

**THE CHANGE IN MALARIA TREATMENT POLICY IN UGANDA:
EXTENT OF ADHERENCE TO ANTIMALARIAL DRUG POLICY IN
RAKAI AND KAMPALA DISTRICTS**

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Dedication

I dedicate this dissertation to my wife Cissy N. Kimera and children (Cynthia, Dennis and Christine) who endured my absence from home during the period I spent at the University to accomplish this assignment. I also dedicate it to my mother Mrs. Kevin Namuswe and my late father Silas Lukongwa (May his soul rest in eternal piece), whose blessing has enabled me to achieve many goals in life. All possible in the name of almighty God!

University of Cape Town

Abstract

Changes in Antimalarial Drug Policies are intended to improve case management and reduce both social and financial burden associated with malaria. To achieve this providers have to translate the policy into practice since they have the privilege of being the primary contact to those affected by malaria. The main aim of this study is to examine the extent of implementation of the change in antimalarial drug policy in Uganda, from chloroquine monotherapy to combination therapy of CQ+SP for management of uncomplicated malaria. Prescribing practice of health personnel in selected health facilities in Rakai and Kampala Districts is used as a measure of level of adherence to the change in policy. Both qualitative and quantitative data are collected. Qualitative data are collected from key stakeholders at national and primary health care levels while quantitative data are collected from a sample of facilities selected from the public and private not for profit sectors. Analysis of data is done by both Microsoft excel and STATA statistical package.

The study findings indicate poor adherence to change in antimalarial drug policy in the study area in Uganda. Out of the 1,171 malaria prescriptions analyzed, only 39% are in line with the recommended treatment in the antimalarial drug policy. Results of interviews with key stakeholders indicate that policy makers anticipate high level of adherence to the policy, especially at primary healthcare level given the resources invested into the process of implementing the change. Other findings indicate that the public health facilities adhere more to the change from chloroquine monotherapy to combination therapy of CQ+SP. However, those that do not adhere to the policy change, mainly prescribe either chloroquine or Quinine monotherapy.. The level of use of chloroquine monotherapy among those that do not adhere to the change in policy, is relatively higher in public health facilities than private not for profit health facilities. This indicates public health facility prescribers' reluctance to change with changes in antimalarial treatment policy. Given the high level of resistance to chloroquine, this reluctance to change might exert high social and economic costs to the affected community.

The study achieved the intended objectives and made useful findings that policy makers will find relevant in guiding implementation of future changes in antimalarial drug policies.

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List of Abbreviations

AMDP	Antimalarial Drug Policy
AQ	Amodiaquine
AS	Artesunate
CO	Clinical Officer
CQ	Chloroquine
DALYs	Disability Adjusted Life Years
DDHS	District Director of Health Services
DMO	District Medical Officer
EANMAT	East Africa Network for Monitoring Antimalarial Treatment
FDC	Fixed Dose Combination
HBMF	Home Based Management of Fevers
HC	Health Care
HIMS	Health Information Management System
HSSP	Health Sector Strategic Plan
MO	Medical Officer
MOH	Ministry of Health
MSF	Medicines Sans Frontiers
MTP	Malaria Treatment Policy
MW	Mid-Wife
NGO	Non Governmental Organizations
NS	Nurse
NSMTG	National Standard Malaria Treatment Guidelines
NSMTGs	National Standard Malaria Treatment Guidelines
PFP	Private for Profit
PHC	Primary Health Care
PNFP	Private Not For Profit
RTI	Acute Respiratory Infection
SP	Sulphadoxizine -Pyrimethamine
STD	Sexually Transmitted Diseases
UNSTGs	Uganda National Standard Treatment Guidelines
WHO	World Health Organization

Chapter 1.0 Background

1.1 Introduction

Until 2002, chloroquine monotherapy was the first line treatment for uncomplicated malaria in Uganda. Chloroquine was the preferred choice because of its combined desirable characteristics; efficacy, affordability and ease to administer. The change in malaria treatment policy from chloroquine monotherapy to combination therapy in Uganda was inevitable due to finding of various studies that provided evidence about chloroquine-resistant *plasmodium falciparum* (Ministry of Health, 2000a; Ministry of Health, 2000b). Use of efficacious drugs is the desired providers' and policy makers' goal because effective antimalarial drugs not only reduces the risk of severe disease and death but also contributes to slowing down development of parasite's resistance to antimalarial drugs (World Health Organization, 2001).

National Antimalarial Drug Policy

Malaria is an acute illness caused by protozoan parasites of the genus *Plasmodium* (Ministry of Health, 2002). There are four¹ species that infect human beings, of these *P. falciparum* is the most common in Uganda (Ministry of Health, 2002). National malaria treatment protocols in Uganda and indeed many other countries in sub-Saharan Africa had traditionally mandated the use of one antimalarial drug (chloroquine) as the first-line treatment. However, this has recently (less than five years ago) changed because resistance to Chloroquine (CQ) has increased dramatically, leading to change in national antimalarial drug Policy (Ministry of Health, 2000a; Ministry of Health, 2000b; Kanya, et al., 2002). The malaria treatment policy changed from use of chloroquine monotherapy as a first line treatment for management of uncomplicated malaria to use of combination therapy of chloroquine plus Sulfadoxine-Pyrimethamine (CQ+SP) (Ministry of Health, 2002). The policy, further states that quinine is the recommended second line drug and should only be given when the first line drugs have failed (Ministry of Health, 2002).

Although resistance to CQ was the major cause of change in first line drugs for treatment of uncomplicated malaria, it is of policy interest to know other factors

¹ The four parasites are; *Plasmodium (P) falciparum*, *P. vivax*, *P. ovale* and *P. malariae*.

beyond efficacy that influence change in antimalarial drug policy from the provider's perspective. Knowing also that there are several options from which Uganda could choose an appropriate replacement therapy for CQ monotherapy (Muheki, 2001), there is need to evaluate the providers (Prescribers) reaction to the recommended practice after the policy change.

This study aims at assessing prescribers' level of adherence to the change in antimalarial drug policy (AMDP)² in Uganda within the existing health care delivery environment.

Country Context

Uganda is landlocked country with a total area of 241,038sq km of which 43,941sq km is water and swamps, and the remaining 197,097sq km land. It is located in East Africa and lies astride the Equator. The country has tropical climate, generally rainy with two dry seasons per year, with heavy rains from March to May and light rains between September and December, with semiarid climate in northeast. This being a good climate for breeding of malaria parasites, malaria transmission is throughout the year especially in the areas around the northern part of Lake Victoria.

The country has a population of 24.7 million, majority (88 percent) living in rural areas (Census, 2002). This rural based population composed of mainly the poor, has the least access to health facilities with most health facilities located in towns alongside main roads. According to the 1992 Uganda Health Facilities inventory, only 49% of the population lives within five kilometers of a health service unit, highlighting the inadequate geographical access to health care. The infant mortality rate is rate is 88 per 1000 (Ministry of Health, 2003b) majority of whom dying of malaria.

Uganda is administratively divided into 56 districts and has a decentralized system of governance where several functions have been delegated to the local governments. However, the central government retains the role of making policy, setting standards and supervising, and for health related policies Ministry of Health (MOH) is the responsible central authority. The economy is predominantly agriculture with

² Antimalarial drug policy interchangeably used with malaria treatment policy

majority of the population dependent on subsistence farming and light agro-based industries.

According to the Monitoring Survey report of Ministry of Finance, Planning and Economic Development-Uganda (1995/96), poverty among the population remains high with approximately 46% of the people living in absolute poverty and high prevalence of communicable disease (with malaria among the top) is among the factors that greatly contribute to poor health situation in the country which is the major underlying cause of poverty.

The country is among those in the category of Least developed Countries, with per capita health expenditure in the range of US \$ 7 to US \$ 12, of this only US \$ 3.95 is attributed to government and donor spending, and the balance being individual out of pocket payments (Ministry of Health,1999a). Therefore, in addition to the disease associated sufferings, the affected population suffers from financials constraints associated with the cost of meeting their health needs.

Uganda Health Care Delivery System

Since gaining political stability in 1990, the government has implemented a wide range of social service reforms all aimed at improving efficiency and effectiveness of service delivery to the population. Such reforms include the decentralization policy. Under the decentralized health care delivery system, the roles of Ministry of Health are mainly³: Policy formulation, setting standards, quality assurance, resource mobilization, capacity development/technical support and monitoring/evaluation of the overall sector performance. Uganda health care delivery system is composed of Ministry of Health (at central level), National and Regional Referral Hospitals, District Hospitals, Health Sub-Districts facilities (Health Centres IV) and primary health care facilities (Health Centres III and II)⁴.

The country recognizes that the public and private sectors have separate but complementary roles and tries to make the best use of efficiency advantages in private sector. According to ministry of health statistics, private not for profit sector

³ According to the Ministry of Health Uganda, Health Sector Strategic Plan; 2000/2001-2004/05, Mid Term review report (April 2003).

⁴ See appendix 6 for definition of health care II, III, IV levels

owns 47% of the 104 hospitals in the country, and out of the 3,075 total health facilities in the country, 48% (1,482) are managed by private not for profits (Ministry of Health, 2003a). Public sector provides free healthcare service while private sector health care financing mechanism is on fee for service basis. However, the services provided by the private not for profit sector are greatly subsidized by other funding institutions, Ministry of Health inclusive.

National health priorities are based on health services that prove to be cost-effective and have the largest impact on reducing mortality and morbidity. Malaria being a major contributor of burden of disease at all levels of health care is given highest priority. Malaria is among the three communicable diseases that form components of the minimum health care package, the other two are STD/HIV/AIDS and Tuberculosis (Ministry of Health, 1999a).

1.2 Statement of the Problem

Several studies show high level of resistance to chloroquine monotherapy, a drug traditionally used as first line treatment for uncomplicated malaria (Kamya et al., 2002; Ezad et al., 2003; Marquino et al., 2003; Bjorkman et al., 2005; Checchi et al., 2005). The resulting treatment failures have lead to changing antimalarial drug policy by affected countries in Africa, Uganda inclusive. Among many treatment options, Uganda recommended use of chloroquine plus sulphadoxine-pyrimethamine (CQ+SP) but there is little evidence about the translation of policy change into prescribing practice. Failure to implement the policy may have serious consequences in terms of health, with indirect consequences in the economic and social aspects of the life of Ugandans.

1.3 Justification of the Study

Correct implementation of changes in antimalarial drug policy is important not only to promote therapeutic success but also to minimize the spread of drug-resistant malaria parasites. In studies of knowledge, attitudes, and practices regarding malaria and its treatment, misperceptions about the disease, the use of ineffective treatments, and the incorrect use of effective treatments are all common (Djimde et al., 1998; Comoro et al., 2003; Kyawt-Kyawt-Swe and Pearson, 2004; Vigneron et al., 2005). Most studies have examined consumers of antimalarial treatments,

antimalarial drugs efficacy and the economic burden malaria exerts on the affected families (Ettling et al., 1994; Wilkins et al., 2002; Abdo-Rabbo, 2003; Ezad et al., 2003; Flores et al., 2003; Ben-Ami et al., 2005). Therefore, identifying factors that influence adherence to change in national antimalarial drug policy, and assessing the level of adherence of prescribers to the change in policy, will aid in devising strategies for increasing the proper use of antimalarials and also guide implementation of future changes in malaria treatment policy.

1.4 Study Objectives

The aim of the study is to examine the extent of implementation of the change in antimalarial drug policy in Uganda, from monotherapy to combination therapy for management of uncomplicated malaria, using prescribing practice of health personnel in selected health facilities in Rakai and Kampala Districts as the outcome measure. The working hypothesis is that implementation of change in national policy for treatment of uncomplicated malaria from CQ monotherapy to combination therapy of CQ+SP does not directly translate into change in prescribing practice.

Specific objectives are:

1. To understand the basis of change in malaria treatment policy in Uganda and define steps that had been taken to ensure efficient implementation of the new policy.
2. To review treatment (prescribing) practices for uncomplicated malaria in public and private not for profit (PNFP) health facilities in Rakai and Kampala districts of Uganda, as a basis for establishing the level of adherence to the national antimalarial drug policy.
3. To find out factors that influence adherence to national malaria treatment guidelines
4. To make recommendations to policy makers on how to improve adherence to national malaria treatment policy.

1.5 Outline of Thesis

Chapter 2 presents a review of literature on global burden of malaria and various studies on antimalarial drug policy changes, with special focus on countries in sub-Saharan Africa. This is followed by methodology chapter which describes how the study was designed and carried out. This chapter also covers ethical considerations made, data management and study limitations. Study results (both qualitative and quantitative) are presented in chapter 4 and discussed in chapter 5. Finally, policy recommendations, and proposed agenda for further research based on the study findings, are put forward in chapter 6.

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Chapter 2.0 Literature Review

2.1 Introduction

Changes in malaria treatment policies in sub-Saharan Africa have been driven by increasing resistance of malarial parasites to commonly used drugs. However, the choice of which drug to switch to has been greatly influenced by various factors beyond efficacy (East African Network for Monitoring Antimalarial Treatment, 2003). Of the 4 species responsible for human malaria disease, *P. falciparum* causes most of the severe disease and deaths, and is the most prevalent in Africa (Olumese, 2005). While it has become general knowledge that use of chloroquine to treat malaria especially that caused by *P. falciparum* is no longer effective, it is not clear which treatment option is most suitable for resource constrained countries with limited access to newer drugs on market (Kamya et al., 2002). A national antimalarial treatment policy is a set of recommendations and regulations concerning the availability and rational use of antimalarials in a country (World Health Organization, 2001). In addition, it includes guidelines that equip decision makers with evidence based recommendations. Such a national policy also provides health workers with clear guidelines for providing diagnosis and prompt treatment, appropriate to the local context (World Health Organization, 2001).

