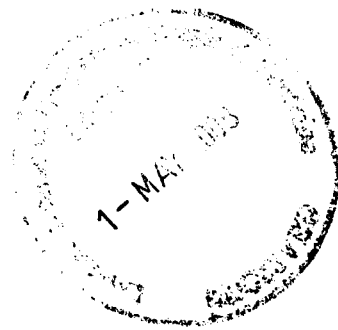# THE EFFECT OF REDUCING THE DIRECT COST OF CARE ON HEALTH SERVICE UTILIZATION AND HEALTH OUTCOMES IN GHANA:

A RANDOMIZED CONTROLLED TRIAL

EVELYN KORKOR ANSAH BSc. MB ChB, MPH

Thesis Submitted to the Faculty of Medicine of the University of London for the Degree of Doctor of Philosophy (PhD)

Clinical Research Unit, Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, University of London

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ABSTRACT

AIM

To improve malaria control in children less than five years of age.

OBJECTIVES

To assess the impact of reducing the direct cost of healthcare on utilization of health services and morbidity associated with malaria among children under 5 years old.

Primary objective

To compare the prevalence of anaemia (Hb<8g/dl) among children six to fifty-nine months of age, from households with and without improved financial access.

Secondary objectives included:

To compare the health service utilization rate among children from households with or without improved financial access; to compare household all-cause mortality between the trial arms, to examine primary and major secondary outcomes by socio-economic status of households, to compare outcomes among children from self-enrolled and trial-enrolled households; and to document community knowledge and attitudes on user fees.

METHODS

2332 households containing 2757 children less than 5 years of age in Dangme West, Ghana were randomised either to be enrolled into a pre-payment scheme operating allowing free access to primary care, including drugs or to a control which paid user fees for their health care as pertained normally. These included 138 households, comprising 165 children, who had enrolled in the pre-payment scheme prior to the closure of the registration window were included in the study as an observational arm.

RESULTS

2194 households comprising 2592 children were allocated randomly into control and intervention groups. 138 households, comprising 165 children had themselves enrolled in the pre-payment scheme. At baseline, the two randomised groups were the same, but the group who self-enrolled were significantly less poor and had better health outcome measures.

Introducing free primary healthcare significantly altered the healthcare seeking behaviour of households, with those randomly allocated to the intervention arm using formal healthcare more (95% CI 1.04-1.20; p=0.001) and home treatment and chemical sellers less than those in the control group. This did not, however, lead to any measurable difference in any of the health outcomes at the end of the six-month trial period. For the primary outcome of moderate anaemia there was no difference seen OR 1.05 (0.66-1.67).

CONCLUSIONS

This study suggests that reducing the direct cost of health care has a significant impact on healthcare-seeking behaviour but cannot, on its own, be assumed to have an impact on health outcomes.

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ABBREVIATIONS

ACPR   -   Adequate Clinical and Parasitological Response

ACT   -   Artemisinin Combination Therapy

CBA   -   Community Based Agent

CI   -   Confidence Interval

CQ   -   Chloroquine

DAB   -   Diaminobenzidine

DALYs   -   Disability Adjusted Life Years

DANIDA   -   Danish International Development Agency

DHIMT   -   District Health Insurance Management Team

DHMT   -   District Health Management Team

EDTA   -   Ethylenediamine Tetraacetic Acid

ELISA   -   Enzyme Linked Immuno-sorbent Assay

ETF   -   Early Treatment Failure

FGD   -   Focus Group Discussion

GDP   -   Gross Domestic Product

GHS   -   Ghana Health Service

GNP   -   Gross National Product

G6PD   -   Glucose-6-Phosphate- Dehydrogenase

HAZ   -   Height-for-age z-score

HH   -   Household

HIV/AIDS   -   Human Immuno Deficiency Syndrome

HRP   -   Enzyme Horse Radish Peroxidase

ID   -   Identification

IE & C   -   Information, Education and Communication

IPT   -   Intermittent Preventive Treatment

IQR   -   Interquartile Range

ITN   -   Insecticide Treated Net

JSS   -   Junior Secondary School

KI   -   Key Informant

LCF	-	Late Clinical Failure
LPF	-	Late Parasitological Failure
LTFU	-	Lost to follow-up
MIU		Micro-insurance units
MSLC	-	Middle School Leaving Certificate
MTHS	-	Medium Term Health Strategy
MOH	-	Ministry of Health
NGO	-	Non Government Organization
NMCP	-	National Malaria Control Programme
OPD	-	Out Patients Department
OR	-	Odds Ratio
PI	-	Principal Investigator
pLDH	-	Parasite Lactate Dehydrogenase
PHC	-	Primary Health Care
RDT	-	Rapid Diagnostic Test
RBC	-	Red Blood Cell
RBM	-	Roll Back Malaria
RR	-	Rate Ratio
SES	-	Socio-economic status
SSNIT	-	Social Security and National Insurance Trust
SSS	-	Senior Secondary School
TBA	-	Traditional Birth Attendant
WAZ	-	Weight-for-age z-score
WBC	-	White Blood Cell
WHO	-	World Health Organization
WHOSIS	-	World Health Organization Statistical Information System
WHZ	-	Weight-for-height z-score

STATEMENT

I have read and understood the School's definition of plagiarism and cheating given in the Research Degrees Handbook. I declare that this thesis is my own work, and that I have acknowledged all results and quotations from published or unpublished work of other people.

Signed..Date..26.04.07

Full Name...EVELYN KORKOR ANSAH...............

DEDICATION

Dedicated to the memory of my late Mum and Dad, Rose and George, who both gave me a rich legacy of education and though they saw the beginning, did not live long enough to see the completion of this work.

ACKNOWLEDGEMENTS

CHAPTER 1 INTRODUCTION

1.1 Organization of thesis

The thesis is divided into nine chapters as follows:

Chapter 1 Introduction

This chapter is the introduction to the thesis. It discusses the rationale of the study and presents the objectives the study aimed to achieve. It also provides a general overview of the organization of the thesis.

Chapter 2 Review of the literature

Chapter two presents a brief review of the malaria situation both globally and in Ghana. A review of the epidemiology and control of malaria in Ghana is then presented. This is followed by a review of existing literature on the epidemiology of severe malaria and the evidence for the use of anaemia as a measure of morbidity due to malaria. The relationship between household socio-economic status and health as well as strategies for overcoming financial barriers to effective treatment both globally and in Ghana are discussed.

Chapter 3 Methods

In chapter three, the design of the study as well as a description of the study site and its population are outlined. A brief description of the methods of a preliminary study and other sub-studies which were carried out is presented. Also described are ethical issues and the overall conduct of the trial including the data sources and procedures used.

Chapter 4 Context of the study

This chapter sets out the context within which the trial was carried out. It provides data from preliminary qualitative studies and from baseline household interviews which give an insight into household perceptions of various malaria-related and health financing issues.

Chapter 5 Results of an *in vivo* assessment of the therapeutic efficacy of chloroquine

Chapter five includes a description of the methods and results of an *in vivo* assessment of the therapeutic efficacy of chloroquine carried out in the study area prior to the trial. It concludes with the consequences following the local dissemination of the results of the assessment.

Chapter 6 Results of the main trial

This chapter presents the results of the main trial. The two randomly allocated arms are compared at baseline. As a group they are also compared to households who enrolled themselves in the pre-payment scheme (the intervention) and were kept as a subsidiary arm of the main trial. The effect of the intervention on the main trial outcomes is presented. The self-enrolled group are compared to the trial enrolled group in terms of the main outcomes. Also presented, is the extent to which distance of household residence from a health facility modifies the effect of the intervention.

Chapter 7 Household socio-economic status and main trial outcomes

In this chapter the association between household socio-economic status and the main trial outcomes are examined.

Chapter 8 Contextual and explanatory factors relevant to the trial

This chapter contains an examination of some contextual and explanatory factors that might have had an effect on the overall outcome of the trial in order to provide assistance in the interpretation of the results of the trial. The first three sections cover sub studies that were carried out in the study area during and after the main trial whilst the last two sections report on-going malaria-control efforts in the study area during the period of the main trial.

Chapter 9 Discussion and conclusion

This final chapter begins by discussing the main findings and their limitations in the light of what is already known. The lessons learnt along with the conclusions that can be drawn are discussed. The questions that remain answered and the implications of the results for policy and practice are presented.

1.2 Rationale of the study

Malaria is a major cause of childhood morbidity and mortality, causing nearly 25% of child mortality in Africa (WHO 2000a). Effective control strategies depend both on preventing disease and on treating those who become infected.

Review of the literature shows that self-treatment ranges from <1% to 94% and self-purchase of drugs from 4% to 87% in different areas. Approximately 50% of cases rely exclusively on self-treatment (McCombie 1996). Attempts made in the past to prevent uncomplicated malaria from progressing to the severe form of the disease, and possibly death, have included the improvement of treatment at the household level with improved recognition of danger signs for which children should be rushed to the health facility. The adequacy of treatment at home, however, is still currently fraught with problems. Apart from those who will not recover due to inadequate doses there will be cases who will not improve due to reasons such as increasing resistance of the malaria parasite to many first line anti-malarials currently in use.

