in which drugs are used and should be an integral part of any discussions on changing policies. Unaffordable anti-malarials may result in poor treatment practices, which is one of the factors that contribute to the development of resistance and further shorten the useful treatment life of the drugs (WHO, 2010).

Affordability and price of anti-malarials highly predicted the drugs that were being used for treatment of malaria in the households. This shows that the consumers tend to use drugs whose prices are fairly competitive in the market and hence affordable. This observation creates a need for the government to regulate the prices of essential drugs in the market. Since in-service training of providers generally influenced their knowledge in dispensing anti-malarials and the use of the drugs in the households, there is still need of such trainings in the implementation of anti-malaria treatment policy.

In the current study, whether the providers sold partial anti-malarial packages or not were a likely determinant of dose used and duration of use of anti-malarials. The implication of such practices by the providers poses a greater challenge in the treatment of malaria. The incomplete treatment course as a result of the practice may result in the whole population developing resistance to such drugs which will thwart the noble reason behind the combination therapy and effectiveness of the anti-malarials. It is important to educate the providers and the consumers alike on the importance of adherence in order to achieve better treatment in the community. This will reduce the chances of the malaria parasite developing resistance against the combined therapy and further leading to a reduced disease burden in endemic regions such as in western Kenya.

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1. Conclusions

1. Availability of anti-malarials (ACTs and quinine) still remains a challenge in the outlets in malaria endemic regions of western Kenya. First-line therapy for uncomplicated malaria, subsidized ACT (AL), was more available in public and not-for-profit facilities although with frequent stock-outs reported in public outlets. Furthermore, the packages for specific weight groups were inadequately stocked while the private outlets had stocked less subsidized ACT. There were most frequent stock outs in public sector, which further constrains the availability in these sector outlets.

2. The prices of ACT and quinine in drug outlets in malaria endemic areas of western Kenya remains high in the private outlets despite the fact that more households get their drugs from this sector. None of the private outlets sold the subsidized ACT (AL) at the recommended price of USD 0.5, while other ACTs were highly priced.

3. The affordability of ACT and quinine in drug outlets in malaria endemic areas of western Kenya is still a challenge especially in private sector. Private-sector marketing of ACTs has resulted into use of sub-optimal doses because of partial sales of course of treatment packages. This practice is dictated by patient's ability to pay. Furthermore, the recommended anti-malarials being sold at higher prices in the private outlets makes the drugs unaffordable to many households.

4. The provider knowledge of treatment policy and dosing regimens of ACT and quinine in malaria endemic areas of western Kenya was inadequate. Knowledge of providers in public outlets was higher than in private outlets. Inadequate involvement of the private outlets in in-service training during the implementation of the new malaria treatment policy has contributed to their poor knowledge on how to correctly dispense the drugs in right regimens.

5. The provider practices of treatment policy and dosing regimens with ACT and quinine in malaria endemic areas of western Kenya is poor. This study showed significant difference in prescribing practices among public, private and not-for-profit outlets with deficiencies recorded in all the sectors and poor adherence to national and WHO guidelines on treatment practices.

6. The use of anti-malarials in the households is influenced by the availability, price and affordability of the drugs. These factors determine the adherence to the dosing schedules during the treatment

course. In addition, knowledge and practices of the health providers in the drug outlets determines the adherence to correct regimen by the consumers.

6.2 Recommendations for action

1. Frequent stock-outs of the required anti-malarials for different weight groups calls for more emphasis on the implementation of malaria treatment policy. Therefore, delivery should include four different subsidized ACT (AL) pack sizes (6, 12, 18 and 24 Tablets Packs) suitable for management of four different weight categories (5-14kg, 15-24kg, 25-34kg and >34kg) of patients respectively. It is highly advised to create private-public partnership in the procurement and distribution of recommended anti-malaria drugs to make them available for the customers in all the outlets. The factors that influence availability should be tackled according to regional context. These should include monitoring net sales/consumption rates through inventory, timeframe estimates and physical stock recording especially according to seasonality of illness and differences in district health needs. Internal agreement to transfer anti-malarials from one sector outlet to another and from one region to another depending on the disease burden and consumption rate is proposed.