This chapter reviews the trend of changes in antimalarial treatment policies in sub-Saharan Africa with special focus on Uganda. The review also includes the basis for antimalarial drug policy changes for management of uncomplicated malaria, made by various countries.

2.2 Malaria burden

Globally, up to an estimate of 3 million people die from malaria and 500 million to 5 billion clinical episodes of malaria that deserve anti-malarial treatment occur (Bjorkman et al., 2005). Malaria was the eighth highest contributor to global loss of disability-adjusted life years (DALYs) in the year 2001 and second in Africa (Bjorkman et al., 2005). Estimates for annual mortality range from half a million to three million people (Marsh, 1998). About 40% of the world's population living in the

poorest countries is at risk of malaria infection (Amexo et al., 2004). Malaria not only cuts lives short but has a huge socio-economic impact. Affected patients are often bedridden and not able to carry out normal daily activities. This suffering leads to considerable loss of income and place a heavy burden on their families, the health system and society as a whole (World Health Organization, 2003a). Malaria has also been described as the world's most important parasitic infection, ranking among the major health and developmental challenges for the poor countries of the world (Sachs, 2002). In World Health Organization report (2003b), it is estimated that \$ 3.2 billion is required per year for effective control of malaria in 82 countries with the highest burden of the disease. This report on access to antimalarial medicines further acknowledges shortfall in monetary investment to malaria both at national and international levels. Such shortfalls imply that the end user (mainly the very poor people) bear main costs of antimalarial interventions (Ettling et al., 1994).

The economic burden of malaria is enormous and it is documented that malaria endemic countries are among the poorest in the world. Gallup et al., (2001), reports that in 1995 malaria endemic countries' income was only a third of non-endemic countries, irrespective of geographical location. The cost of resistance to antimalarials is significant when one takes into account the cost of loss of working days for adults and absence from school for children. Therefore, appearance of resistance to antimalarial drugs has increased the global cost of the disease (World Health Organization, 2003a). Both direct and indirect costs greatly contribute to the malaria burden. In a critical review of the economic impact of malaria in Africa, the average indirect cost per episode was estimated to be in the range of \$0.68 for cases in children less than 10 years of age in Malawi to \$23 per adult episode in Ethiopia (Chima et al., 2003).

At household level, the indirect⁵ costs of malaria amounted to 2.6% of annual household income in Malawi (Ettling et al., 1994). On the other hand, household direct monthly per capita expenditure on malaria-related treatment⁶ was reported to range between \$0.41 and \$3.88 per person, equivalent to between \$1.88 and \$26 per household (Chima et al., 2003). Looking at the burden from production

⁵ Indirect costs considered include value of productive labour time lost due to illness by both affected individual and attendants.

⁶ Direct malaria-related treatment costs considered include out-of-pocket expenditures for consultation fees, drugs, transport and the cost of subsistence at a distant health facility.

perspective, the review by Chima (2003) indicates an estimate of 2-6% and 1-5% of GDP in Kenya and Nigeria respectively, as total annual value of malaria related production loss. In Uganda, like many other sub-Saharan African countries, malaria is a leading killer disease affecting both urban and rural communities. The disease accounts for 15.4% of the life years lost due to premature death and remain the leading cause of morbidity and mortality in the country (Ministry of Health, 1999a). Malaria is responsible for 25-40% of out patient visits, 20% of admissions and 9-14% of patients' deaths (Ministry of Health, 2004). For example, in Bundibugyo hospital in Uganda, 60% of hospital stays in the paediatric department is due to malaria (Ministry of Health, 1999b). It is also the number one cause of hospital stays for children, and the major cause of death in this hospital (Ministry of Health, 1999b). The situation is not much different in other districts of Uganda. It is therefore, important that adherence to national treatment guidelines is observed to ensure effective management of such a deadly disease that affect majority of our population.

2.3 Treatment options for resistant malaria in Uganda

In Uganda, alternative options considered prior to changing first line treatment from chloroquine monotherapy to either other monotherapy or combination therapy options include (Ministry of Health, 2000a, Ministry of Health, 2000b):

Monotherapy options:

Sulphadoxine-pyrimethamine(SP), Amodiaquine(AQ), Mefloquine(M) and Artesunate(AS).

Combination therapy options:

- Chloroquine and SP combined (CQ+SP),
- Atovaquone-proguanil
- Mefloquine and SP (M+SP)
- Amodiaquine and SP combined (AQ+SP)
- Artesunate and CQ (AS+CQ)
- Artesunate and AQ (AS+AQ)
- Artesunate and SP combined (AS+SP)
- Artesunate and Mefloquine (AS+M)
- Co-Artesunate fixed combinations (Artemether and Lumefantrine).

Among these, Uganda opted for a change from chloroquine monotherapy to a combination therapy of CQ+SP (Ministry of Health, 2000a).

The replacement therapy for CQ selected by Uganda, differed from selections made by neighboring countries like, Rwanda, Burundi and Kenya which changed from CQ to SP+AQ for Rwanda and SP monotherapy for both Burundi and Kenya (East African Network for Monitoring Antimalarial Treatment, 2003). Changing from chloroquine which has been for long relied on as an affordable effective first line drug for treatment of uncomplicated malaria requires studies to provide relevant information on cost–effectiveness of possible replacement choices (Talisuna, 2001).

2.4 Malaria resistance

Availability of affordable, efficacious and low side effect profile antimalarials like chloroquine has been the major means of controlling the ever increasing burden of malaria in sub-Saharan Africa. However, resistance to CQ is now an established fact and resistance to another relatively affordable drug - SP is also rapidly developing in the great lake regions, central and southern Africa, and a public health concern because of multi-drug resistant malaria that has been predicted (Kamya et al., 2002; Talisuna et al., 2004b).

In Ghana, a study that examined the efficacy of chloroquine (CQ), amodiaquine (AQ) and sulphadoxine–pyrimethamine (SP) for the treatment of uncomplicated *Plasmodium falciparum* malaria⁷, found that CQ has the least efficacy (46.7%) compared with SP - 77.6% and AQ - 86.1% (Oduro et al., 2005). Results of this study formed basis for suggesting that CQ is no longer useful in Ghana and should be replaced as a first-line treatment of malaria and therefore, driving changes in the countries' AMDP policy. An assessment study of antimalarial drug resistance in Peru on use of CQ⁸ and SP⁹ in the treatment of uncomplicated *P. falciparum* infections also indicated high resistance to CQ. Results for SP were better, with no RIII failures observed among patients who received SP. In a related study, early treatment failures were observed in 27.1% of the CQ patients but in no patients receiving SP, pointing to SP as possible viable CQ replacement option (Marquino et al., 2003).

Analysis of the impact of drug resistant malaria on disease and its effect on health systems in sub-Saharan Africa, revealed that drug resistant malaria may not only

⁷ Using the WHO 14-day in vivo antimalarial testing guidelines

⁸ 25 mg/kg

⁹ 25 mg/kg of the sulphadoxine component

increase malaria specific mortality but may also influence all-cause mortality (Bjorkman et al., 2005). From efficacy perspective, change from chloroquine monotherapy to a combination therapy of CQ+SP in Uganda, was seen as an option that will delay the development of resistance to either drug when used alone (Sendagire et al., 2005). However, other studies done a year later reflect that there is a notable decrease in adequate clinical response by day 14 from 92.7% with SP to 80% with the combination of CQ+SP (Sendagire et al., 2005). Such findings indicate that there has been rapid development of resistance to CQ+SP combination therapy.

In World Health Organization report (2003a), it is acknowledged that there is growing evidence for high failure rates on using both SP alone and CQ or SP containing combinations. It is further uncertain whether combining drugs such as artesunate and SP, could postpone development of drug resistance given the high malaria transmission rate in Africa. This reservation is logical considering the fact that many treatments are given in an uncontrolled way through the private sector, with the risk of inappropriate use of drugs (Ogwal-Okeng et al., 2004). Such uncertainties have lead to recommending that the replacement choices may be increasingly limited to AS+AQ and artemether-lumefantrine (Checchi et al., 2005). However, implementing such desirable options certainly requires increased funding to facilitate the appropriate use and purchase of optimal but costly antimalarials.

2.5 Trend of antimalarial national policy changes

Between 1998 and 2001, Kenya, Uganda, Tanzania, Zanzibar and Rwanda changed antimalarial drug policy due to widespread chloroquine resistance (East African Network for Monitoring Antimalarial Treatment, 2003). The decision to change from chloroquine monotherapy as first line treatment for uncomplicated *P. falciparum* malaria was made in: June 2000, February 2001, 1998 and 1999 for Uganda, Rwanda, Kenya and Tanzania respectively (East African Network for Monitoring Antimalarial Treatment, 2001).

In Sierra Leone, malaria is also considered to the top public health problem, accounting for 48% of total outpatient morbidity country wide (Checchi et al., 2005). However, change in policy in this country was driven by evidence from 5 in vivo efficacy studies of chloroquine, sulphadoxine-pyrimethamine and amodiaquine which

established high CQ treatment failure ranging from 39.5% to 78.8% (Checchi et al., 2005). The same study also revealed disappointing SP efficacy with failure rates ranging from 23.2% to 46.1%, leading to exclusion of all CQ and SP containing combination from possible replacement regimen for CQ monotherapy. Basing on such evidence, the country opted for artesunate plus amodiaquine as the most suitable alternative for the new national antimalarial drug policy (Checchi et al., 2005). These findings are in line with those of a three-arm study in carried out in Uganda where combination of CQ+SP did not offer any significant advantage over SP monotherapy (Talisuna et al., 2004a). Although in a related study on CQ efficacy also established that it was no longer efficacious for treatment of *P. falciparum* malaria, Ezard et al. (2003) recommends that CQ should retain its place as preferred first line therapy for *P. vivax* malaria which respond poorly to SP. Probably, this justifies the use of the combination of CQ+SP in areas where both *P. vivax* and *P. falciparum* are both common. Given the above, the issue of whether Uganda made the most suitable decision by choosing CQ+SP is debatable.

Changes in antimalarial treatment policy in Uganda were made when chloroquine resistance levels approached a national average of 40% by the year 2000 (Kamya et al., 2002). Finding of this study on increasing antimalarial drug resistance carried out in Uganda and comparison with regional information on chloroquine resistance, resulted in the Ministry of Health to recommend a change from CQ monotherapy to a combination therapy of CQ+SP for management of uncomplicated malaria (Ministry of Health, 2000a). A few years later, results of a randomized, multisite trial to guide national policy in Uganda describe the risk of treatment failure with CQ+SP as unacceptably high (Bakyaita et al., 2005). Such information presents another perspective where further change from combination of CQ+SP to more efficacious regimen is being considered. In a study which assessed cost-effectiveness of artemether-lumefantrine (AL) relative to SP in South Africa, results indicate greater effectiveness and significant cost savings associated with the implementation of AL (Muheki et al., 2004). Reaffirming this position, Artesunate fixed dose combinations (FDCs) are currently fronted for use in Africa as most suitable first line drugs for treatment of malaria (World Health Organization, 2003a).

Therapeutics options with potential for deployment under this category include (World Health Organization, 2003a):

1. Artemether/Lumefantrine (Coartem®);
2. Artesunate 3 days plus Amodiaquine as FDC;
3. Artesunate (3 days) plus SP as FDC, in areas where SP efficacy is high.

However, effectiveness of the above trend of changes in antimalarial drug policy and probably more changes yet to come is greatly dependant on level of translation of policies into actual prescribing practice. Therefore, investigating providers prescribing practice in response to change from chloroquine monotherapy to combination therapy of CQ+SP in Uganda, will inform policy makes on how best to devise means of promoting adherence to current as well as likely future changes in antimalarial drug policy.

2.6 Factors that influence implementation of new antimalarial policies

Factors that that influence implementation of rational malaria treatment policies include political, legal, social–cultural, economic, biomedical/technological, environmental/epidemiological and those relates to health system (Williams et al., 2004). The complexity of the above mentioned factors requires greater attention to be put on operational effectiveness. Designing rational and appropriate antimalarial drug policy does not necessarily guarantee proper use of antimalarials by providers, dispensers or consumers (Williams et al., 2004).

Reviews of implementation progress of antimalarial treatment policy are increasingly revealing that efficacy data, although a necessary component for deciding effective treatment policy, are not alone sufficient or necessarily the major factor driving change (Shretta et al., 2000; East African Network for Monitoring Antimalarial Treatment, 2001; Kanya et al., 2002; Williams et al., 2004). Although the selection of replacement drugs should be guided by safety, therapeutic efficacy, cost /affordability, availability and simplicity of regimens, potential for correct wide spread use by provider is highlighted as equally important (World Health Organization, 2003a).