More recently, the rectal form of an effective anti-malarial, artesunate, has been advocated for children who are not able to take drugs by mouth. This is known to work by massively reducing parasitaemia and temporarily halting the logarithmic increase in parasites with each successive cycle, buying time for the patient to be able to reach the nearest health facility. Patients are still expected to continue to the health facility for definitive treatment without which the situation will reverse (WHO 2000a) with tragic consequences. Delay in seeking care for severe cases has often ended in death of the sick child before or within a short time after reaching the clinic (Greenwood *et al.* 1987a).

The link between the home and the health facility, therefore, still remains important in the control of malaria. However, cost considerations may deter many from going to the health facility even though their illness is not resolving, or for definitive care after receiving rectal artesunate, and some may well be tempted to take advantage of the respite given by the rectal artesunate to seek cheaper, alternative but inadequate follow-on care.

Recognizing the barrier created by the cost of health care, many countries, especially those in sub-Saharan Africa (SSA) are seeking to improve financial access to health care as part of health sector reforms. One of the ways they are doing this is through health insurance or pre-payment schemes. In these schemes, people contribute to the cost of care at a time when their cash incomes are highest and it is easiest for them to do so. Some health insurance schemes in Africa have shown greatly improved access to health care (Preker *et al.* 2002; Schneider and Diop 2001) but most show a low uptake for various reasons. The most important reason is probably the fact that the direct benefit from financial access to health care is not always clear to the target population; particularly as they are expected to pay for insurance when they are not ill. Arguments have been made in the past for providing free care or exemptions for malaria as a method of assisting malaria control efforts. In addition, discussions have been held over the years on the possibility of targeted subsidies for the poor as well as groups that are especially vulnerable in terms of disease like children under five years of age.

The WHO believes that since guaranteed access to early diagnosis and appropriate treatment of febrile illness is key to malaria morbidity and mortality, any change which influences the provision of prompt and effective treatment is of critical importance to malaria control efforts (WHO 2000a). There are many barriers preventing access to prompt and effective treatment. These barriers may occur at many levels, including failure by parents to recognize illness in a child until it is too late, difficulties in accessing health services leading to delayed presentation and inadequacy of diagnosis or treatment once medical services are accessed.

These issues can be divided into problems in accessing appropriate health care and problems once health care is accessed. Problems in accessing health care may include socio-cultural issues, particularly in relation to the concept of disease causation and treatment, the non-availability of health facilities, distance from health facilities, travel costs to health facilities and opportunity costs of seeking health care. In addition, the perception by the household of poor quality of care in the health facility may result in their reluctance to seek care there. Problems that come into play once health care is accessed include mis-diagnosis, mismanagement, drug resistance and non-adherence to

therapy (Agyepong *et al.* 2002; Amexo *et al.* 2004; Ansah *et al.* 2001; Yeboah-Antwi *et al.* 2001). A study in Kenya reported sensitivity and specificity of routine microscopy in 17 health facilities of 68.6% and 61.5% respectively. They found that 79.3% of patients with negative blood slide results still received an anti-malarial whilst 4.5% of those with positive slide results were not given any anti-malarial by the clinician (Zurovac *et al.* 2006).

Public health practitioners and policy makers who make decisions and policies regarding access to health care for the poor and vulnerable are usually convinced by empirical evidence of positive impact on the health status of beneficiaries. Most governments, because of the perceived cost, and lack of empirical evidence of benefits in terms of health status have not been pro-active in improving financial access or adopting the strategy of free care for malaria. Although improvement in financial access through whichever means should, theoretically, reduce some of the financial barriers leading to people reporting promptly whenever they are ill, thereby reducing the progression to severe or chronic disease (Meer and Rosen 2004), their actual impact has not been directly assessed or demonstrated for malaria by means of an intervention trial.

It is not easy to set up intervention studies that investigate new approaches to payment for health care. Several studies in this area have, therefore, made use of time series data collected before and after the introduction of an intervention, used case studies or multivariate statistical analyses of cross-sectional household data. Others have simulated user responses to surrogate measures of the intervention being studied. Some very useful studies have examined the impact of different kinds of financing schemes and levels of financial access on equity, the level of out-of-pocket expenditures, utilization, efficiency of services, the type of care accessed, effectiveness of protection from catastrophic health care costs, efficiency in resource mobilization and other econometric indices. Increased utilization of health care services is not an end in itself and demonstration of a link between this and health outcomes is very important.

In most of these studies, there was absence of socio-economic data, an absence of controls and difficulty in defining the desired outcome. Sometimes more than one intervention was implemented making it difficult to tease out causality. Many studies

took advantage of natural experiments or used data that were not obtained specifically for the purpose of the investigation. In some of these studies, randomization was difficult ethically and practically (Palmer *et al.* 2004). It has also been difficult to avoid the biases associated with differences in socio-economic status between the insured and uninsured (Levy and Meltzer 2001). It is well known that those who choose to, and are able to, register in a health insurance scheme are different in many ways from those who do not choose to or are unable to do so for various reasons.

The limitations of these studies, which are unavoidable and accepted by the investigators, are that it is difficult to avoid the biases associated with differences in socio-economic status between the different groups being compared. Randomized controlled trials by design are able to deal with biases, making comparison of the two groups much easier in terms of the issue being assessed.

Some of the barriers to accessing health care are amenable to intervention, others (such as distance to healthcare) less so. This study concentrated on modifiable financial barriers to achieving effective treatment for malaria. The study aimed to determine by means of a randomized trial the impact of reducing financial barriers to health care on health outcomes among children 6 to 59 months of age and on outpatient utilization. An existing pre-payment scheme in the study area was utilized to improve financial access for half of 2151 households with eligible children who had not enrolled in the scheme at the time of closure of the registration window for the year 2004. The impact of the intervention on anaemia, mean haemoglobin concentration and anthropometric indicators was assessed. Health service utilization was measured in both groups by passive surveillance and compared. Patients' perceptions of malaria, the quality of care in the health facilities, poverty and health financing were explored.

The study contributes to current knowledge on the relative importance of direct cost of care as a barrier to health care and the relative contribution of the removal of this barrier to malaria control.

1.3 Objectives

To assess by means of an open, randomized trial, the impact of improving financial access to health care on utilization of health services and morbidity associated with malaria among children six to fifty-nine months of age.

1.3.1 Primary objective

To compare the prevalence of anaemia (Hb<8g/dl) among children six to fifty-nine months of age, from households randomized to improved financial access or without for one year.

1.3.2 Secondary objectives

1. To compare the proportions of children six to fifty-nine months of age with severe anaemia (Hb<6 g/dl) from households with or without improved financial access.

2. To compare the health service utilization rate among children six to fifty-nine months of age from households with or without improved financial access.

3. To compare the mean haemoglobin concentration among children six months to fifty-nine months of age from households with or without improved financial access.

4. To compare anthropometric indicators among children six to fifty-nine months of age from households with or without improved financial access.

5. To compare child (6 to 59 months) as well as household all cause mortality among households with or without improved financial access.

6. To examine primary and major secondary outcomes by socio-economic status of households.

7. To compare primary and major secondary outcomes among children from self-enrolled and trial-enrolled households.

8. To document community knowledge, attitude and practice with regards to severe malaria, user fees, exemptions, the existing pre-payment scheme and indicators of poverty.

CHAPTER 2 REVIEW OF THE LITERATURE

2.1 Global burden of malaria

Malaria is a public health problem in 107 countries and territories, inhabited by a total of about 3.2 billion people, where there is a risk of its transmission. The World Health Organization (WHO) estimates that 350-500 million clinical malaria episodes occur annually, with most of these infections being caused by *Plasmodium falciparum* and *P. vivax*. *P. falciparum* is thought to cause directly more than 1 million deaths each year, as well as contributing to many additional deaths, mainly in young children, through synergy with other infections and illnesses. Sub-Saharan Africa is responsible for about 75% of the *P. falciparum* global burden and 60% of the overall malaria burden. An estimated 80% of malaria deaths occur in Africa south of the Sahara (WHO 2005). The disease also takes an economic toll because it causes reduced productivity (Sachs 2001).

The World Health Organization (WHO) estimates that malaria causes approximately one million deaths each year among children less than five years of age (WHO 2000a). These childhood deaths constitute nearly 25% of child mortality in Africa (Greenwood *et al.* 1987a; WHO 2000a). Malaria causes severe childhood morbidity and mortality through two main mechanisms: anaemia and cerebral malaria (Bruce-Chwatt 1952; Greenwood *et al.* 1987b; Marsh *et al.* 1995; Schellenberg *et al.* 1999).