2. The observation that anti-malarials prices are high at the private sector can be counteracted by the government establishing accredited drug dispensing outlet as a private sector supplement for the distribution of subsidized ACT in order to increase access to the first-line anti-malarial drugs in rural and underserved areas. Tanzania has designated a special cadre of accredited shops that are permitted to sell ACT over the counter. Establishment of Accredited Drug Dispensing Outlets (ADDOs) and provision of subsidized ACT through this channel has greatly improved and expanded access to ACT (Rutta *et al.*, 2011).

3. Affordability of anti-malarials in this region affects the poorest households most. Ensuring that the right drugs are sold in all outlets at the recommended subsidized price is one way of enhancing affordability. It is also necessary to educate people on the free malaria treatment policy available in public sector. The health care workers reported to have procured anti-malarials from the commercial outlets to make it available for patients who visited the health facilities, which they then charged on the patients. While this was not part of the study objectives, it is worth mentioning that the practice affects the affordability to recommended treatment in the public sector. Therefore measures to curtail the absence of anti-malarials in the outlets are recommended.

4. In-service training during the implementation of a new policy has been identified as a major determinant of the knowledge and practices of providers. It is therefore recommended that changes in treatment guidelines should be accompanied by subsequent implementation activities, which should involve all sector players. The assumptions that providers will follow the guidelines on paper are merely a guess and therefore there is need for frequent sensitization through education, information and communication. Although drug shops are ideally licensed to sell different categories of drugs, most of them are not manned by professional pharmacists at all times. The low knowledge of providers dispensing drugs at the counter in the private drug outlets would have been attributed to the observed pattern of employing people without clinical training while the qualified personnel own the licenses to operate. This is a factor which needs urgent and further actions by the relevant authorities.

5. The reported practices of the health providers may further constrain the successful up-scaling of combination therapy, and may limit the desire to turn efficacy to effectiveness of the programme. It is therefore recommended that efforts to improve malaria treatment practices in the dawn of policy changes should include frequent monitoring and evaluation for the achievements and failures of the policy changes and subsequent re-planning for better results.

6. The findings that under-treatment is frequent with doses of artemether/lumefantrine highlight the potential contribution of incorrect drug use to the genesis of drug resistant malaria in these settings. These factors if not given serious consideration will only increase the continent's malaria burden and will therefore strain the desire to the achievement of two key millennium development goals: reduce by two thirds the mortality rate of under-five children by 2015 and begin to reverse the incidence of malaria by 2015. If in the short term Kenya want to reduce morbidity and mortality due to malaria and in the longer term to move towards elimination, sufficient attention needs to be paid to the broader context, particularly health system constraints. This will include the government through their policies to initiate training of personnel at the sources (including those issuing drugs over the counters) on the importance of making available to the users only the most effective anti-malarial drugs with proper prescription and consumer awareness on treatment regimen, that are likely to impact upon the effectiveness and sustainability of the policy to improve prompt and effective treatment. The consumers require access to correct and comprehensible information with regard to the possible benefits and risks associated with the use of drugs, including self-prescription.

Appropriate health promotion programmes on the importance of anti-malarial adherence can be made available to the community as it has been done in the promotion of rational use of other drugs,

like the anti-retroviral therapy. This could be done, for example, through pamphlets in medical facilities, regular public service announcements and mass media including use of television, radio and video shows. Following a switch in national drug policy to ACT, behaviour change communication is recommended during which all outlets staff should be trained in unbiased manner on the current malaria policy to improve drug use in the community. In areas where such interventions have been done, then further scaling up of these programmes is necessary.

6.3 Recommendations for further research

Further research should be done to evaluate if subsidy policy on AL and subsequently free provision in government facilities have influenced the use of this drug in the households. More exploration of factors influencing providers' behaviours and practices need to be investigated. The studies on their perceptions regarding new treatment guidelines would help to inform the design of interventions to improve diagnosis and prescribing practices. More exploratory studies are needed to understand barriers to access on the side of the consumers. These studies could focus on the irrational drug use and perception of consumers on the treatment policy. Further research should be done on the impact of change of knowledge of the providers and consumers on actual behaviour since it is not that changes in knowledge will necessarily correlate with changes in behaviour.

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