It is recognized that there are several challenges associated with the process of implementation changes in antimalarial policies in various countries; such challenges include (Williams et al., 2004):

- Lack of standardized data on drug resistance
- Difficulty of translating evidence into rational policy
- Poor communication between stakeholders
- Prescribing practice that differ from policy
- Inadequate resources both financial and human
- Political changes affecting political stability
- Competition from others and, at times more pressing national priorities
- Defensive postures of Ministries of Health when interacting with the media

Inclusion of prescribing practices that differ from policy among the key challenges mentioned above further highlights the importance of this study.

2.7 The role of providers in implementing new antimalarial policies

In a study by Armstrong et al. (1996) which explores general practitioners' reasons for change in their prescribing behaviour in east London, conclusion was made that multiple factors are involved in general practitioners' decisions to change their prescribing habits. These include prescribers that change because of volume and authority of evidence obtained, and those whose behavior change following a dramatic or conflictual clinical event. The study further mentions that for others, change takes place against a background of willingness to change, influenced by other factors such as cost pressures (Armstrong et al., 1996). Waller (2005), in his publication on rational prescribing, highlights that experienced prescribers believe that the principals of rational prescribing or prescribing according to guidelines limits their choice of therapy. In another study on economic costs associated with inadequate drug prescribing, Flores et al. (2003), present that losses attributed to inadequate prescribing in Chiapas State – Mexico averaged USD 47 per patient. Therefore, appropriate prescribing by providers can not be taken for granted.

In malaria treatment, like many other diseases, inappropriate use of antimalarial drugs promotes emergency and spread of drug-resistant malaria. Providers face a challenge in choosing the right drug in an environment where it is known that irrational self-medication is done at households. Consumers play a big role in promoting proper use of antimalarials. A study in Mali, demonstrates that even when most peripheral health providers are well-trained in correct use of antimalarials, there

is need for additional measures targeting consumers in order to improve practice (Djimde et al., 1998). However, in a household survey of treatment of malaria in Yemen, people mentioned lack of confidence in health services as one of the cause of increased self medication (Abdo-Rabbo, 2003). The provider is positioned in a midline between the policy maker and the consumer, and is expected to use personal judgment to manage interests of both parties.

Antimalarial prescribing practice does not necessarily change after introducing new national Antimalarial treatment policies. In Tanzania, before the policy change in 2001, some prescribers had already changed their prescribing practice to other drugs other than chloroquine, because from their perspective further delay to change was compromising their patients' health (Williams et al., 2004). In Uganda, findings from a study that compared prescribing practices between public and private sector indicate that prescribing for adult malaria and acute respiratory infection by both private and public practitioners did not adhere to Uganda national standard treatment guidelines (Ogwal-Okeng et al., 2004). The above publications highlight presence of a general challenge in prescribing practice of many providers which is unfortunately associated with higher economic cost. Therefore, it can not be guaranteed that changes in antimalarial treatment policy in Uganda were automatically translated into recommended prescribing practice.

2.8 Summary

The high level of resistance of *P. falciparum* to chloroquine has been the major factor for replacing this inexpensive and relatively safe antimalarial drug with alternative first-line treatments. Since 1996, World Health Organization regional office for Africa has provided technical support to a number of countries to promote rational use of antimalarial drug (East African Network for Monitoring Antimalarial Treatment, 2003). Activities supported include monitoring drug efficacy (122 sites in 37 countries) and updating treatment policies according to agreed frameworks, through networks of consultants and inter-country consultations (East African Network for Monitoring Antimalarial Treatment, 2003). So far, there is little focus on prescribers' level of adherence to changes made in antimalarial treatment policies of various countries. There is also limited documentation on antimalarial prescribing practices of health workers in Uganda since the change of antimalarial treatment policy in 2000. Most

studies that looked at the effect of the change in national malaria drug policy focus on antimalarial drugs' efficacy and the process of formulating policy change. This study looks at policy change implementation, from the provider's perspective.

A combination therapy of CQ+SP was chosen in Uganda among the available options because it was envisaged to provide the best combination of effectiveness, accessibility and cost. However, this does not seem to be the reality given the rapid development of resistance to this combination. This would be valid justification for prescribers to deviate from the national antimalarial drug policy but it is not known whether the providers' prescribing practice ever adhered to the policy in the first place. Therefore, this study aims to evaluate actual antimalarial prescribing practice in selected public and private not for profit health facilities in Rakai and Kampala districts of Uganda.

University of Cape Town

Chapter 3.0 Research Methodology

3.1 Introduction

This chapter presents the conceptual framework within which the study was carried out. Subsequently study design, area, scope, sampling method and instruments used are described. The chapter further covers how data used for this study were collected, managed and analyzed, and draws attention to limitations of the study.

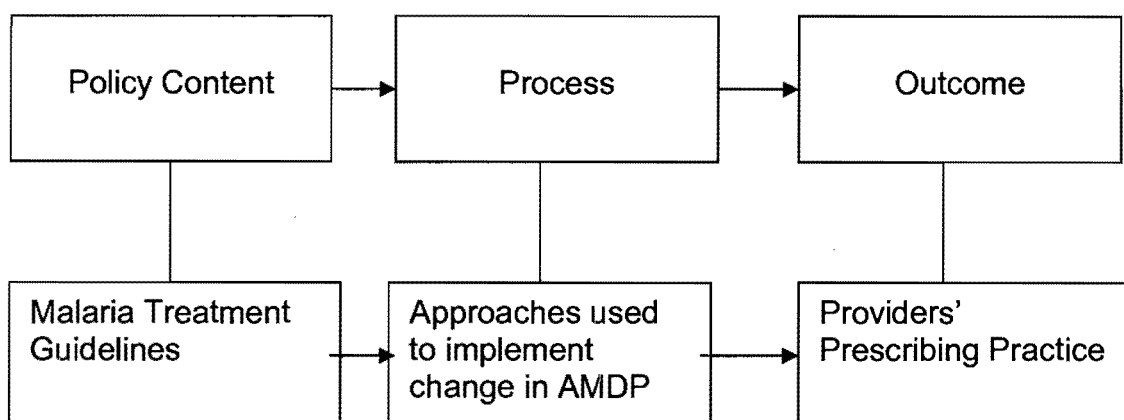
3.2 Conceptual framework

Examining the extent of implementation of the change in antimalarial drug policy in Uganda requires thorough understanding of the policy and clear definition of the basis for change. Although effective policy implementation is expected to improve the well being of community as the desired outcome, it is not easy to measure such a long term benefit therefore, this study uses prescribing practice as an indicative measure of desired outcome.

It is known that policy change alone cannot result into desired effects if no proper strategy is designed for its effective implementation. It is anticipated that some of the desired effects of a new policy are greatly influenced by the implementation process. Walt and Gilson (1994) put it that "*technically sound policy documents or ideas are not enough to bring about change in practice*". Therefore, in this study three aspects of the change in guidelines for management of uncomplicated malaria have been reviewed, these are: content of the malaria treatment policy, implementation process of the change in policy and prescribing practice.

Figure 3.1 below is a conceptual framework of the study, a model that explains the linkage of changes in malaria treatment policy, its implementation approach and prescribing practice to policy content, process and outcome respectively.

Figure 3.1: Conceptual Framework



Model redeveloped in reference to policy analysis triangle (Walt and Gilson, 1994).

Malaria policy content is examined and in-depth understanding of basis for change in case management of uncomplicated malaria sought from policy makers and other key stakeholders. This is then followed by exploring factors that are known at central level to be promoting adherence¹⁰ to the new policy. Thereafter, these factors are compared with findings from prescribers' perspective and results of records review on actual prescribing practice at selected health facilities.

3.3 Study Design

In order to understand the change in malaria treatment policy in Uganda and assess the extent to which prescribers adhere to treatment guidelines, the study involved both quantitative and qualitative methods. Data was obtained from both primary and secondary sources. Quantitative data on prescribing practice was collected by records review method from patient / prescriptions registers. Semi-structured interviews were used to collect data from prescribers found on duty at the time of the visit and heads of health facilities selected for the study, which was coded and translated into quantitative data. In the qualitative part of the study, key stakeholders at national level were interviewed to understand the basis for change in malaria treatment policy, and factors that were considered to be promoting or impeding adherence to the new policy.

To fully address all objectives of the study, four research methods were used,

¹⁰ Measure of adherence is proportion of prescriptions for uncomplicated malaria in line with AMDP

namely: document review, key informant interview, semi-structured interviews and patient records review. Table 3.1 indicates the method (s) use for each objective.

Table 3.1: Objectives and Instruments used

	Objective	Methods used
1	To understand the basis of change in malaria treatment policy in Uganda and define steps that had been taken to ensure efficient implementation of the new policy.	Document review and key informants interview guide
2	To review treatment (Prescribing) practices for uncomplicated malaria in public and Private Not for Profit health facilities in Rakai and Kampala districts of Uganda, as a basis for establishing the level of adherence to the national antimalarial treatment guidelines.	Patient records review
3	To find out factors that influence adherence to national malaria treatment guidelines.	Semi-structured interviews with prescribers and heads of health facilities
4	To make recommendations to policy makers on how to improve adherence to national malaria treatment guidelines.	Based on all data collected using above methods

3.4 Study Area and Scope

Study Area

The study was carried out in Uganda focusing on malaria control program - Ministry of Health and two purposively selected districts of Kampala and Rakai, where a total of 12 Primary Health Care (PHC) facilities were selected, 6 from each district. In each district, out of the 6 health facilities selected 3 were from public and the other three from Private Not for Profit (PNFP) Sector. Only primary health care (PHC) facilities were considered for this study because the major change in malaria treatment policy was in regard to first line treatment regimen for uncomplicated

malaria, which cases are mostly managed at PHC level. Complicated malaria cases are referred to nearby hospitals therefore, the exclusion of hospitals.

Table 3.2: Facilities from which data was collected

Level of Care	KAMPALA DISTRICT		RAKAI DISTRICT		Total number of Health Facilities
	Public	private not for profit	Public	private not for profit	
Level II	1	1	1	1	4
Level III	1	1	1	1	4
Level IV	1	1	1	1	4
Total	3	3	3	3	12

Kampala, the most densely populated district in Uganda was purposively selected for the study because of its urban characteristics, especially the slum surroundings that are proved good breeding environment for the mosquitoes that transmit malaria. In addition, Kampala being the seat of MOH-malaria control program, it is assumed to have adequate awareness about the change in malaria treatment policy, therefore a good site for determining whether the high level of awareness about the new policy was translated into adherence to treatment guidelines.

Kampala district has a population of 1, 208, 544 (Census, 2002) and a total number of 872 PHC facilities, of which 5 are Health Centre (HC) level IV, 30 HC level III and 837 HC level II. The district is divided into five administrative divisions of Nakawa, Kawempe, Makindye, Rubaga and Central. The six health facilities selected were from four out of the five divisions.

Rakai district was selected because of its typical rural characteristics and high reported burden of malaria. The district is also one of the model districts in Uganda with well maintained health information management system (HIMS) an assurance of presence of accurate records. Rakai district has a total population of 471,806 sparsely distributed throughout four health sub-districts (Census, 2002). It has total of 92 PHC facilities of which 2 are HC level IV, 22 HC level III and 68 HC level II. Six health facilities were selected from the district, 2 from each of the three levels of care.

Kampala and Rakai districts have 99.3% and 39.3% physical access to health services¹¹ but the facility utilization is in the reverse order of 0.07 and 0.99 per capita health facility utilization for Kampala and Rakai districts respectively (Ministry of Health, 2003b).

The 12 Primary Health Care facilities were selected from three levels of Primary Health Care in Uganda; level II, III, and IV. The three levels of care are the main providers of basic health care services for the community within the respective catchment areas. Only Primary Health Care facilities were considered because majority of uncomplicated malaria cases are managed at this level of health care. At each level of care, 4 facilities were selected for the study of which 2 were from public sector and the other 2 from PNFP sector.

Table 3.3, is a summary of health facilities selected from each district, categorized by ownership and level of care.

Table 3.3: Names of facilities from which data was collected per level of care

Level of Care	KAMPALA DISTRICT		RAKAI DISTRICT		Total number of Health Facilities
	Public	private not for profit	Public	private not for profit	
Level II	KCC staff Clinic	Katwe Dispensary	Kabuwoko H/C	St. Elizabeth Kijukizo Disp.	4
Level III	Kampala Dispensary	Joy Medical Centre	Mutukula H/C	Lyantonde Muslim	4
Level IV	Naguru Health Centre	Namungoona H/C	Lyantonde H/C	Biikira H/C	4
Total	3	3	3	3	12

Study Scope

The study was restricted to the public and Private not- for- profit health facilities. The Private for Profit sector was excluded due to results of the pilot study that reflected records inaccessibly within this sector.