Breman suggests that the actual burden of malaria is often not accurately estimated for many reasons. These include the fact that surveillance systems in many parts of Africa are weak. Also many febrile illnesses mimic malaria and facilities to differentiate these from malaria are often unavailable. Furthermore, most fever episodes are treated at home and never become visible to formal health system; thus they remain undocumented by health management information systems. The relatively few ill patients who have any contact with the health services represent the "ears of the hippopotamus". He rightly summarizes that the burden of malaria is a challenge to quantify given that infections cover a wide continuum from asymptomatic parasitaemia in partially immune persons to acute catastrophic illness, such as cerebral malaria that often has a fatal outcome (Breman 2001). Snow and others who have recently mapped the global distribution of malaria, provide an estimate of clinical episodes of *P. falciparum* that are up to 50%

higher than those reported by WHO and 200% higher for areas outside Africa. They argue that WHO underestimates the burden of the disease due to its reliance upon passive national reporting. They estimate that for the year 2002, 2.2 billion people were exposed to the threat of *P. falciparum* malaria resulting in a conservative estimate of 515 (range 300-660) million clinical attacks attributable to that parasite during that year (Snow *et al.* 2005).

Malaria has been recognized as both a cause and a consequence of the poor socio-economic situation found in most of sub-Saharan Africa. This area happens to be one of the poorest regions in the world (RBM/WHO 1999). Income levels in countries where malaria is endemic are about a third less than those in countries with a similar socio-economic status without malaria. The estimated annual direct and indirect costs of malaria in Africa are more than 2000 million United States dollars (Gallup and Sachs 2001; Sachs and Malaney 2002). Malaria imposes suffering and poverty on individuals, households and governments of endemic countries (Bloland *et al.* 1996; Breman 2001; Breman *et al.* 2001; RBM/WHO 1999).

It has been estimated that the economic burden is also extremely high, accounting for a reduction of 1.3% in the annual economic growth rate of malaria endemic countries and a reduction of their Gross National Product (GNP) by more than half in the long term (Sachs and Malaney 2002). Sachs estimates that, in the short term, an economy whose population is at zero risk of malaria tends to grow more than 1 percentage point per year more rapidly than an economy with high malaria risk, controlling for other determinants of growth such as income level, schooling, quality of institutions and fiscal policy. Over time, the country with malaria ends up with a per capita income that is roughly half the per capita income of the country without malaria (Sachs 2001).

Initial attempts to eradicate malaria were not successful (WHO 1993), especially in sub-Saharan Africa where there is high transmission of *P. falciparum*, the principal cause of the severe form of the disease. Other successful strategies that have been tried are the introduction of treated bed nets which have been found to reduce morbidity and mortality (D'Alessandro *et al.* 1995b; Nevill *et al.* 1996) but raise questions about their sustainability in view of possible development of insecticide resistance in the vectors

(Greenwood 1997). Routine chemoprophylaxis is thought to run the risk of affecting the development of immunity. New strategies aimed at reducing the incidence of disease as well as its progression to severe malaria include intermittent presumptive treatment of children and the use of rectal artesunate capsules respectively. All these strategies rely on the back up of health care at the health facility. Currently, therefore, prompt and adequate treatment with an effective anti-malarial remains the mainstay of control. One of the core technical strategies of the Roll Back Malaria Partnership is the improvement of access to prompt and effective treatment. Early and effective treatment saves lives by preventing disease progression to severe malaria (WHO 2003). At the year 2000 Abuja meeting of African heads of states, it was declared that by the end of 2005, at least 60% of those infected with malaria should have easy access to appropriate, affordable treatment within 24hours of the onset of the illness (WHO 2000e).

2.2 Malaria in Ghana

2.2.1 Demographic and socio-economic information

Ghana is a tropical country situated in West Africa, south of the Sahara. It is bordered by Togo on the East, Cote d'Iviore on the West, Burkina Faso on the North and the Gulf of Guinea on the South (Figure 2.1). It is made up of a total of 10 regions and 138 administrative districts. The total area it covers is 239,460 sq km.

Its estimated total population for 2005 was 22,113,000 based on a census carried out in the year 2000. Life expectancy at birth is on average 57.2 years; being 56 years for males and 58 years for females. The estimated under-five mortality rate for 2004 was 112 per 1000 live births. Adult literacy between the year 2000 and 2004 was estimated to be about 54.1% (WHOSIS 2006).

Figure 2.1: Map of Ghana showing boundaries in West Africa

The per capita Gross Domestic Product (GDP) of the country in 2003 was USD 1,223 with the total expenditure on health being 4.5% of the GDP. The budgetary expenditure on health for 2003 was approximately C1,154 billion cedis (USD 134.26 million (WHOSIS 2006). Central government expenditure on health for the same year was estimated to be about 5% of total government expenditure. The government contributed about 38% of total health expenditure, whilst 68.2% of this was private expenditure. Out of pocket expenditure made up 100% of private expenditure on health (WHO 2006). The per capita expenditure on health was approximately US$5 (average exchange rate) compared to the US$34 recommended by the WHO Macroeconomics Commission on Health for low income countries to provide basic health care services (Sachs 2001). The Global fund approved an initial amount in the year 2003 to accelerate access to prevention, care support and treatment of malaria for 20 districts and this has since been expanded to cover all districts in the subsequent phase which began in 2005 (WHOSIS 2006).

As part of the Medium Term Health Strategy (MTHS), a Ghana Health Service (GHS) was created with the passage of the Ghana Health Service and Teaching Hospitals Act in 1996. The GHS is distinct from the Ministry of Health and not part of the General Civil Service. It is responsible mainly for service delivery whilst the Ministry of Health is a policy-making body. Organization of health care is based on a three-tier Primary Health Care (PHC) system. Functional District Health Management Teams (DHMTs) are responsible for the planning, implementation and management of health services in all districts; these teams vary considerably across districts in their capacities to carry out these responsibilities.

2.2.2 The burden of malaria in Ghana

Malaria remains a major contributor to morbidity and mortality in Ghana. It is the most commonly reported disease at outpatient departments (OPD) and accounts for approximately 40% of total OPD attendance and 33% of deaths among children less than five years of age (MOH 2000; WHOSIS 2006). It is also the single most important contributor to the greatest number of "healthy days of life lost" in Ghana (GHAT 1981).

Between 1952 and 1954, Colbourne and Wright carried out a series of studies on malaria epidemiology in Ghana (then Gold Coast). They classified the country for the purposes of malaria transmission into 3 ecological zones; the relatively dry coastal plains, the forest belt with high rainfall unevenly distributed throughout the year and the northern savanna with a total rainfall similar to the coastal plains.

There were 24 infective bites per person per year in the forest belt and very little seasonal variation in malaria transmission with parasite rates being only slightly higher after the rains. The number of infected bites per person in the suburban parts of Accra at the time was about 200 times what pertained in the urban part; spleen and parasite rates in 1-4 year olds were above 75% during the rainy season in the suburban areas and approximately 30% and 50% respectively in the urban part of the city (Colbourne and Wright 1955a; Colbourne and Wright 1955b). The stratification described by Colbourne and Wright remains broadly valid today, even though malaria is increasingly being

recognized as varying in epidemiology over small distances. Later studies indicated that the rural parts of the coastal plains were different. In the Danfa area, which is rural, spleen rates were consistently above 45% but below 50%. Parasite rates there were above 30% with little seasonal variation (Wurapa *et al.* 1978).

In the northern savanna of the country, Binka and others found marked seasonal variation with parasite rates among children ranging from 85-95% in the wet season. Malaria deaths were highly correlated with rainfall in the previous two months (r=0.90 p<0.001). The predominant parasite species was *P. falciparum*. They found that parasite rates were highest and haemoglobin concentrations lowest among children aged 6-11 months (Binka *et al.* 1994). In the southern part of the country, Afari and others showed that crude parasite rates ranged between 19.6% and 33.5% in the dry season and 33% to 44% in the wet season. In this area also, *P. falciparum* was found to be the predominant parasite species with high prevalence rates of up to 96% in the rainy season and 80% in the dry season. The prevalence of *P. malariae* was 20.4% and that of *P. ovale* 2.7% (Afari *et al.* 1992; Afari *et al.* 1993)

In the Dangme West district, which is also coastal and rural, and situated in the southern part of Ghana, parasite rates were found to be 42% in the dry season and 51.3% in the wet season (Afari *et al.* 1995).

More recent studies carried out by the Ministry of Health in Ghana indicate that generally, crude parasite rates in the population range from 10 to 70%, with *P. falciparum* accounting for 80-90% of parasites. Only three species of *Plasmodium* are present. These are *P. falciparum* (80-90%), *P. malariae* (20-36%) and *P ovale* (0.15%). Mixed infections of *P. falciparum* and *P. malariae* are not uncommon. The principal vectors are *Anopheles gambiae* complex and *A. funestus* accounting for 95% of all catches. A. *gambiae s.s* of the complex is the predominant species. *A. melas* and *A. arabiensis* exist in small proportions (MOH 2000).

2.3 Control of malaria in Ghana

Between 1961 and 1962, Ghana, like many other African countries, initiated with the support of World Health Organization (WHO), the malaria eradication programme (MOH 1962). Towards the end of 1967, it was realized that the programme was not sustainable resulting in its termination on the advice of WHO. Contributing to this was the emergence of global resistance to DDT, which also stalled the programme in many other countries.