Although the Malaria policy (Ministry of Health, 2002) covers both preventive and case management (malaria treatment) guidelines, the study was limited to review of

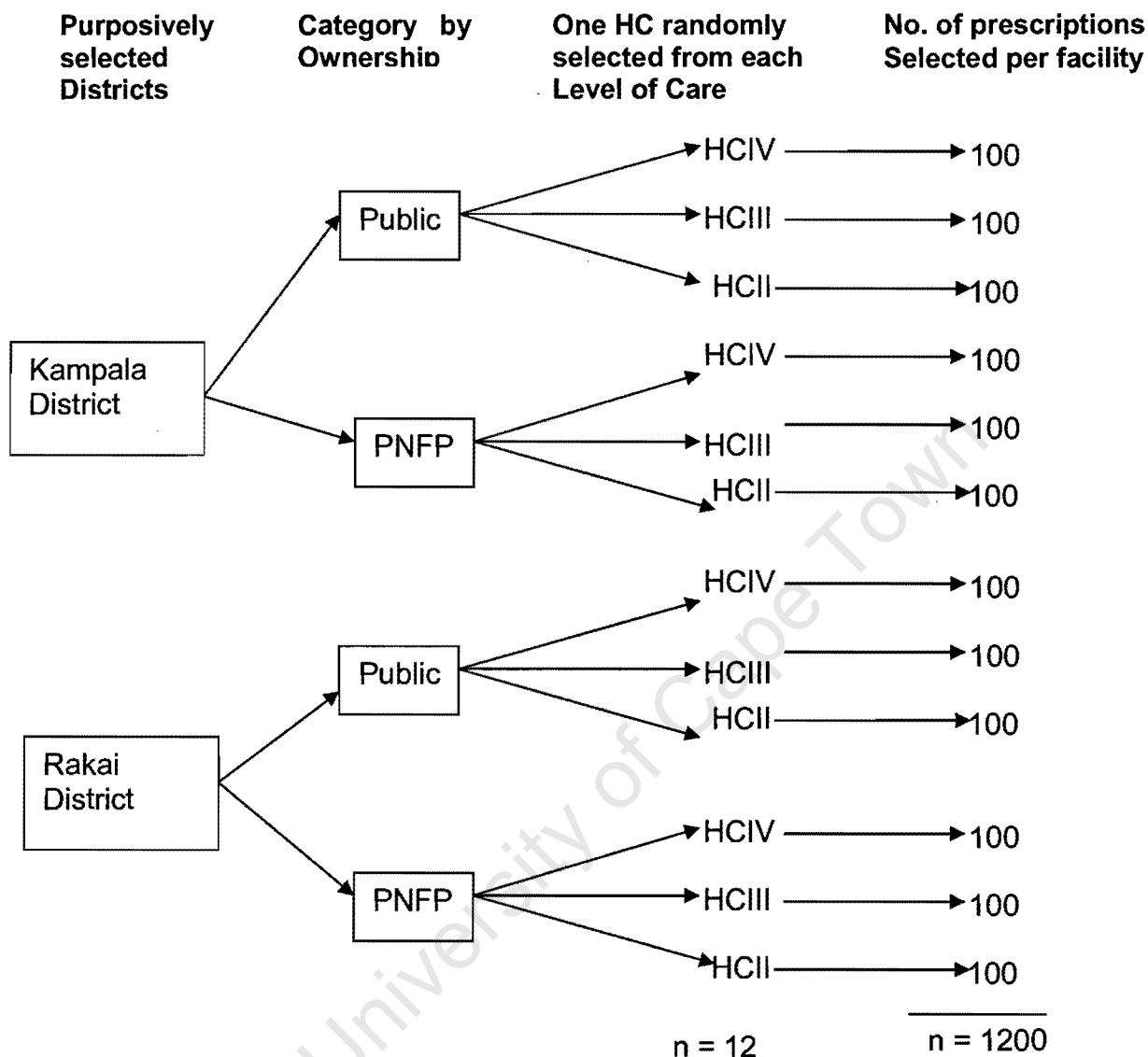
¹¹ Physical access to health services defined as: proportion of the population that lives with 5 Kms from the nearest health facility

change in case management of un-complicated malaria, because the major change in policy was from Chloroquine monotherapy to combination therapy of chloroquine + Sulfadoxine-Pyrimethamine as first line treatment for un complicated malaria. The study further focused on Provider adherence to AMDP and therefore, excludes known factors like dosing, timing, labeling, packaging and information given to patients that affect patient adherence.

3.5 Sampling Method

The study was conducted in two districts of Uganda, Rakai and Kampala districts which were purposively selected to represent rural and urban setting respectively. Within each district, a stratified random sampling approach was used to select 12 health facilities involved in the study, 50% (6) of which were from public sector and the other 50% from Private Not for Profit sector. Public health facilities in Uganda offer medical services free of charge to the patients while PNFP facilities offer medical services at a fee, though subsidized in most cases. In this respect it is assumed that the two groups of health facilities will have differences in coping up with changes in malaria treatment guidelines, therefore, the public versus private not for profit stratification. To enable getting a representative sample from each level of care, health facilities in each stratum (Public versus PNFP) were further stratified into three categories by level of care: Levels II, III and IV. See appendix 6 for definition of healthcare levels of care (Ministry of Health, 2003a). This multistage stratified random sampling as indicated in Figure 3.2 overleaf enabled selection 6 facilities from each district, 6 facilities from each sector and 4 facilities from each of the three levels of health care.

Figure 3.2: Multistage stratified random sampling



At each selected health facility, prescriptions reviewed were selected by systematic random sampling at varying intervals per health facility. Malaria prescription selection intervals used at each health facility were determined by the total number of malaria cases diagnosed in the previous six months divided by 100. The 100 represents the targeted number of malaria prescriptions reviewed per health facility. Data on treatment prescribed for malaria was collected from only out patient register/ prescription book to ensure collection of data on only uncomplicated malaria cases.

Interviews

Using purposive sampling, 5 respondents were selected for open ended interviews about malaria policy change basis and implementation process, these were senior officers of malarial control program-MOH, Health Sector Support Program and World Health Organization–malaria consortium. These were selected because of their technical roles in malaria policy formulation and implementation at national level.

The 22 prescribers and 12 heads of health facilities to which the semi-structured questionnaires were administered, were conveniently selected from the 12 health facilities involved in the study. This method was used to enable comparison of responses from face to face interviews with data obtained from review of records.

Records Review

Due to lack of adequate information on expected level of adherence to the new malaria treatment guideline, it was estimated that about 50% of prescriptions complied with the new policy. Using that estimated level of adherence of 50% a sample size that could enable comparison of prescribing practice among levels of care, (public versus PNFP and rural versus urban) at 5% level of significance was calculated as follows (Gujarati, 1995):

$$\text{Sample size (n)} = \frac{Z^2 * (p) * (1-p)}{C^2}$$

Where Z = the standard normal value corresponding to 95% confidence interval (1.96)

p = is the expected proportion of prescriptions that adhere to the policy. (50%)

C = is the desired level of confidence (5%)

$$\begin{aligned} \text{Therefore } n &= \frac{(1.96)^2 * (50)^2}{5^2} \\ &= 384 \end{aligned}$$

Therefore, 100 prescriptions were reviewed at each health facility to ensure review of at least 384 malaria prescriptions in each stratum (by sector, level of care, and rural versus urban). 600 prescriptions were selected from each stratum by sector (public versus PNFP) and location (rural versus urban).

Table 3.4 below shows the number of prescriptions that were reviewed at each level of health care stratified by ownership category and by urban versus rural.

Table 3.4: Selected number of malaria cases for review

Level of Health Care	Kampala District (Urban)		Rakai District (Rural)		Total
	Public	Private not for profit	Public	Private not for profit	
Level II	100	100	100	100	400
Level III	100	100	100	100	400
Level IV	100	100	100	100	400
Total	300	300	300	300	1200

At each health facility, a total number of malaria case diagnosed in the previous 6 months were calculated from monthly summary reports (HMIS records). The total number of malaria diagnosis calculated above was then divided by the targeted number of prescription (100) to get the appropriate interval (I). The most recent malaria diagnosis recorded by the time of visiting was selected as a starting point. Then the interval was used to review prescription for every Ith malaria diagnosis up to the 100th prescription. Information on the facility and drug prescribed for selected malaria diagnosis from out patient registers was recorded in the prescription review tool (Appendix 4).

In each facility visited for the study, data was first collected on the general characteristics of the sites that included number of total staff, number of prescribing staff and their respective highest level of training, and availability of malaria treatment guidelines.

3.6 Instruments used and data collection process

Instruments used for the study were as presented below.

Document Review

To get in depth understanding of various issues related to policy formulation in Ministry of Health Uganda, the following documents were reviewed:

- National Health Policy –Ministry of Health Uganda, September 1999.
- Ministry of Health, Health Sector Strategic Plan (HSSP) 2000/01 – 2004/05
- The Uganda Pharmaceutical Sector Baseline Survey, September 2002
- Management of uncomplicated Malaria, A practical guide for Health Workers, Malaria Control Program –Ministry of Health, 2002

Information gathered from the above documents helped in refining questions included in the data collection instruments and probing for relevant information during the key informant in-depth interviews.

Key informant interview guide

The key informant interview guide (Appendix 1) was used to collect qualitative data from three officials of Malaria Control Program-MOH purposively selected, in addition to two officials, one from Health Sector Support Program and the other from World Health Organization - Uganda office. The instrument had one introductory question on MOH strategy for combating malaria and six questions focusing on malaria case management. All questions were open ended to ensure an in-depth understanding of the policy formulation process and the basis for change in malaria treatment policy.

Face-to-face interviews were carried out with each of the above five key stakeholders at national level. During the interview the officers described issues about the malaria policy change initiation and implementation process, but also kept touching on other general Government health policy issues.

Semi-structured Questionnaires

Heads of health facilities involved in the study were interviewed using a semi structured questionnaire (Appendix 2) and another semi-structured questionnaire (Appendix 3) with a different set of questions was used to interview prescribers found at the facility at the date(s) of visiting. The above tools were used to establish the health facility interpretation of the antimalarial drug policy and their views on factors influencing adherence to the treatment policy.

The interview of the heads of health facilities was also by a face to face administered questionnaire (Appendix 2) which had six questions. Three questions were structured and the other three open ended. The heads of health facilities were interviewed after interviews with the prescribers and the open ended questions asked were mainly to validate information provided by prescriber and also probe more on issues that required more clarification.

The questionnaire (Appendix 3) administered to prescribers by a face to face interview had nine questions of which five questions were structured and the other four open ended. The open ended questions enabled the prescribers to raise other relevant issues that had not been covered in the interview.

Patients Records Review

A malaria prescription review form (Appendix 4) was designed to collect data on drugs prescribed per each case of un-complicated malaria diagnosis. In addition, the form was also used to collect data on number of staff, their respective level of qualification, and availability of malaria treatment guideline per facility. To ensure accuracy in collecting required data on each prescription, the prescription review data collection tool required recording the details per case that included patient number, diagnosis, age, sex, and all drugs prescribed for each selected malaria case.

3.7 Data collection process

Data was collected in March–April 2003 by a team that included retired Para-medical staff conversant with patient records and medical language, under direct supervision of the principal investigator. All data collectors were trained in using the instruments and under went mock interviews before the field visits.

Preceding the data collection process, the semi-structured questionnaire for prescribers, heads of health facility, and the records review form were piloted in one public, one private for profit and one private not for profit health facilities that had not been selected for the study. The piloting phase revealed that prescription data from

Private for Profit sector was inaccessible. Since the major aim of the study was assessment of adherence to treatment guideline, the assessment was greatly dependant on accessing prescription records. Therefore, PFP sector health facilities were dropped from the study due to data inaccessibility. The key informant interview guide was pre-tested with a colleague working with Ministry of Health.

After the pre-test, the instruments were reviewed thoroughly and produced final copies addressed all the objectives of the study and enabled asking questions that did not offend responds. Before commencing the data collection process, the sites were visited to ask for permission to collect data as well as schedule dates for study visits.

At each health facility a brief discussion was held with the head of the facility who thereafter introduced the interviewers to other facility staff. After the data collection process at each facility, the team leader held a meeting with the head of each facility and other available staff for feedback on preliminary finding and probing for more information.

3.8 Ethical considerations

Before conducting the study, approval was requested from the Research Ethics Committee, University of Cape Town. On receipt of Research Ethics Committee approval, further authority to conduct the study and review relevant records in Uganda was obtained from Ministry of Health, Uganda.

Prior to collection of data from each health and individual staff, the heads of the facility and other respondents were given a copy of the study synopsis/consent form (Appendix 5). The synopsis outlined objectives of the study and also highlighted that data collected was to be used for academic purposes and participation was on voluntary basis. Staff were also informed that any policy recommendation made from the study and found to be appropriate for sharing beyond academic environment, shall not disclose specific names of data source. The last section of this study synopsis requested for formal consent and highlighted that the respondents had the option of accepting or declining to participate in the study.

3.9 Data Management and Analysis

Data Management

Quantitative data was collected from a total of 1200 malaria prescriptions in 12 health facilities. Additional data was collected from 22 prescribers and 12 heads of health facilities that responded to the semi-structured questionnaire. Some qualitative data obtained from responses to the semi-structured questionnaires was coded for data management purposes. Data obtained from interviewing key informant and some response to open ended question answered by prescribers were condensed into similar concepts and themes, and where necessary more some interviewees were contacted clarification.

Quantitative data was entered into excel software while still in the field to ease cross-checking any observed major discrepancies. To guard against data entry error, two sets of data were entered separately and any found inconsistencies were rectified by referring to the original questionnaires until there was zero variation.

Three data sets were kept; one on results from records review, the second on responses from prescribers and heads of health facilities and the third on responses from key stakeholders.

Data Analysis

Quantitative data was analyzed using excel software and STATA program. STATA was used to get descriptive statistics and to:

- Assess level of adherence to the recommended combination therapy
- Make comparison of prescribing practices among various Strata

Microsoft excel was used at both data entry stage and coming up with suitable data presentation formats.

Qualitative data was sequentially analyzed to come up with some common categories that were compared for various responses until some definite themes were derived.