Since then, the focus has been on control of the disease with emphasis on early diagnosis followed by prompt and adequate treatment. The first line drug for treatment of malaria in Ghana until the year 2005 was either chloroquine or amodiaquine. Chloroquine and many other anti-malarial drugs are available at health facilities, licensed pharmacies and chemical sellers as well from "table top" traders selling other petty items in the market or at home. In addition, there are numerous drug peddlers moving from house to house, especially in the rural areas, selling anti-malarial drugs (MOH/GHS 2001). The knowledge of these unlicensed sellers of the correct dosage is uncertain but probably poor. Management of the disease at most health facilities is presumptive since most primary care facilities in the country do not have laboratory services and those that do have them are overwhelmed.

Self-medication is very common and seems to have increased with concomitant reduction in the utilization of health facilities when user fees were introduced in 1985. It is frequently the first option many households take (Adjei and Aryee 1995; Asenso-Okyere et al. 1997; MOH/GHS 2001; Waddington and Enyimayew 1989). Studies have shown that there are misconceptions about the causation of the malaria, although symptoms and signs are readily described by caretakers. Watling and Gyebi-Ofosu reported that only 29% of caretakers in the Ashanti region of Ghana could link malaria with the mosquito (Watling et al. 1995). In a study carried out in the Dangme West District in 1994, only 10% of rural respondents mentioned mosquitoes as a primary cause of malaria although about 33% included the mosquitoes among the causes they mentioned (Agyepong and Manderson 1994). In a recent study in two communities in

different parts of Ghana, 69% of child caretakers mentioned the mosquito spontaneously as the cause of malaria, but only half of them sought appropriate care within 48 hrs of the onset of the illness (Ahorlu *et al.* 2006).

Personal protective measures commonly used in both urban and rural areas throughout the country include screening of houses, use of bed nets, as well as the use of pyrethrum mosquito coils, aerosols and other mosquito repellents.

Between 1988 and 1990, an *in vivo* test for susceptibility of *P. falciparum* to chloroquine was carried out among children aged 6-15 years in three ecological zones in Ghana. The results showed chloroquine resistance rates of 17.1-22.7% in the coastal zone, 8.6-10% in the northern savanna and 3.1–6.3% in the forest zone (Afari *et al.* 1992). More recently, a study in six sites in different eco-epidemiological areas of the country showed parasitological failure rates ranging from 22% to 49% in the coastal areas, 37% to 47% in the northern savanna and 46% in the forest zone (Koram 2003a). A change of policy with regards to the first line anti-malarial drug for treatment has recently been carried out from chloroquine to an artemisinin combination drug (ACT), amodiaquine-artesunate.

Since the founding of the Roll Back Malaria Partnership (RBM) with the goal of halving the world's malaria burden by 2010, the National Malaria Control Programme (NMCP) and Roll Back Malaria secretariat in Ghana have drawn up and begun implementation of their strategic plan. A baseline survey for on-going monitoring and evaluation of their progress towards the goal of the partnership has also been carried out. The RBM secretariat in Ghana conducted a series of consultative missions in the year 2003 to first determine the additional inputs the country would require to support the attainment of the Abuja targets, and also to re-invigorate co-operation between the RBM partners to support the needed progress (Ghana-RBM 2004).

2.4 The epidemiology of severe malaria

The WHO defines severe malaria in children as any child with asexual parasitaemia and no other confirmed cause for his/her symptoms and one or more of the following clinical

or laboratory features: prostration, impaired consciousness, respiratory distress (acidotic breathing), multiple convulsions, circulatory collapse, pulmonary oedema (radiological), abnormal bleeding, jaundice, haemoglobinuria, or severe anaemia (Hb<5g/dl) (WHO, 2000b). It is estimated that there are 1.42 to 5.66 million cases of severe malaria each year with a greater than 13% case fatality among children under 5 years of age (Murphy and Breman 2001).

The principal cause of the disease in areas of high transmission is *P. falciparum*. Over 90% of all life-threatening cases of malaria are in African children and most of the estimated one million malaria deaths are in children up to 5 years old who live in areas of intense transmission of *P. falciparum,* especially in sub-Saharan Africa (WHO 1996). In parts of the world where endemicity of *falciparum* malaria is stable, severe malaria is mainly a disease of children from the first few months of life to the age of five years. It is less common in older children and adults because of acquisition of partial immunity.

Within sub-Saharan Africa, there are areas with low or epidemic transmission, where severe malaria occurs more commonly in adults than it does elsewhere in Africa (Endeshaw *et al.* 1991) as well as in children. Non-immune or partially immune travelers and migrant workers are also vulnerable to severe malaria. Many studies describe a pattern of disease in African children that differs considerably from that seen in non-immune adults (Brewster *et al.* 1990; Marsh *et al.* 1995; Molyneux *et al.* 1989). It is uncertain whether these differences in clinical manifestations of severe disease are due mainly to the age of the affected individuals or to other differences between populations in the characteristics of host, parasite, pattern of exposure, or provision of services. Some studies have suggested that approximately one infection in a hundred go on to cause complications (Greenwood *et al.* 1991). It is, however, thought that these figures differ between populations depending on transmission characteristics, health service provision, drug sensitivities and a variety of parasite and host factors (WHO 2000b).

The clinical spectrum of severe malaria varies with age. The mean age of children who present with severe malarial anaemia is about 1.8 years, compared to 3 years in those who present with cerebral malaria (WHO 2000b). Existing data suggest that in populations subjected to high inoculation rates throughout the year, severe anaemia may

be the commonest complication, affecting mainly infants and young children, while in areas with less intense or seasonal transmission, cerebral malaria in slightly older children may predominate (Slutsker *et al.* 1994a; Snow *et al.* 1994; Snow and Marsh 1998). Recent evidence indicates that metabolic acidosis, presenting as the clinical syndrome of respiratory distress, is an important feature of severe malaria that may present separately or in combination with either cerebral malaria or anaemia. Mortality among anaemic children was greatly increased when there was associated respiratory distress (Lackritz *et al.* 1992; Marsh *et al.* 1995).

2.5 Anaemia as a measure of malaria morbidity

The WHO defines severe malarial anaemia as a haemoglobin concentration of less than 5 g/dl or a haematocrit (packed cell volume) of less than 15% in the presence of *P falciparum* infection (WHO 2000b). Malaria accounts for about 18% of disability-adjusted life-years (DALYs) due to anaemia (defined as haemoglobin (Hb) concentration less than 11 g/dl) according to the Global Burden of Disease for 1990 (Murray and Lopez 1996).

Anaemia is a multi-factorial problem, and may result from factors such as dietary deficiencies, iron loss through helminth infection or destruction and decreased production of red blood cells by infectious diseases. Sickle cell disease has also been recognized as an important risk factor for anaemia in sub-Saharan African countries (Akenzua *et al.* 1985; Fleming and Werblinska 1982; Menendez *et al.* 2000; Nussenblatt and Semba 2002; Stoltzfus *et al.* 2000). Several of these factors may operate in the same individual (Fleming and Werblinska 1982; Menendez *et al.* 2000). All forms of anaemia may act as a risk factor, predisposing children suffering from any illness to fatal outcomes (Brabin *et al.* 2001).

Studies have shown that in areas of high and stable transmission, malaria is the major contributor to anaemia which is responsible for more deaths than cerebral malaria (Kahigwa *et al.* 2002; Koram *et al.* 2000; Menendez *et al.* 1997; Murphy and Breman 2001; Newton *et al.* 1997; Slutsker *et al.* 1994a; Snow *et al.* 1994; Stoltzfus *et al.* 2000).

Parasitaemia is reported to be the primary cause of anaemia in Africa, especially among very young children (Kahigwa *et al.* 2002; Kitua *et al.* 1997; Koram *et al.* 2000; Menendez *et al.* 1997; Stoltzfus *et al.* 2000).

Studies in Northern Ghana, found a significant drop in the mean Hb concentration of children less than 5 years of age by the end of the high transmission season with no difference in anthropometric indices (Koram *et al.* 2003b; Koram *et al.* 2000). A randomized controlled trial carried out in Tanzania showed that in a highly endemic area, malaria accounts for about 60% of anaemic episodes whilst iron deficiency contributes only 30% (Menendez *et al.* 1997). Another study in the same country, which investigated several risk factors for anaemia including sickle cell status and nutritional status among others, found that the single most important causative factor was *P. falciparum* parasitaemia [OR 4.3, 95% CI 2.9-6.5, P<0.001](Kahigwa *et al.* 2002). Repeated as well as chronic episodes of malaria are known to contribute to severe anaemia in children (Miller *et al.* 1994; Newton *et al.* 1998; WHO 2000c).

P. falciparum infection is known to contribute to the aetiology and severity of anaemia through several mechanisms, including the direct destruction of parasitized red blood cells, immune mechanisms (including the direct destruction of non-parasitized red blood cells), and dyserythropoiesis (Facer 1980; Facer and Brown 1979; Weatherall and Abdalla 1982). Malaria may also contribute to iron deficiency, and thus anaemia, by reducing iron absorption during acute episodes (Molyneux *et al.* 1989) and through sequestration of iron in malaria pigment (Clark and Tomlinson 1949). Although malarial anaemia can occur as a consequence of repeated cycles of invasion, replication, and ultimately bursting of red blood cells (RBCs) due to the parasite, this form of anaemia frequently begins 1 or 2 days after the clinical onset of infection and resolves in approximately 7 days in patients receiving anti-malarial treatment (Hillman and Finch 1969).

In addition to the direct destruction of RBCs by the parasite, non-parasitized RBCs are also destroyed through increased activity of the reticuloendothelial system. Loss of parasitized and non-parasitized RBCs through host-induced immune responses in

conjunction with immune-mediated suppression of erythropoiesis, results in malarial anaemia.

Two clinically distinguishable types of malarial anaemia have been described: anaemia that develops rapidly following an acute attack of malaria and anaemia that develops insidiously due to persistent parasitaemia (Abdalla *et al.* 1980; Weatherall and Abdalla 1982). In general, the more severe the infection, the faster and greater the drop in haematocrit. In some children, repeated untreated episodes of otherwise uncomplicated malaria may lead to normochromic anaemia in which dyserythropoeitic changes in bone marrow are prominent. In these cases there is often monocytosis. The rate at which anaemia develops is an important determinant of the involvement of compensatory mechanisms such as the rightward shift in the oxygen dissociation curve. Hyperventilation, often termed respiratory distress, is an important indicator of decompensation (WHO 2000c).

Severe anaemia accounts for between 17% and 54% of malaria-attributed deaths in African hospitals among children less than 5 years of age (Biemba *et al.* 2000; Koram *et al.* 2000; Marsh *et al.* 1995; Slutsker *et al.* 1994a). In northern Ghana, the number of transfusions for young children at the district hospital followed the malaria transmission/rainy season closely (Owusu-Agyei *et al.* 2002).

Figure 2.2 below from the northern part of Ghana shows the seasonal variations in blood transfusions carried out on children at a district hospital.

Figure 2.2: Seasonal pattern of blood transfusion of young children in a district hospital in northern Ghana
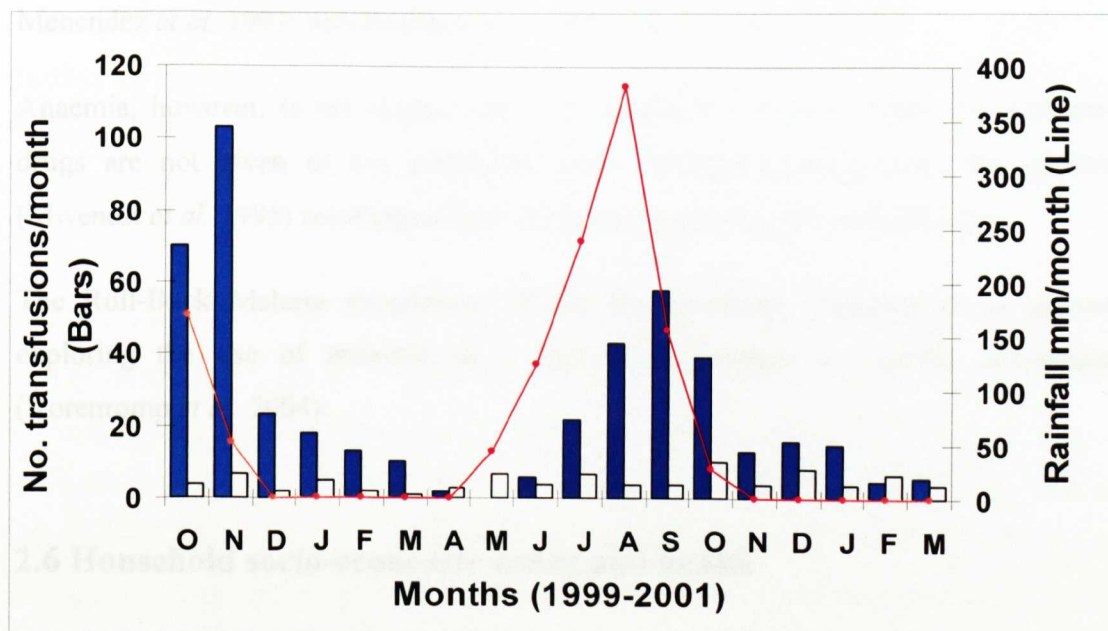
Courtesy Owusu-Agyei et al (2002), Am J Trop Med Hyg; 67(4): 371-7

Anaemia has been used as one of the main outcome measures for several malaria control measures in recent times. These have included the use of insecticide treated bed-nets. Malaria control with treated nets has been found to reduce the level of anaemia (Abdulla *et al.* 2001; Binka *et al.* 1996; Browne *et al.* 2001; Fraser-Hurt *et al.* 1999; Marbiah *et al.* 1998; Premji *et al.* 1995a; ter Kuile *et al.* 2003). Several intervention studies involving anti-malarial chemoprophylaxis, defined as the administration of an anti-malarial to an at-risk population in sub-therapeutic doses with the aim of preventing infection or its clinical manifestations, have also used anaemia as an outcome (Bradley-Moore *et al.* 1985b; Greenwood *et al.* 1989; Menendez *et al.* 1997). More recently, studies on intermittent preventive treatment which involves the administration of a full therapeutic course of an anti-malarial at intervals to an at-risk population at specified times regardless of whether they are infected (Greenwood 2004), have had as one of their main outcomes, anaemia (Dicko *et al.* 2004; Massaga *et al.* 2003; Schellenberg *et al.* 2001).

Indeed most malaria control trials have been known to be associated with improvements in haematological indices in both children and pregnant women (Greenwood *et al.* 1989; Menendez *et al.* 1997; Schellenberg *et al.* 2001; Shulman *et al.* 1999).

Anaemia, however, is not always linked to malaria by mothers/carers and sometimes drugs are not given or are withdrawn from children suffering from the condition (Mwenesi *et al.* 1995) resulting in such children progressing to severe anaemia.

The Roll-Back Malaria programme of the World Health Organization is currently exploring the use of anaemia as a measure of impact of malaria interventions (Korenromp *et al.* 2004).

2.6 Household socio-economic status and health

There is a well documented relationship between household socio-economic status and various aspects of health. Re-analysis of data from Demographic and Health Surveys of various countries by the World Bank has shown important differentials between richer and poorer households in mortality, nutrition, and care-seeking behaviour (Gwatkin *et al.* 2000).

Although the risk of malarial fever appears to vary little across socio-economic quintiles (Filmer 2005), an important gradient between the least poor and the poorest with regards to the risk of adverse outcomes has been recognized (Nathan *et al.* 2004). A similar gradient has been found between the poorest and the least poor in the utilization of health services.

2.6.1 Socio-economic status and utilization of health services

Household socio-economic status is known to influence care-seeking for childhood illness. In particular, this is brought to the fore in areas where payment of user fees out of pocket and at the point of use is in place. User fees are known to restrict utilisation of health services and create a large pool of unmet need (Deininger and Mpuga 2004). It

may encourage inappropriate self treatment and use of partial drug doses or may act as a barrier to prompt use or any use of health facilities (Russell 2004). Out of pocket payment (including user fees) has been found to be more regressive than any other method of financing health care, since it takes a higher proportion of the income of poor households than less poor ones (Van Doorslaer and Wagstaff 1993). Several studies have reported that members of the poorest households are less likely to seek care than people from more affluent households (Gotsadze *et al.* 2005; Taffa and Chepngeno 2005).

The poorest were reported to have consulted any modern health care giver half as often and to do nothing twice as often as the least poor in Burkina Faso (Develay *et al.* 1996). Among slum dwellers of Nairobi in Kenya, sick children belonging to households with the lowest monthly expenditures were 20-30% less likely to be taken to health facilities (Taffa and Chepngeno 2005). In Albania, Hotchkiss and others found that service utilization varied substantially by household wealth and geographic location. Although the prevalence of self-reported chronic and acute health problems did not vary substantially by household wealth, those in the highest quintile were more likely to seek care than those in the lowest quintile (53.8% versus 30.1%). They also found that the poor were more likely to pay for consultations but less likely to make gift payments than better off clients (Hotchkiss *et al.* 2005).

In Tanzania and Malawi, a higher educational level of the head of household was associated with seeking care from a health care provider or attending a clinic (Slutsker *et al.* 1994b; Tarimo *et al.* 1998). In a comparison of two communities of different socio-economic status in Ghana, Britwum and Welbeck found that the poorer community with lower levels of education was more likely to engage in self-treatment (Biritwum *et al.* 2000). In Tanzania, it was found that the main difference between the poorest and those who were better off was not in the likelihood of falling ill but in the probability of obtaining suitable treatment once ill. Carers of children from wealthier families had better knowledge about danger signs and were more likely to send their children to a health facility when ill than carers from poor families (Schellenberg *et al.* 2003). Gertler and van der Gaag suggest that the poor are more sensitive to the cost of services than the

less poor and tend to reduce utilization disproportionately more in the face of rising health care costs (Gertler and van der Gaag 1990).