3.10 Limitations of the study

Initially, the study was intended to cover all the three categories of health care provision; Public, Private Not for Profit (PNFP) and Private for Profit (PFP) but due to inaccessibility of patient records in private sector, it was limited to public and PNFP owned health facilities.

Although the change in treatment guidelines for uncomplicated malaria was implemented at all levels of health cares that is; primary (Health Centres), secondary (District Hospitals) and tertiary (National referral Hospitals), the study limits itself to primary level. This is because secondary and tertiary health facilities handle many complicated malaria referral cases that are not easily distinguishable in patient records from uncomplicated malaria cases. Interpretation of findings of this study should be done putting into consideration the fact that it did not cover information on:

- Relationship between drug prescription and methods and accuracy of malaria diagnosis.
- Patients' medication before visiting the health facility

Due to resource constraints, the study included facilities sampled from only two districts out of Uganda. Given that Uganda has 56 districts, the findings from this study especially on prescribing practice may not necessarily be used to generalize practice for the whole of Uganda.

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Chapter 4.0 Study Results

4.1 Introduction

Results of the study are presented in three sections. The first section presents findings on the basis for policy change and implementation process, followed by results from review of patient records in the second section. Records review results are further sub-grouped into: facility characteristics, general level of adherence to combination therapy and comparison of adherence among various strata. The third section presents results on factors that influence adherence to national treatment guidelines from provider's perspective.

4.2 Basis for change of malaria treatment policy and steps taken.

Results of interviews with key stakeholders pointed to some common themes that influenced change in malaria treatment policy and its subsequent implementation. These themes have been categorized into case management, policy implementation process and promoters for adherence to policy.

Interviews with MOH officials revealed that Government put emphasis on both preventive and curative measures of controlling malaria. However, case management was more prominent because of associated high direct cost especially for buying the required drugs.

The core interventions for malaria control mentioned were:

- Improving case managements at health facilities and home
- Intermittent presumptive treatment of pregnant women
- Vector control; involving promoting large scale use of insecticide-treated mosquito nets and in door residual spraying
- Improving epidemic preparedness and response

One Ministry of health officer said:

"If it were not for limited financial resources all these good plans would have been turned into action and we would have achieved our goal of preventing, and reducing mortality and morbidity due to malaria with corresponding reduction in associated economic costs".

That was a clear indicator that despite the good plans put in place, financial resources to some extent limited implementation of malaria control programs and therefore, a high possibility of not achieving all the desired targets.

Case management and treatment options considered

Further focusing of respondents on scope of the study—Antimalarial treatment policy, indicated that MOH-Malaria control program had a national strategic operational plan for improving case management. The main aims of this case management operation plan outlined were: Improving access to effective diagnostic and treatment behavior, improving treatment seeking behavior and ensuring adequate supply of effective drugs and ancillary supplies.

Below are the options mentioned by all officials interviewed as possible combinations evaluated before recommending the change from CQ monotherapy to combination therapy of CQ+SP:

- Sulphadoxine-pyrimethamine (SP)
- Chloroquine and SP combined (CQ+SP)
- Amodiaquine and SP combined (AQ+SP)
- Artesunate and SP combined (AS+SP)
- COARTEM (Fixed combinations of Artemether and Lumefantrine)

Consideration of more than one option was further emphasized by a statement made at policy level.

“Several options were evaluated and of course the combination of chloroquine and SP might not be the most effective treatment of malaria but given that we are a poor country it is the most cost-effective option”. (A Senior Government official in malaria control program)

It was not possible to see copy of the evaluation criteria used for the various combinations that lead to the choice of CQ+SP as most cost-effective combination. Further probes on option appraisal indicated that the decision was made in line with technical advice from bilateral and multilateral agencies, in particular World Health Organization- Uganda office.

Interviews with World Health Organization officials involved sharing of information on documentary review of malaria treatment policies of various sub-Saharan African countries carried out by World Health Organization. From this discussion, it was clear that the choice of combination therapy of Chloroquine and SP as first line treatment for malaria in Uganda was greatly influenced by multilateral agency initiatives.

Through documentary review, the issues discussed below were underscored as decisive factors that form basis for bilateral and multilateral agencies recommendations on the most suitable antimalarial combination.

Therapeutic effectiveness

This considers the selected combination's effectiveness as demonstrated in practice and how soon clinical recovery is achieved by use of a particular combination.

Safety

Safety of available options is assessed in terms chemical interactions that can decrease efficacy, or increase toxicity or reduce the shelf life of each individual drug. Safety issues also include possible adverse drug reactions and pharmacokinetic interactions.

Consumer acceptability

Consumer perceived characteristics like product presentation, ease of administration, taste and drug colour are additional aspects considered for purposes of promoting patient adherence.

Drug costs

The direct drug cost is an important indicator for sustainable affordability of the recommended treatment and therefore important in deciding suitable combinations especially for resource constrained countries. The indicative unit cost for CQ, SP and AS¹² is \$0.13, \$0.14 and \$1.00 - 3.00 respectively (WHO, UNICEF, 2003).

¹² AS = Artesunate

Potential for delay or prevent development of resistance

Evidence of effectiveness in delaying development of resistance was another important factor highlighted.

Therefore it can be summarized that the process of choosing CQ+SP combination as a suitable replacement for CQ monotherapy in Uganda, took into consideration issues related to effectiveness, safety, affordability, ease to administer and potential for delaying development of resistance.

However, response from one World Health Organization officer as quoted below has some indication that in the case of Uganda, affordability issues skewed the decision against other important consideration.

“The best option would have been Artesunate based combination therapy but Uganda being a country where chloroquine still gets out of stock in many health facilities, affordability issues had to be critically considered, the recommended CQ-SP combination is a good transition to better options, it is far much better than chloroquine monotherapy” (World Health Organization official).

Other technical issues mentioned to influence the process of selecting suitable combination therapy in Uganda were related to drug regulatory requirements like drug registration, importation, distribution controls and availability of a system for quality assurance.

4.3 Policy Implementation process

In this section, results from interviews with providers and heads of facilities are presented in additions to some findings from documents review. Minutes seen for meetings held to build consensus on the government recommendation for change in malaria treatment policy from chloroquine monotherapy to CQ+SP combination therapy, highlighted stakeholders' agreement on choice of combination adopted. There was also agreement among all officials interviewed that the change from chloroquine monotherapy as first line treatment for malaria was long overdue.

Actions taken to ensure effective implementation of new policy

The respondents mentioned that a lot of time was spent on building consensus on policy content and implementation strategy. During this period several technical stakeholders were invited to participate in the decision making process and their views were taken to be those representing the interests of the organizations they were representing. Table 4.1 below presents a summary of documentation seen regarding institutions resented and their respective roles.

Table 4.1: Characteristics of institution represented in policy formulation process

Name of Institution	Role
Malaria Control Program	Responsible for policy formulation
World Health Organization	Bilateral agency providing technical support
Mulago Hospital	National Referral Hospital with senior consultants for promoting technical acceptance
National Drug Authority	Drug regulatory agency responsible to National formulary, regulating imports, drug quality assurance and products registration
National Medical Stores	Government agency responsible for drug procurement and distribution
Nsambya Hospital	Private Not For profit hospitals representing interests of that sector
USAID	Bilateral Agency for technical advise
Pharmaceutical section – Ministry of Health	Responsible for guiding MOH on Pharmaceutical related issues.

When asked about the implementation process, government officials interviewed mentioned similar steps that were taken to promote effective implementation of the change in policy and these were:

- Printing and circulation of a revised practical guideline for management of uncomplicated malaria (A practical guide to health workers, Ministry of Health Malaria control Program 2nd, edition, 2002) to all health facilities in the country
- Training of selected health workers at national, district and lower levels
- Dissemination of its content by both electronic and print media
- Advocacy among political and opinion leaders to promote consumer acceptance of new policy
- Support supervision through quality assurance visits to health facilities

Further discussion with policy makers revealed that in addition to change from monotherapy to combination therapy, a home based management of fever (HBMF) strategy was introduced. This was introduced as measure of ensuring that safe and effective antimalarials for treatment of uncomplicated malaria were made available within communities, targeting mainly children and pregnant mothers. This strategy was to promote quick access to pre-packed first line drugs (CQ+SP combination therapy) as soon as children/adults develop symptoms of malaria.

The home based management of fever, put more emphasis on achieving rapid reduction in morbidity and mortality than high specificity diagnosis and evolution of resistance.

When asked about their impression on level adherence to the recommended combination therapy as a first line regimen for treatment of uncomplicated malaria, MOH officials mentioned that it was quite high in public hospitals.

“Apart from NGO hospitals where we do not have direct support supervision the public health facilities especially all lower level have adhered to the guidelines”.
(Government official, Ministry Of Health)

Major factors considered to be promoting adherence to guidelines

Asked about what factors were considered to have promoted adherence to the new malaria treatment policy, all respondents at policy level mentioned extensive training through various workshops as the number one factor. Other factors mentioned were:

- Support supervision
- Politician sensitization
- Public mobilization through media campaigns
- Effective dissemination of treatment guidelines

Knowledge about policy- Heads of health facilities

When asked to describe the National treatment guidelines, all Prescribers heading the health facilities selected for the study correctly described the malaria treatment guidelines with the exception of one. The exceptional prescriber described the change in policy to be about management of malaria in children under five years.

Knowledge about policy- Prescribers at Facility

Responding to a question on drugs recommended by the AMDP, 72.7% of the prescribers correctly stated the recommended drugs (CQ+SP). The other drugs mentioned by other respondents were CQ monotherapy (13.6%) and SP monotherapy (13.6%).

Drug Availability

Both prescriber responses and review of stock cards indicated that there was no stock out of both chloroquine and Sulphadoxine-Pyrimethamine over the period of the study (previous six months from date of data collection). This rather good stock position was attributed to centrally supplied stock to both public and private not for profit facilities by Ministry of Health, through National Medical Stores.

4.4 Review of patient records for malaria case management

Characteristics of Health Facility

In this section data is presented on the characteristics of health facilities involved in the study and levels adherence to the treatment combination therapy. Findings are further presented on comparison of levels of adherence by ownership category, health care levels and rural versus urban health facilities' prescribing practice.

Although the study design targeted collection of data on one hundred (100) malaria diagnosis per facility and therefore a total of 1200 prescriptions, some miscoded information lead to dropping of 29 prescriptions during the data cleaning process, and therefore, the analysis presented was based on 1171 instead of the anticipated 1200 uncomplicated malaria prescriptions.

Overleaf find table 4.2 which outline the facilities involved in the study and a summary of their characteristics.

Table 4.2: Description of health facilities involved in the study

CHARACTERISTICS OF HEALTH FACILITIES				NUMBER OF STAFF BY QUALIFICATION			
	Health Facility	Level of Care	District	Medical Officers	Clinical Officers	Nurses / Midwives	Other staff
Public facilities							
1	St. Elizabeth	II	Rakai	0	0	3	2
2	KCC-Staff Clinic	II	Kampala	1	1	2	1
3	Mutukula	III	Rakai	0	0	1	3
4	Kampala Disp.	III	Kampala	0	2	10	12
5	Lyantonde	IV	Rakai	2	3	6	6
6	Naguru	IV	Kampala	2	2	26	12
	Sub-Total			5	8	48	36
Private not for profit facilities							
7	Kabuwoko	II	Rakai	0	0	2	7
8	Katwe Disp.	II	Kampala	1	0	2	2
9	Lyantonde Moslem	III	Rakai	0	0	2	3
10	Joy Med. Centre	III	Kampala	3	2	4	6
11	Biikira	IV	Rakai	0	3	10	16
12	Namungoona	IV	Kampala	2	2	14	5
	Sub-Total			6	7	34	39

Staff numbers and level of qualification

The 12 health facilities selected for the study had a total of 183 staff ranging from four to forty two per facility. Majority of the staff were in the category of Nurses/Midwife (44.8%), followed by support staff (41%), and only 8.2% and 6% were in the category of Clinical Officers and Medical Officers respectively.

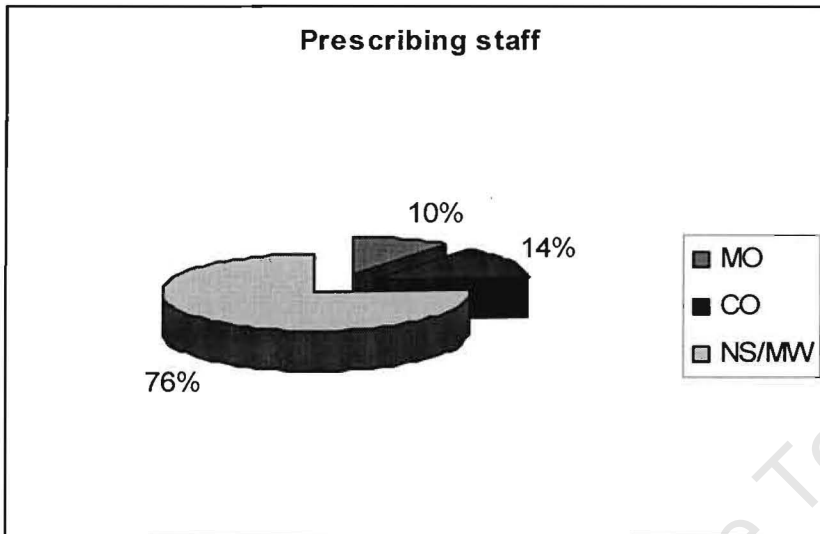
Majority of the staff 62.3% were in the urban district, Kampala. Among the eleven Medical Officers only two were in the rural district, Rakai and were both at a public health facility, Lyantonde Health Centre IV. The total number of prescribing staff at each level of care increased with increasing level of care, with an average of 3 (2:4), 6 (1:12) and 18 (11:30) for health care levels II, III and IV respectively.