2.6.2 Socio-economic status and health outcomes

In both developed and developing countries, on a macro level, poverty or low income has been shown to be an important determinant of the health status of the population (Backlund et al. 1996; Filmer and Pritchett 1999; Gwatkin et al. 2003; Marmot 1999; Shaw et al. 1999). A 1993 World Bank report examined the relationship between life expectancy and Gross National Product (GNP) per capita in more than 100 countries from 1900 to 1990 and found that at low levels of GNP, a small increase in GNP was associated with a large increase in life expectancy. As GNP increases, however, the relationship levels off (WorldBank 1993).

Some studies have also shown that health improves with income (Ettner 1996; McDonough et al. 1997; Meara 2001). Household food insecurity arising from poor socio-economic status has also been found to be associated with poor health among children ≤ 36 months of age in the United States (Cook et al. 2004). Some studies in Africa have reported a significant association between household socio-economic status and malaria (Kahigwa et al. 2002; Klinkenberg et al. 2006; Ong'echa et al. 2006).

The direction of the causal relationship remains unclear, however, (Meer et al. 2003) and it is not certain whether it is because individuals with more wealth can afford better care and live in healthier environments (Ettner 1996; Smith 1999) or because healthier individuals are able to work more than those who are ill, enabling them to accumulate more wealth (McClellan 1998; Wu 2003). Using an econometric model, Meer and others concluded that the wealth-health connection is not driven by short-run changes in wealth while not ruling out the possibility of a long-term impact (Meer et al. 2003). Benzeval and Judge, in their analysis of data from the British Household Panel Survey 1991-1997, suggest that persistent poverty is more harmful for health than occasional episodes and conclude that long-term income is more important for health than current income (Benzeval and Judge 2001).

Bauman and others examined the cumulative effects of 'social disadvantage' (poverty, low parental education and single-parent household) on child health by analyzing data from the National Health Interview Survey Disability Supplement of 1994 and 1995 in the United States. They found a strong association between social disadvantage and poor child health, and that having insurance did not appear to reduce the observed disparities (Bauman *et al.* 2006).

Two studies in Gabon and Gambia, however, did not find any association between socio-economic status and severe malaria (Koram *et al.* 1995; Luckner *et al.* 1998).

2.7 Improving access to effective treatment for malaria

Much current research concentrates on preventing individuals (especially children and pregnant women) from becoming infected with malaria. There are currently a number of proven effective preventive measures including the use of treated nets and intermittent preventive treatment. Preventing disease is clearly the ideal; however, in areas of high endemicity, some infections will occur even when good control measures are in place. Most deaths from malaria are preventable using currently available treatment, if they are applied early enough in the infection.

A study in Niger by Chawla and Ellis reported that only 2.7% of the population they studied sought formal care, even though 20% were ill over the period of the study (Chawla and Ellis 2000). Mugisha and others found that in Burkina Faso, regardless of the illness in question, a substantial number of patients (81.2% for malaria and 64.3% for all other illnesses) chose self-treatment (Mugisha *et al.* 2002). In Ghana, Asenso-Okyere and others found that self-medication was the first choice of treatment for 65.8% of children, 69.1% of adult males and 58.9% of adult females (Asenso-Okyere *et al.* 1998).

Barriers to effective treatment may occur at many levels, including failure by parents to recognize illness in a child until it is too late, difficulties in accessing health services leading to delayed presentation and inadequacy of diagnosis or treatment once medical services are accessed. These issues can be divided into problems in accessing appropriate

health care and problems once health care is accessed. Problems in accessing health care may include socio-cultural issues particularly in relation to the concept of disease causation and treatment, the non-availability of health facilities, distance from health facilities, travel costs to health facilities, and opportunity costs of seeking health care. In addition, the perception by the household of poor quality of care in the health facility may result in their reluctance in seeking care there. Problems that come into play once health care is accessed include mis-diagnosis, mismanagement, drug resistance and non-adherence to therapy (Agyepong *et al.* 2002; Amexo *et al.* 2004; Ansah *et al.* 2001; Yeboah-Antwi *et al.* 2001). Many deaths are likely to be due to several factors combining to cause delay in receiving adequate treatment rather than to one single reason.

Some of the issues that influence access to formal health care are considered below:

Perceived quality of service

Variables affecting quality of care include the number and types of health personnel available, the variety and consistency of drug supply and the physical condition of the facilities themselves (Shaw and Griffin 1995). In addition, provider attitude and behaviour reflect the quality of care from the user's perspective. Some authors believe that the cost of health services does not affect utilization as much as the quality of care. Results from some studies suggest that some of the harmful effects of user fees on access to care can be mitigated if fee income is used effectively to improve quality of care as perceived by the population (Akin *et al.* 1986; Lavy and Germain 1995; Lavy and Quigley 1993; Litvack and Bodart 1993). A "natural experiment" in Cameroon involved the study of the effect of the introduction of user fees alongside improvements in the quality of services. This showed that proportionately more poor people sought care at facilities that also improved quality. Conversely, the poorest were least likely to use the "control" health centres where no improvements in quality were achieved (Litvack and Bodart 1993).

Socio-cultural factors

Some socio-cultural factors have been found to affect the response of the family to an infection and therefore its outcome (Caldwell 1979). The experience of illness including its prevalence in the community, the frequency of infection of household members, the past history of episodes of illness in the affected individual, familiarity with and access to different treatment modalities and therapies and a variety of other social factors are known to influence care and treatment (Agyepong and Manderson 1994; Csete 1993; Fitzpatrick *et al.* 1984). Previous interaction with the health system encourages use of the system for an illness episode. In the Danfa project, it was found that previous interaction with the health system was more likely to result in use of the system for an illness episode (Belcher *et al.* 1975).

Social norms and practices have also been found to influence treatment seeking behaviour. Mwenesi found in Western Kenya, that although mothers could recognize mild malaria, they did not link the symptoms of severe malaria to the disease (Mwenesi *et al.* 1995). Convulsions in many communities are thought to be "not a hospital disease" and therefore ought to be treated at home. In a Ghanaian study, belief in a supernatural cause of illness led to delays in treatment because time was spent finding out what the cause of the illness was (Asenso-Okyere *et al.* 1998). In about 80% of cases of those who died from severe malaria in a Gambian study, the mother either did not seek treatment or had used ineffective traditional treatment (Greenwood *et al.* 1987b).

In Thailand, it was reported that people came to the clinics after an average of 2.3 to 6 days after the onset of symptoms and most of them had tried self-medication prior to seeking care at the clinics (Kaewsonthi and Harding 1986). In Uganda, 38% of those who presented at a health center had had symptoms for more than a week (Kengeya-Kayondo 1993).

The educational level of the mother has a major influence on health related behaviour (McCombie 1996). A mother's response to an infection may depend on her individual situation, socio-cultural practices in that community as well as the organization and resources for health care in that community. Maternal recognition of certain signs and

symptoms of childhood illness has been cited as a critical factor determining health care seeking behaviour and some argue that this and health beliefs are important barriers to care-seeking (D'Souza 1999; de Silva *et al.* 2001; Goldman and Heuveline 2000; Hill *et al.* 2003; Yoder and Hornik 1996). Rural-urban differences in health-seeking behaviour have also been observed (Glik *et al.* 1989).

Availability of health services

Availability of health facilities has been recognized as important (Glik *et al.* 1989; Stock 1983). The availability of services as well as the distribution and organization of alternative sources of care also affect the choice of sources of health care that people make. Some studies have found that mothers in urban areas are more likely to use health facilities than those in the rural areas (Glik *et al.* 1989; Odebiyi 1992). In some rural areas in Ghana, Asenso-Okyere and others reported that the only contact the inhabitants have with orthodox medicine is through untrained, semi-literate drug peddlers who move from one village to another to sell drugs and who sometimes give injections (Asenso-Okyere *et al.* 1998).

Distance and travel costs

Distance from the health facility and travel costs have been identified by several authors as having significant effects on access to health care (Glik *et al.* 1989; Stock 1983). They argue that these are more important than the actual cost of the services. In a Ghanaian study, the direct effect of user fees on utilization was found to be less significant than the effects of distance and travel costs (Lavy and Germain 1995). In Tanzania and Guinea, mothers were more likely to use a public health facility if it was close by (Glik *et al.* 1989; Mtango *et al.* 1992). Roovali and Kiivet found that hospitalization and re-admission rates declined with increasing travel time to the nearest hospital in Estonia (Roovali and Kiivet 2006).

However, some studies found that although travel distance had a significant negative effect on user's ability to choose their health facility it was less important than the actual

price users paid for services (Shaw and Griffin 1995). Not all patients used the closest source of care in Thailand (Kaewsonthi and Harding 1986). A study in Ghanaian rural communities discovered that children with severe illness were being treated at home because the parents could not afford the bills at the health facility only five kilometres away (Asenso-Okyere *et al.* 1998). Stock reported that even though per capita consumption of health care decreases exponentially for concentric distance bands, individual villages show great disparities in utilization rates, which are only partly attributable to distance (Stock 1983).