Qualification of Prescribing Staff in health facilities selected

Figure 4.1 overleaf describes the level of qualification of prescribing staff in the units visited. Majority of the prescribers were in the category of Nurses, Mid-wives and

Senior Nursing Aids. Only 10% (11) of the total prescribers (108) had Degree level medical qualification.

Figure 4.1: Proportion of prescribing staff



MO = Medical Officer, CO = Clinical Officer, NS = Nurse, MW = Midwife

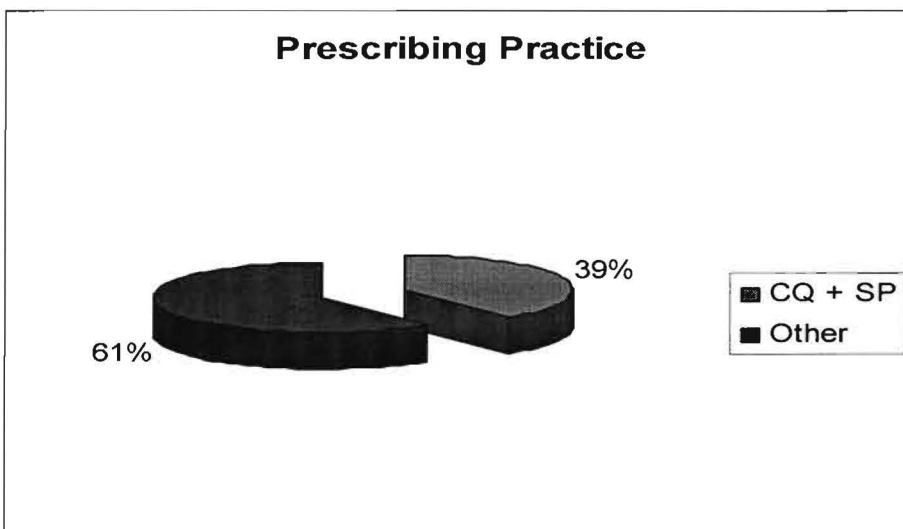
Availability of up-to-date malaria treatment guidelines

83% (10 out of 12) of health units visited had Malaria treatment guidelines in the form of either National Standard Malaria Treatment Guidelines (NSMTG) or Malaria Treatment Policy (MTP) or MOH circular on malaria in place.

Level Adherence to Combination Therapy

Figure 4.2 below indicates that of the 1117 total malaria prescription reviewed; only 39% adhered to recommended un-complicated malaria policy. However, Figure 4.3 (page 40) indicate significance difference (P value = 0.000) between private not for profit and public sector prescribing behavior.

Figure 4.2: Proportion of CQ+SP prescriptions for uncomplicated malaria



There was wide variation in prescribing practice per health facility, ranging from 0% to 88% adherence to combination therapy, as presented in table 4.3 below.

Table 4.3: Prescribing Practice per health Facility

Health Facility	CQ+SP		Other	
	n	%	n	%
Namugooona	0	0.0	100	100.0
Katwe Dispensary	2	2.0	98	98.0
Lyantonde	2	2.0	98	98.0
Biikira	12	16.9	59	83.1
St. Elizabeth	22	22.0	78	78.0
Joy Med Centre	28	28.0	72	72.0
Kijjambu C/Kabuwoko	51	51.0	49	49.0
Naguru	52	52.0	48	48.0
Lyantonde Moslem H/C	63	63.0	37	37.0
Kampala Dispensary	66	66.0	34	34.0
KCC-Staff Clinic	76	76.0	24	24.0
Mutukula	88	88.0	12	12.0
Total	462	39.5	709	60.5

The table above clearly indicates that majority of malaria prescriptions in health the selected facilities were for other drugs other than the recommended CQ+SP combination therapy.

Table 4.4: Range of Prescribed Antimalarials

Category	CQ+SP		SP + QNN		CQ only		SP only		QNN only		Other		Total			
	n	%	N	%	n	%	n	%	n	%	n	%	n	%		
Public	335	55.8	6	1	14	24.	7	5	35	5.8	37	6.2	40	6.7	600	0
PNFP	127	22.2	45	7.9	85	14.	9	70	3	196	3	48	8.4	571	0	
Total	462	39.5	51	4.4	23	19.	2	8	5	9	233	9	88	7.5	117	10

Table 4.4 above, indicates that the most prescribed treatment for uncomplicated malaria in PNFP facilities was quinine (QNN) monotherapy (34.3%), followed by

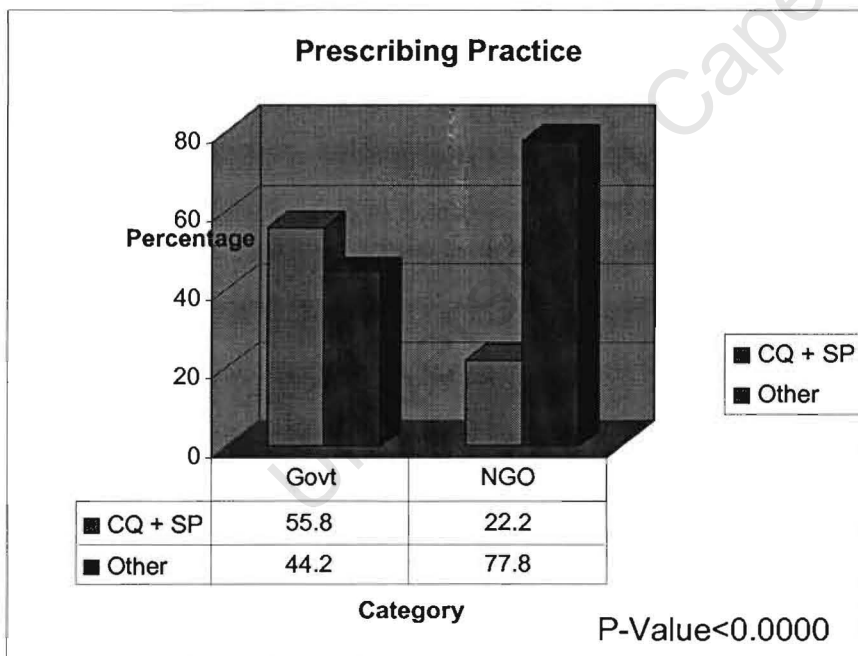
CQ+SP combination (22.2%), while in public facilities the combination of CQ+SP was prescribed most (55.8%) followed by Chloroquine monotherapy (24.5%).

Comparison of prescribing practice by various categories

Public versus PNFP facilities

Figure 4.3 below: describes prescribing practice by ownership category. Majority (77.8%) of malaria prescriptions of private not for profit owned health facilities were not according to the recommended combination therapy of CQ+SP.

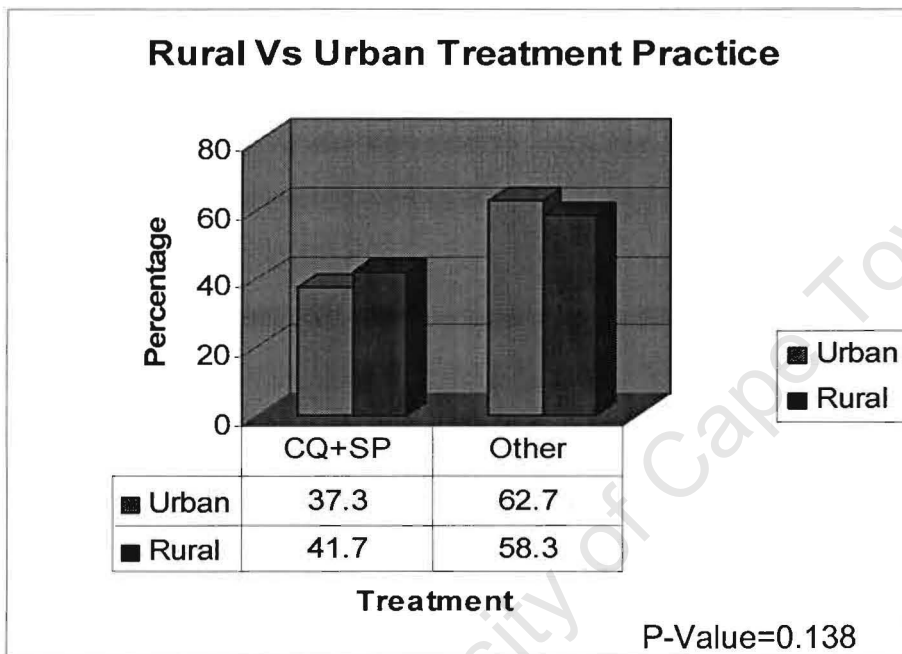
Figure 4.3: Public versus Private not for profit Prescribing Practice



Prescribing practice of rural versus urban (figure 4.4)

Further analysis of Urban versus Rural treatment practice indicated that more (41.7%) prescriptions of rural health facilities adhered to combination therapy as compared to 37.3% of malaria prescription of urban health facilities.

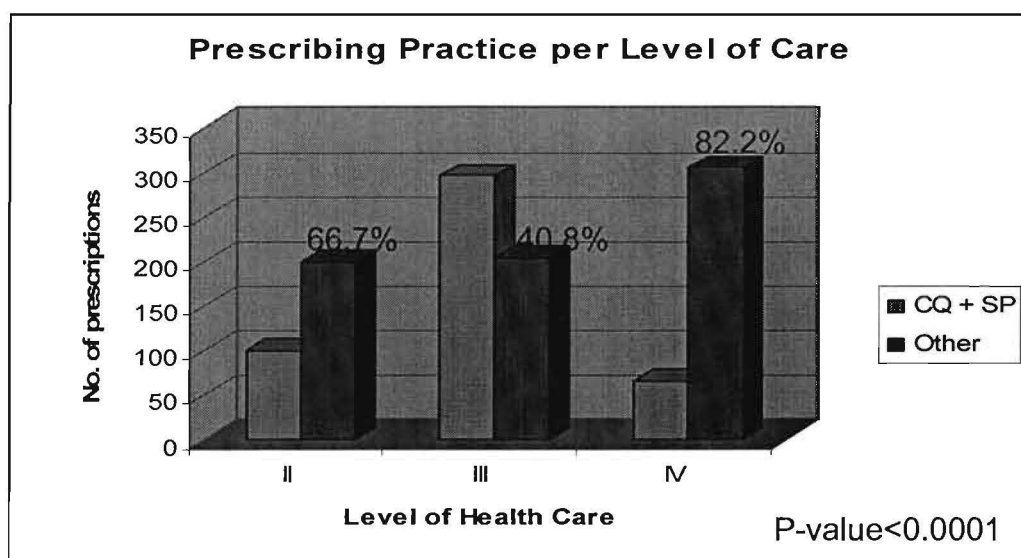
Figure 4.4: Rural versus Urban treatment practice



Prescribing practice at various levels of Primary Health Care

Majority of the prescriptions of Health Centre IV facilities (82.2%) were for other antimalarials other than the recommended CQ-SP combination therapy as indicated in figure 4.5 below:

Figure 4.5: Prescribing practice per level of care



Prescribing practice in health facilities with Medical Officer(s) compared those without any Medical Officer.

Table 4.5: Prescribing Practice and Level of qualification

	Number of Health facilities	CQ+SP		OTHER		p-value
		n	%	n	%	
Facility with at least one Medical Officer						
Yes	6	160	26.7	440	73.3	0.0000
No	6	302	52.9	269	47.1	

n = total number of prescriptions for malaria cases

Table 4.5 above indicates that there was a significant difference (P; 0.0000) between malaria prescriptions of facilities with Medical Officers and those without. Health facilities without any Medical Officer among the prescribing team adhered more (52.9%) to the policy that those with Medical Officers. In facilities with at least one Medical officer, only 26.7% of the prescriptions for uncomplicated malaria adhered to combination therapy of CQ+SP.

4.5 Factors that influence adherence to national malaria treatment guidelines

The face to face interviews with heads of health facilities, explored the factors that promoted adherence or deviation from 1st line treatment for uncomplicated malaria recommended in the national malaria treatment guidelines. Eleven out of twelve heads of selected health facilities responded to this question. The interviewees raised various reasons that affect their antimalarial prescribing practice as presented in table 4.6 overleaf.

Table 4.6: Factors that influence prescribers' behavior

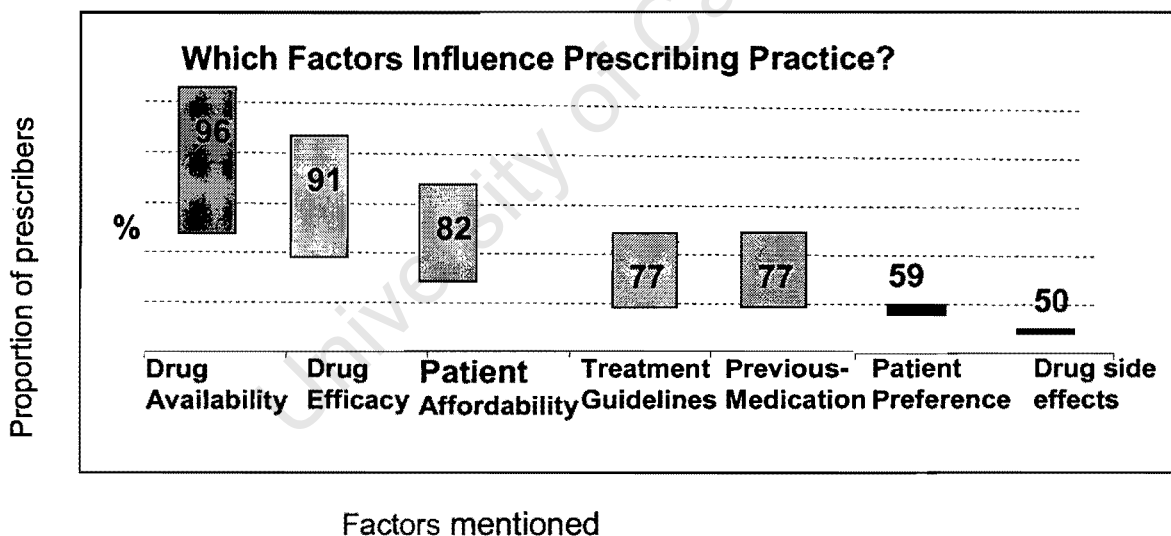
Respondent No.	Type	Does the staff in this facility always follow Govt. Guidelines?	In your Opinion what do you think are the factors that influences the prescribers behavior
1	PNFP	Yes	<i>"Advertisement on Radio" "Support supervision from DMO's Office"</i>
2	PNFP	Yes	<i>"When recommended drugs are not out of stock"</i>
3	PNFP	NO	<i>"It is not easy to adhere to it because most of the time patients do self medication before seeking proper treatment and the medical personnel cannot follow the policy or lines of treatment"</i>
4	PNFP	Yes	<i>"It reminds the prescribers all the time on doses to give to different patients of different ages"</i>
5	PNFP	Yes	<i>"The treatment works, and it is easy to administer and shorter therefore it becomes easy to give to the patients"</i>
6	Public	Yes	<i>"Because of the positive response to treatment"</i>
7	Public	Yes	<i>"Workshops on malaria treatment by MOH, Public awareness through the media, Support supervision by DDHS office"</i>
8	Public	Yes	<i>"workshops on malaria treatment by MOH, Public awareness through media, Support supervision by DDHS' Office, the way patients are responding to the new treatment guidelines"</i>
9	Public	Yes	<i>" The treatment is effective"</i>
10	Public	Yes	<i>"Because patients respond when treatment guidelines are followed"</i>

11	Public	Yes	"The patients in most cases respond to the treatment"
12	PNFP		No specific response given

Findings from prescription records review earlier presented indicate that majority of the prescribers did not adhere to the recommended combination therapy, However, 10 out of the 11 heads of health facilities that responded to this question , answered that the respective facility staff were prescribing according to the national treatment guidelines.

In a related question "On what basis do you choose the drugs prescribed for uncomplicated malaria?¹³" prescribers (22)¹⁴ found at facilities at the time of the study visit mentioned several factors of which drug availability had the highest (96%) frequency. Figure 4.6 presents details of responses to this question.

Figure 4.6: Factors that influence prescribers practice



In addition to drug availability, known drug efficacy and affordability were among the factors ranked high. Sensitization through workshops as a possible factor that influences prescribing practice was only mentioned twice. One prescriber said:

"Only one person represents us in such workshops and keeps getting invited from one workshop to the other without time to share knowledge acquired".

¹³ A question that was asked to establish factors that influence observed prescribing practices.

¹⁴ Total number of prescribers found on duty at the time of visiting various facilities

Diagnostic methods used were also probed to find out the various methods used for diagnosing malaria at primary health care facility level. All the 22 prescribers mentioned that they use laboratory tests to detect for malaria parasites. All had diagnostic equipment and reagents supplied by MOH as part of implementation process for change in antimalarial drug policy. In addition, 81% of the respondents mentioned use of signs and symptoms and 54% mentioned patient history.

4.6 Summary

Results from in-depth interview signify a consultative process taken during policy formulation but the initial trigger of change having been from bilateral agencies. Analysis of response from Stakeholders point at direct cost of malaria drugs as one of the major factors that influenced choice of CQ+SP as suitable replacement for CQ monotherapy. Findings from both PFP and Public owned health facilities indicate poor adherence to the change in AMDP but the degree of deviation differed from facility to facility. Results indicate that public sector health facilities adhered more to the policy than PNFP health facilities. Quinine is the most prescribed antimalarial drug among PNFP facilities that deviate from policy while chloroquine is the most prescribed drug among public facilities that deviate from the policy. The above results have significant interpretation as discussed in the next chapter.

Chapter 5.0 Discussion

5.1 Introduction

In this chapter, findings presented in chapter 4 are discussed in reference to the study objectives and literature reviewed. Findings on the process of antimalarial drug policy change and implementation at policy level are matched with those of providers. The revealed low level of adherence to antimalarial drug policy is discussed in general and subsequently results comparing practice by ownership, level of care and rural versus urban are probed for possible interpretations. Qualitative results where applicable have been used to make some interpretation of study results, in reference to finding from other studies.

5.2 Discussion of Findings

Change of malaria treatment policy in Uganda was systematically handled, several pre-implementation key stakeholders' meetings were held to discuss and agree on the most appropriate implementation approach. The basis of change was poor chloroquine efficacy due established high level of resistance of *P. falciparum* to chloroquine monotherapy (Kamya et al., 2002; Bjorkman et al., 2005; Checchi et al., 2005). Several options were considered before making the choice of CQ+SP combination therapy as a suitable replacement for chloroquine (Ministry of Health 2000a; Ministry of Health 2000b). However, there was no documentation seen on the evaluation criteria used to choose CQ+SP among other possible options. Although cost was mentioned, the issue of cost-effectiveness might have been undermined. More so, when neighboring countries with similar levels of resistance chose other options like SP (Burundi and Kenya) and SP+AQ (Rwanda). In a study that explored economic aspects of implementation of artemether-lumefantrine (AL) to replace SP, findings indicate that although artemether-lumefantrine unit cost is far much higher than the unit cost of SP, it's use has greater effectiveness and significant cost savings¹⁵(Muheki et al., 2004). However, the use of CQ+SP as recommended in the

¹⁵ Cost savings resulted from improved clinical cure rates and decrease in malaria transmission.

Uganda antimalarial drug policy has now been considered a transitional policy as stakeholders look for funding for more cost-effective alternative (Bakyaita et al., 2005).

Results of this study indicate that the implementation approach used in changing the AMDP was effective in terms of ensuring availability of treatment guidelines in all health facility and equipping prescribers with knowledge about the change in policy. However, this did not directly translate in prescribing the recommended combination therapy of CQ+SP. This motivates exploring factors that lead to the observed low (39%) level of adherence to the recommended malaria treatment regimen.

There is variance between factors considered by policy makers and prescriber to have influenced adherence to recommended malaria treatment guidelines. Policy makers put much emphasis on implementation process issues like ensuring availability of policy document at each facility, organizing workshops to sensitize providers, and advocacy among political/opinion leaders. On the other hand, providers consider known drug efficacy, drug accessibility (availability, affordability) and anticipated outcome in terms of minimal treatment failure as the key factors that influence their prescribing practice. Probably the factors mentioned by the providers were not mentioned by policy makers because these had been addressed at the policy formulation stage.

While interviews with key informants at policy level rate dissemination through workshops and support supervision as the major implementation success factors, prescribers at facility level consider workshops and support supervision to be the least rated success factors. Results from providers' perspective do not favor dissemination of change in policy through workshops because it is usually by representation. As put by one respondent, representatives to such workshops rarely get time to carry out further dissemination. Interpretation of the results from this angle highlights the two perspectives of looking at policy implementation as a policy maker and as a provider. In this case, the policy makers look for cost-effective options of policy dissemination (workshops) while the providers prefer maximum acquisition of knowledge through direct participation for as many prescribers as possible. If the measure of implementation effectiveness is translation into maximum adherence to policy, then this study results indicate that workshops might not be the

most cost-effective approach to change prescribers practice. However, visits to the health facilities indicate that adequate communication of change in policy was done. At most (83%) health facility visited, a copy of malaria management practical guide for health workers was available. In addition, some other forms of guidelines like letters from MOH or District Director of Health Services communicating the change, and copies of press releases were also found at most of the health facilities visited. Interviews with the Heads of health facilities also reveal adequate knowledge about the change from chloroquine monotherapy to a combination therapy of CQ+SP. Such indicators show wide policy dissemination done and this would be expected to yield maximum adherence but as later discussed, this was not the case.

Further findings from interviews with prescribers prior to analysis of records review results, indicates high level of knowledge about the change in antimalarial drug policy, 72.7% of prescribers that responded correctly stated the recommended drugs. If knowledge about the policy was to be directly translated into practice, a similar level of adherence would be expected on review of prescription records but results differ as discussed below.

On review of patient records for prescriptions written for treatment of uncomplicated malaria within the previous six months, only a few prescriptions were for combination therapy of CQ+SP, as indicated in figure 4.2. This clearly shows deviation from the anticipated high level of adherence by policy makers. Further review as summarized in figure 4.3, reveal that there is a significant difference ($P < 0.000$) between public and private not for profit prescribing practices for uncomplicated malaria. Within public health facilities a reasonable proportion of prescriptions are for the recommended combination therapy (CQ+SP) as compared to only a few for private not for profit health Facilities. This implies that public health facilities are relatively faster in adapting to the new malaria treatment guidelines than private not for profit facilities.

On analysis of a detailed product range prescribed by private not for profit health facilities for uncomplicated malaria as per table 5.3, majority of prescriptions are of quinine tablets monotherapy. Discussion with some prescribers within this sector indicates that they do not wholly trust the efficacy of the recommended combination (CQ+SP). This can not be entirely disputed given that some resistance surveillance

studies have indicated parasitological failure at day 28 of 48% in children treated with CQ+SP (Talisuna et al., 2004a). In private not for profit facilities, patients that can afford quinine and promise to comply with the dosage schedule are given oral quinine as the 1st line treatment for uncomplicated malaria. This flexibility in using other treatment alternatives can also be partially attributed to the fee for service financing mechanism for the private not for profit health facilities as compared to free service in public health facilities.

This finding, where private not for profit facilities prescribe more of what is considered to be a second line regimen could be justified by findings from other studies that indicated that most uncomplicated malaria cases are managed outside the formal health sector (Mwenesi et al., 1995), with drugs bought from shops or kiosks (Snow et al., 1992). This school of thought is further supported by Amexo et al. (2004), by indicating that over 70% of malaria cases do not present initially to health facilities but diagnose and manage their malaria at home. It, therefore, makes clinical sense to assume that most malaria cases seeking treatment at the health facility level have already used some first line treatment. This practice of prescribing more quinine than CQ+SP at PNFP facilities is further strengthened by the well publicized malaria home management strategy that recommends use of CQ+SP at household level. However, in public health facilities, chloroquine is still being prescribed for a significant (55.8%) proportion of cases, which could be explained by the historically known position of chloroquine as a 1st line treatment. Implementation approach that equips prescribers with adequate knowledge remains an issue, given that in public sector deviation from policy was more due to failure to change from old practices than change to a drug considered to be more effective.

On analysis of data stratified by rural versus urban, it is noticed that rural based facilities adhere more to the recommended malaria treatment policy than urban based health facilities. Given the intensive dissemination of policy change in the urban district area, facilities in Kampala would be expected to have higher level of adherence but it is not the case. This further emphasizes that failure to adhere to the new policy is not due to lack of policy awareness.

Results of this study indicate that antimalarial drug policy change from Chloroquine monotherapy to combination therapy of CQ+SP is not fully translated into expected

change in prescribing practice. The results are in line with findings in a study that compared prescribing practices between public and private sector physicians in Uganda (Ogwal-Okeng et al. 2004), where prescribing for adult malaria and acute respiratory infection by both private and public practitioners does not conform to the Uganda National Standard Treatment Guidelines.

Factors such as urban-versus rural, financing mechanism, supportive supervision, technical guidance and level of health care facility had some influence on actual practice. Availability of affordable alternatives, indecision about ideal timing and an emotional historical attachment to chloroquine are highlighted as some of the reasons for most East African countries' reluctance to change their malaria drug policies (Williams et al., 2003). If this reluctance occurs at policy maker level it is not a surprise that providers' adherence to change in antimalarial drug policy is minimal.

The low level of adherence to the national malaria treatment policy by prescribers at health facility level may also be due to the effect of the home based management of fever national policy in Uganda. This HBMF strategy is implemented concurrently with the change in antimalarial treatment policy that recommends use of same (CQ+SP) first line antimalarial drugs at community level. However, the above explanation may only be true for prescriptions that were for second line antimalarials like quinine (which was only common in private not for profit facilities) but does not account for majority of chloroquine monotherapy prescriptions, which formed a good proportion of antimalarial treatments in public sector facilities involved in the study.