Cost of services

The cost of services is one of the more modifiable barriers to health care. In an effort to solve the problem of facilitating access to health care, various mechanisms have been tried in different countries. There is an on-going debate about the impact of user fees on utilization of and access to health services, especially by the poor.

Payment of (increased) health care fees has been shown to become an unacceptable burden on some households, leading to delayed or adapted treatment-seeking, use of informal and less effective sources of health care, and further impoverishment of marginalized families (Asenso-Okyere *et al.* 1998; Gilson and McIntyre 2005; Mbugua *et al.* 1995; Russell 1996). Studies in Ghana, Burkina Faso and elsewhere have shown that the introduction of user fees deterred people, especially the poor and children, from using health care services (Acharya *et al.* 1993; Fabricant *et al.* 1999; Pannarunothai and Mills 1997; Sauerborn *et al.* 1994; Sen 1997; Waddington and Enyimayew 1989). It has been found that healthcare financing mechanisms that place considerable emphasis on out-of-pocket payments can impoverish households. The World Bank acknowledges that out-of-pocket payments -especially for hospital care- can make the difference between a household being poor or not (Claeson *et al.* 2001).

Costs of ill health to the household comprise direct and indirect costs (McCombie 1996; McIntyre *et al.* 2006). The direct cost of care covers financial costs of health care (consultation, diagnostic services and drugs) as well as other financial costs related to

seeking care such as transport costs and food for the sick person and his/her caretaker. Indirect costs cover the time costs of the person who is ill and that of his/her caretaker. In this study, we reduced the barrier due to the direct cost of care by paying the premium for the study subjects which took care of the financial costs of health care leaving other direct costs such as transport and meals. The indirect costs of health care also remained as it was.

McIntyre and others provide a simplified flow chart of key issues that relate to the economic consequences of illness below (Figure 2.3):

Figure 2.3: Simplified flow-chart of key issues relating to economic consequences of illness
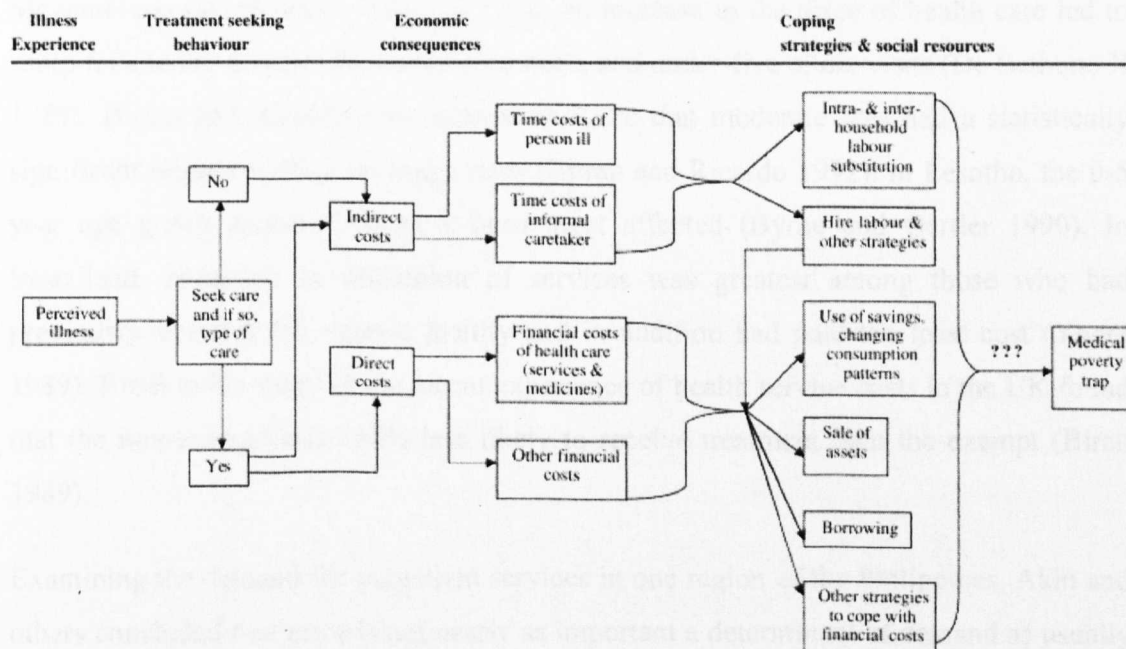
McIntyre D et al (2006), Social Science and Medicine 62:858-865

In Burkina Faso, it was found that much more out-of pocket money was spent on treatment from health workers than on self-treatment or traditional healers (Mugisha *et al*. 2002) and this deterred many from using the health facilities. User fees have, as a consequence, been found to have a negative impact on the utilization of health facilities

especially by the poor (Russell and Gilson 1997; Waddington and Enyimayew 1989). Data from the Nairobi Demographic and Surveillance system (NDSS) showed that 49.6% of households cited lack of finances as the main reason for not seeking care outside the home (Taffa and Chepngeno 2005). People are known to postpone seeking care from health facilities partly because of the fear of paying user fees (D'Souza 1999; Foster 1991).

Studies in Ghana, Zaire, Mozambique and elsewhere showed that the introduction of user fees was associated with a drop in utilization. In Ghana, when user fees were introduced in 1985, attendances dropped to a quarter of the 1984 levels with a gradual rise to the original level in urban areas but with persistence of low levels of attendance in rural areas (Waddington and Enyimayew 1990). A similar situation was observed in Mozambique (WorldBank 1994). In Zaire, an increase in the price of health care led to sharp falls in the demand for curative contacts and under-five clinic visits (De Bethune X 1989). Bitran and Ricardo also showed in Zaire that moderate fees had a statistically significant negative effect on usage rates (Bitran and Ricardo 1992). In Lesotho, the 0-5 year age group appeared to have been most affected (Byrne and Gertler 1990). In Swaziland, reduction in utilization of services was greatest among those who had previously attended the nearest facility and in addition had paid the least cost (Yoder 1989). Birch in his study of the recent experience of health service costs in the UK found that the non-exempt were 40% less likely to receive treatment than the exempt (Birch 1989).

Examining the demand for outpatient services in one region of the Philippines, Akin and others concluded that price is not nearly as important a determinant of demand as usually assumed. They found that a price increase in one source had caused a switch in favour of alternatives (Akin *et al.* 1986), which may not always be desirable. The study, however, was unable to study the differences by income groups. Gertler *et al* did and found price elasticity to be much higher for lower income groups (Gertler *et al.* 1987). Shaw and others believe that the major disadvantage of some of these studies is that there is very little information on the socio-economic characteristics of users, the quality of services

and other confounding factors and therefore the drop in utilization patterns following the introduction of fees may be over-stated (Shaw and Griffin 1995; Yoder 1989).

Creese, however, cites several recent papers from utilization reviews in both low income and industrialized countries which provide evidence that the use of health services by the poor is more affected by price increases than is use by the rich. He contends that none of the demand studies so far refer to actual field experiments in which user fees were introduced and their effects studied (Creese 1991). Birch concludes that findings from the US Rand study imply that at least some of the service utilization deterred by charges leads to adverse health outcomes (Birch 1989).

It is not, therefore, certain to what extent the financial barrier to health care is important in the control of diseases such as malaria, particularly in children less than five years of age. Various mechanisms aimed at addressing this have been tried in the past and are still being used.

2.8 Methods of overcoming financial barriers to obtaining effective treatment

Even the most optimistic studies of willingness and ability to pay find that some proportion of the population truly cannot pay and requires assistance (Shaw and Griffin 1995). To avoid the problems associated with trying to identify those who cannot pay, some governments and ministries of health have instituted universal coverage with free primary care for identified groups such as children under five who are vulnerable to many infectious diseases including malaria. It is expected that reducing financial barriers will lead to prompt seeking of appropriate health care for acute episodes of illness avoiding a chronic course that could result in severe disease such as severe malarial anaemia.

Stierle et al classified the mechanisms used for overcoming financial barriers into three main categories: *differentiation of prices, subsidizing specific services and activities that address specific target groups (targeted subsidy)* and *exemption from payment* (Stierle *et al.* 1999). Others have also instituted pre-payment schemes.

Price differentiation

Price differentiation which introduces lower prices for the target group than for all others may be based on socio-economic factors such as income, demographic factors such as age and gender or health factors such as infection with a contagious disease or a combination of these factors. Sometimes, in areas where a large proportion of the population is poor, prices are maintained at a low level throughout that community but set higher in other areas with higher purchasing power (Stierle *et al.* 1999).