In conclusion, findings from this study indicate poor adherence to change in antimalarial drug policy in the study area in Uganda, 61% of prescriptions reviewed do not adhere to the recommended CQ+SP combination therapy. From these results it can be inferred that despite the good implementation plan and actions from policy maker's perspective, providers had a differing interpretation of the policy change. The implementation process of change in AMDP in Uganda can be considered effective in terms of dissemination of new policy as reflected by almost 100% availability of treatment guidelines at all facilities visited and the high level prescribers' knowledge about the documented changes in policy but this is not fully translated into practice.

Chapter 6.0 Policy Recommendations and Conclusion

6.1 Recommendations

Given the evidence about high level of resistance to CQ and associated treatment failures in Uganda and the neighboring countries, the prescribing practice in public health care facilities does not only increase the disease social burden but also increases the cost of seeking treatment by the affected individuals (mainly the poor). It is therefore recommended that level of adherence to drugs in the antimalarial drug policy be included among routine indicators to be monitored by Malaria Control Program–MOH for guiding further policy implementation activities.

It is further recommended that studies on prescribers' level of adherence to antimalarial drug policy be included in routine surveys carried out by East African Network for Monitoring Antimalarial Treatment. This suggestion will enable the EANMAT to guide policy makers on key implementation strategies that promote quick translation of changes in AMDP into desired providers' practice.

Although stakeholders involvement was mentioned among approaches used in formulating and implementing the AMDP change in Uganda, on reviewing the characteristics of institution represented in the policy formulation process there was no representation of providers at primary health care level. This might have lead to omission of some key drivers for quick policy implementation. It is therefore recommended that in future antimalarial treatment policy changes, providers at primary health care level be considered among key stakeholders at both policy formulation and implementation stages.

Results indicate 100% availability of policy document at all facilities involved in the study. However, basing on the results, availability of antimalarial drug policy document did not promote adherence. Therefore, it is recommended that at implementation stage more resources should be allocated to training of prescribers of all levels. Findings also indicate that training about AMDP changes was through

sending representatives to workshops but such representatives (usually the bosses) never had time carry out further face to face dissemination of information to all health facility prescribing staff. Resources allowing and subject to further studies on reasons for lack of adherence, Malaria Control Program-MOH needs to consider change in training approach from inviting facility representatives to centralized workshops to sending trainer(s) to facilities as this gives opportunity for direct training more number of prescribing staff.

In private not for profit owned health facilities, the most commonly prescribed first line antimalarial was quinine monotherapy (34.3%), this could be interpreted as irrational prescribing practice. However, given results of several studies that have indicated growing resistance to CQ+SP, providers in PNFP sector might have resorted to Quinine as a follow back position. This interpretation is further justified by the fee for service (though subsidized) financing mechanism in PNFP sector. The fee for service financing mechanism is a motivator for using the most efficacious drug available to achieve high cure rate and therefore gaining more trust from the community. Though contentious, the option for inclusion of a section in the AMDP on other first line antimalarial drugs recommended where resources allow, would promote rational use of suitable alternatives. In addition, such a comprehensive policy would also promote private sector's confidence in national antimalarial drug policy.

Home based management of fevers, an antimalarial management strategy which was introduced concurrently with the change in AMDP, was one of the reasons used to assume that most patients affected with malaria seek treatment from health facilities after treatment failure with recommended first line treatment. However, this can only be true for prescribers that changed to second line drugs, mainly those in PNFP health facilities. Nevertheless, to promote rational antimalarial drugs prescribing practice, malaria control program should develop some special forms¹⁶ for use by community workers as reference document. The community members would then be sensitized to carry such forms whenever visiting PHC facilities after treatment failure at community level. In addition to acting like community referral

¹⁶ Some category of simplified prescription, indicating drugs given to patients at community level

forms, such documentation would also promote cautiousness among community workers while diagnosing and dispensing antimalarials to the community.

6.2 Agenda for further study

This study identified some information gaps that would be of interest for further research and guiding future policies. These include:

- A similar research on level of adherence to national antimalarial policy could be conducted in Private for Profit sector. Knowing that the PFP sector practice is to some extent influenced by profitability, inclusion of an extra objective for establishing the cost at which various drugs are prescribed would be of added interest.
- Given the pending further change in antimalarial drug policy in Uganda from CQ+SP to one of the Artesunate based fixed dose combinations to be used to treat malaria at both health facility and Home based Management of Fevers, it would of policy interest to study the impact of home based management of fever strategy on case management of uncomplicated malaria at health facilities level. D'Alessandro et al. (2005), cautions that use Artesunate based combination treatment under the HBMF approach should be carefully considered because the potential benefits might be outweighed by the negative consequences.
- Since 1998, various countries in sub-Saharan Africa have changed respective national antimalarial drug policies and common to all, was the change from chloroquine monotherapy due to high level of resistance to *P. falciparum*. However, the replacement therapy differed and some countries like Uganda opted for a transition policy of using CQ+SP alluding to financial resource constraints. It would be of research interest to evaluate the cost of implementing such a transitional policy change versus additional resources required to implement a more ideal malaria treatment regimen.

6.3 Conclusion

While changing policy emphasis should be equally put on policy content, process as well as intended intermediary outcome like providers practice. Special interests of various categories of healthcare providers require close scrutiny at policy formulation stage to ensure designing multi strategies that address each category's justified interests.

Implementing changes in antimalarial drug policy is of interest to all stakeholders', prescribers and patients inclusive. However, more effort needs to be put in activities that are envisaged to promoted adherence to the policy from provider's perspective, since these translate the policy into practice. This study brings forward significant aspects of implementing changes in antimalarial drug policy from provider's point of view that are worth policy makers' attention.

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Appendices

Appendix 1: Key Informant Interview Guide

Appendix 2: Interview guide for heads of health facilities

Appendix 3: Questionnaire for prescribers

Appendix 4: Malaria prescriptions review form

Appendix 5: Study Synopsis / consent form

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University of Cape Town

Appendix 1: Key Informant Interview Guide

Data collection form 1: Key Informant Interview Guide

1. In Uganda, malaria is still the major cause of morbidity and mortality what are the major Government (MOH) strategies for managing the disease?
2. Early 2001, there was change in malaria treatment policy from chloroquine monotherapy for uncomplicated malaria to combination therapy, what were the major reasons for this change?
3. What were the options considered for combination therapy and why did Ministry of Health recommend SP-CQ among all available options?
4. What specific actions were taken to ensure implementation of the new policy?
5. In your view, do you think all prescribers adhere to the recommended treatment (prescribing) guidelines?
6. What would you consider as the major factors influencing the prescribing practice of malaria treatment?
7. How do you plan to monitor progress of change from monotherapy to combination therapy for management of uncomplicated malaria?

Thank you for your time

Appendix 2: Interview guide for heads of health facilities

Data collection form 2: Interview guide for heads of health facilities

Name of facility:	Level:	Ownership:
Highest qualification of head of facility:	Duration in service:	Duration at the facility:
1. Are there any treatment guidelines for malaria at this facility?		
2. May I see a copy of these treatment guidelines? <i>(data collectors should record all the guidelines SEEN)</i>		
3. What is government current policy on the treatment of malaria?		
4. Do the staff/Prescribers in this facility/clinic <u>ALWAYS</u> follow Govt's official treatment guidelines when prescribing drugs?		
5. (If YES) to 4 above), in your opinion, what do you think are the factors that have INFLUENCED prescribers' behavior to ADHERE to treatment guidelines?		
6. (If NO to 4 above) In your opinion, what do you think are the factors that have INFLUNCED prescribers Behavior NOT to ADHERE to treatment guidelines?		

Thank you for your time

Appendix 3: Questionnaire for prescribers

Data collection form 3: Questionnaire for prescribers

This is to thank you in advance for agreeing to participate in this research. The main objective is to collect your views as a Prescriber on management of malaria. This research is purely for academic purposes and all due care will be taken to ensure confidentiality of the information you provide.

Date:	Qualification of interviewee:
Name of health unit:	Number of years in service:
Ownership:	Age:
District:	Sex:
Level of care:	

Qn.1. As a health worker how do you diagnose patients with malaria? (Write down the whole explanation)

.....

Qn. 2 What drug or drugs do you prescribe for the following categories of patients with uncomplicated malaria?

(2.1) Uncomplicated malaria in adults

.....

(2.2) Uncomplicated malaria in pregnant women

.....

(2.3) Uncomplicated malaria in children under 5 years

.....

Qn. 3 On what basis do you choose the drugs mentioned above?
 (Record everything the interviewee says)

.....

Qn 4 Are the drugs mentioned above always in stock whenever you prescribe them? (Put a circle around one of the two options)

YES:

NO:

Qn 5. Do you know of any government policy on treatment of uncomplicated malaria? (Put a circle around one of the two options)

YES:

NO:

Qn. 6 What is government current policy on treatment of uncomplicated malaria for
(6.1) ADULTS

(6.2) PREGNANT WOMEN

(6.3) CHILDREN UNDER 5 YEARS

Qn. 7 What is your view on this policy

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

Qn. 8 In your opinion you are your current prescribing practices in line with current government treatment guidelines for of uncomplicated malaria? (Put a circle around one of the two options)

YES:

NO:

Qn 9. If NO to question 8 above, what are the reasons for prescribing differently from government treatment guidelines?

.....
.....

Thank you for your time

Appendix 4: Malaria prescriptions review

Data collection form 4: Malaria prescriptions review

Identification of health facility										
Date:					Qualification of prescribers 1. Medical officers Number..... 2. Clinical officers Number..... 3. Nurse/Midwife Number..... 4. Other Number.....					
Data collectors name:					Availability of document on Malaria treatment policy. Yes No 1. Standard treatment guidelines <input type="checkbox"/> <input type="checkbox"/> 2. Malaria treatment policy <input type="checkbox"/> <input type="checkbox"/> 3. MoH Notice on Malaria <input type="checkbox"/> <input type="checkbox"/> 4. Other (write).....					
Name of Health Unit:										
Ownership:										
Level of care:										
Data collector					1. Review the number of malaria cases in the last 6 months from the HMIS. Divide the total number of malaria cases in the last 6 months by 100 to get the appropriate interval to use when selecting the cases to record. 2. Record information on the selected malaria cases from OPD register in the space below. 3. The case should be selected even if there is another diagnosis concurrent with malaria. 4. Pick 100 cases from each selected health unit					
Cases	Patient number	Diagnosis	Age	Sex	Drugs prescribed for each malaria case selected. (Tick if prescribed and write down if any other drug is prescribed)					
					CQ	S/P	QNN	Other	Other	Other
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17-100										

Thank you for your time

Appendix 5: Study Synopsis / Consent Form

Date

Dear Sir/Madam,

RE: THE CHANGE IN MALARIA TREATMENT POLICY IN UGAND: ANTIMALARIAL
DRUG PRESCRIBING PRACTICE

1.1 Introduction

Until June 2002 Chloroquine monotherapy was the first line treatment for uncomplicated malaria in Uganda. Thereafter, there was change in national antimalarial treatment policy. The principal researcher (Deogratus Kimera) as introduced to you by Ministry of Health is a student pursuing a Masters of Public Health in Health Economics at University of Cape Town.

1.2 Study Objective

The study for which your participation is requested aims to establish the extent of implementation of the change in antimalarial drug policy in Uganda. It is to be carried out in selected facilities in Kampala and Rakai districts of Uganda. The selection process will ensure involvement of both private not for profit and Public health facilities.

1.3 Request for your participation

Yours/your facility involvement will require responding to some questions during a face to face interview and review of prescription records. Our preliminary major findings will be discussed with after the data collection process. All participants' identity and information given will be treated with confidentiality. All information given and that obtained through records review shall only be used for academic purposes, and participation by you or your staff is on voluntary basis. Any policy recommendation to be made from the study and found to be appropriate for sharing beyond academic environment, shall not disclose specific names of data source.

Having read and understood the above, this is to request for your participation in the study but you have the option of accepting or declining to participate in the study.

(1) I Accept

(2) I do not accept

Signature.....Health Facility.....

Appendix 6: Definition of Primary Health Care levels

Health Centre I

This level of care provides health services for the community within the catchment area of a village (approximately 1,000 people). Health centre I offers Community based preventive and promotive health services through village health committees.

Health Centre II

This is the primary contact for health services for the community within the catchment area of a parish (approximately 5,000 people) and offers only basic health services usually referred to as curative out patient care.

Health Centre III

This is a primary healthcare facility that offers maternity services in addition to basic health care services, within a catchment area of approximately 20,000 people.

Health Centre IV

This level of care has offers surgical and admission services in addition to maternity and basic healthcare services. Health centre IV covers a catchment area of approximately 100,000 people. It acts also as the referral facility for patients from HCl, II and III.

However, in practice people do not necessarily follow the above hierarchy when seeking healthcare. The practice is to seek treatment from the nearest health facility irrespective of level of care.

Level Of Care	Serving	Catchment	Services
HC I	VILLAGE	1,000	Community based preventive and promotive health services e.g village health committees
HC II	PARISH	5,000	Preventive and curative out patient care
HC III	SUBCOUNTY	20,000	OPD, Maternity and lab services
HC ¹⁷ IV	COUNTY	100,000	OPD ¹⁸ , Maternity, In Patients and Emergency Surgery

Source: MOH Health Sector Strategic Plan 2000/01 to 2004/05

¹⁷ HC = Health Centre

¹⁸ OPD = Out Patient Department

Appendix 7: Location of study sites