Subsidizing specific services and activities that address specific target groups

Subsidies of services or specific activities are recommended for activities that yield a high level of externalities e.g immunization. An externality is an effect of a purchase or use decision by one set of parties on others who did not have a choice and whose interests were not taken into account. So even though the interests of other members of the community are not taken into account when certain households choose to immunize their children, those other households benefit from the reduction in disease burden. Subsidies help to deliver these services free or at a very low price to the poor who are usually the ones most in need of the services. Subsidies of specific activities are, however, not necessarily targeted to the very poor (Stierle *et al.* 1999).

Exemption schemes

Stierle and others identify two types of exemption schemes. The first type links eligibility to professional status e.g civil servants whilst the other links eligibility to socio-economic or health status e.g poverty or age. Most countries implement either one or both types of the scheme in some form. Exemption schemes introduced by numerous African countries have been plagued with problems yielding inequitable and inefficient results. The problems result from insufficient practical direction on how the exemptions should be implemented (Stierle *et al.* 1999).

The procedures are sometimes humiliating and arbitrary and it appears that most persons including the very poor tend to avoid situations where they have to officially explain their economic situation, knowing their request may be rejected (Wouters and Kouzis 1994). There are also issues of how to identify the poor. In most cases, the same organization, in this case the local health facility staff, is responsible for authorizing exemptions and for financial viability of the health facility. There is, in addition, often limited managerial capacity to carry out all these tasks in addition to delivering health care (Stierle *et al.* 1999). Evidence from many countries demonstrates the problems associated with implementing exemptions with the aim of targeting the poor and vulnerable. In Ghana, the inability of the existing exemption scheme to protect the poor and vulnerable has been documented (Garshong *et al.* 2001).

Pre-payment schemes

The major objective of pre-payment schemes, is to protect subscribers from unaffordable health care costs at times when they are least able to pay, by collecting a contribution when their cash incomes are highest (Lambo 1996). It is suggested that systems of pre-payment and health insurance may overcome some difficulties in financing health services and have the potential to facilitate access to health care. Insurance-like systems have an important advantage of separation of time of payment from time of use of services so that payment does not occur at the moment of greatest vulnerability. These systems do not directly solve the problem of permanent exclusion of the poor and vulnerable from health care but it may be possible to provide exemptions from premium payment for the very poor or vulnerable by having a third party such as the local government or other public institution, pay or subsidize their premium (Stierle *et al.* 1999).

The traditional kind of health insurance or pre-payment scheme involves the sharing of the risks of incurring health care costs by a group of individuals. Under such schemes, each year households pay a certain fixed amount of money regardless of whether they are ill or not. This contribution is referred to as a premium. An appropriate management structure is then assigned the responsibility of administering the funds to support services

at particular health facilities. Benefits are defined for those who have contributed to the fund, and some conditions usually spelt out for claiming those benefits. Any time members of the scheme are ill, money is taken from the fund to which they have contributed to take care of their health care costs. This system is especially useful for people in the informal sector who do not earn income on a regular basis. Unless the government provides such people with free health services, or they have somebody such as a relative to pay for their behalf, such people may not have access when they need it.

Schemes such as this should be able to eliminate "under the table" fees often taken by some corrupt providers from patients who are not clear about the pricing system at the clinic or hospital and are often made to pay more than they should. This may not, however, be the case when re-imbursement of the insured is less than the actual cost of care since in that case, demand greatly exceeds supply. Such schemes can also promote community involvement in the provision and management of health care and strengthen the referral system by improving utilization of primary care clinics for uncomplicated illness whilst freeing secondary and tertiary centres to take care of more complicated illness. Since in some of these schemes at least part of the referral cost is taken care of and patients do not need to immediately produce money on arrival, people who are referred are more likely to go to the referral facilities unlike the situation when they have to pay up front. In the latter case, they take the referral note, go home and hope for the best.

Schneider and others found in their work on pre-payment schemes in Rwanda, that non-members paid about four times more for an episode of illness than non-members. Expenditure for an episode of illness in this case included the cost of care incurred for that same episode before visiting a provider and out-of-pocket expenditure during the visit to that provider and any other providers later on (Schneider and Diop 2001).

It is expected that improved financial access is likely to improve utilization which, in turn, will improve the health status of patients. Subscribers to schemes such as this are more likely to seek care promptly when they are ill avoiding a situation where the illness takes a chronic course or becomes more severe.

2.9 Health insurance in Ghana

With the re-introduction of user fees in Ghana in 1985 and increasing health care costs, it is becoming increasingly difficult for people to pay for their health care at the point of use. This is because the income of most people is meagre and does not enable setting aside any part of it for eventualities. Health care costs, therefore, represent a significant proportion of household income. In view of this, the idea of initiating a health insurance scheme became a viable option. In the late 1980s the government and the Ministry of Health, tried to identify groups that might be covered by a "National Health Insurance scheme". In 1994, the Ministry commissioned a consultancy to explore the feasibility of operating such a scheme. Community insurance was not considered and the scheme never took off.

Ghana's earliest experience with community health insurance was the Nkoranza Hospital Insurance scheme. This was started in 1992 by the Catholic Mission hospital for the people of that area. The benefits covered the full cost of admission in the Medical, surgical and maternity wards. Outpatient care was excluded. The scheme is still operational and has recently included outpatient care in its benefit package.

Subsequently, some local communities and groups came together to form schemes which were social-security related. The community participated in the design and implementation and fully or partially controlled the pool of resources through its representatives. In these schemes, the premium level and payment schedules were usually compatible with the pattern and level of cash income and community participation was paramount (Arhin 1995). However, all these schemes focused on catastrophic illness and did not include primary or preventive care in the benefits. Some smaller schemes had benefits that included transport to hospital for emergencies. Premiums and benefits varied from scheme to scheme and were locally defined.

The Dangme West Scheme, which began in the year 2000, was the first district-wide scheme as well as the first scheme in the country to have primary and preventive care included in its benefits. In subsequent years, with the assistance of the Danish Development Agency (DANIDA) and other NGOs, many more community and district-

wide schemes have been set up. Since the past five years the government has begun to revive the idea of a National Insurance Scheme which is not one monolithic structure but is a body for coordinating the different kinds of health insurance and pre-payment schemes currently in operation in the country and covering various informal sector groupings. It has also introduced social health insurance for those in formal employment. The private health insurance market is still in its infancy and insignificant relative to national expenditure on health care. In recent years, several insurance companies based in the capital have begun to offer health insurance policies (Arhin 1995).

The Ghanaian Parliament by an Act last year established the National Health Insurance scheme. However, the only subsidies listed in the Act relate to indigents. The National Health Insurance Scheme is on district-wide basis such as the Dangme West one and is at various levels of implementation in the 138 administrative districts. Some schemes like the Dangme West one which started earlier as a community initiative have instituted some changes in order to align themselves with the guidelines of the National Health Insurance scheme. A total of 135 district-wide schemes were operational as at the end of September, 2006.

CHAPTER 3 METHODS

3.1 Study design

The study was a two-arm, open, randomized controlled trial with a third observational arm. The third arm comprised households who had themselves enrolled in the pre-payment scheme during the period when the registration window was open. This arm was included in part to test the need for randomized approaches when examining the impact of interventions of this type, particularly because people who choose to enrol in a pre-payment scheme tend to be a self-selected group and may be different from those who do not, in many ways. This is especially so in areas where the enrolment is very low. It would also provide an opportunity to measure the bias that results from comparing such a group with non-enrolled individuals in observational studies. It also allowed for a comparison of the group who self-enrol with those who do not, both in health, health-seeking behaviour and socioeconomic status.

The study had a quantitative element based on pre-determined outcomes as well as a qualitative element.

3.2 Study site

The study was carried out in the Dangme West District in southern Ghana, a purely rural district with an estimated 2004 mid-year population of 115,005. The population lives in scattered small communities of less than 2000 people. There is widespread poverty in the district. It has been identified by the Government of Ghana as very deprived and as such selected to benefit from the Poverty Reduction Programme. The main local language is Dangme. The district is divided into four administrative sub-districts. There are 4 health centres and 6 community clinics in the district. Private sector facilities include two private clinics and one private maternity home. The doctor: population ratio is 1: 57,500 whilst the nurse: population ratio is 1:1,355. There are 300 traditional healers, a total of 92 trained traditional birth attendants (TBAs) & "wanzams" (local circumcisers) and an equal number of untrained TBAs who provide alternative medical services. There is one publicly owned laboratory based in the health centre situated in the district capital and

two privately owned laboratories in two other sub-districts. The district currently has no hospital, although one of the health centres is in the process of being upgraded to a district hospital. The inhabitants use all five surrounding hospitals for referral care as well as for some primary care.

Malaria control in the area at the time of the trial was based on prompt diagnosis and presumptive treatment of cases with chloroquine. The cost of treating a child with an acute episode of malaria in the publicly owned primary care health facilities in the district was approximately C10,000 (£0.75). Although exemption for children under five years became policy in the country in 1997, a recent review of the policy showed that only 6% of all children less than five years visiting public health facilities in Greater Accra Region, where the study district is located, were in practice exempted from paying fees for curative care (Garshong *et al.* 2001).

Figure 3.1: Map of the Dangme West district showing its location in Ghana
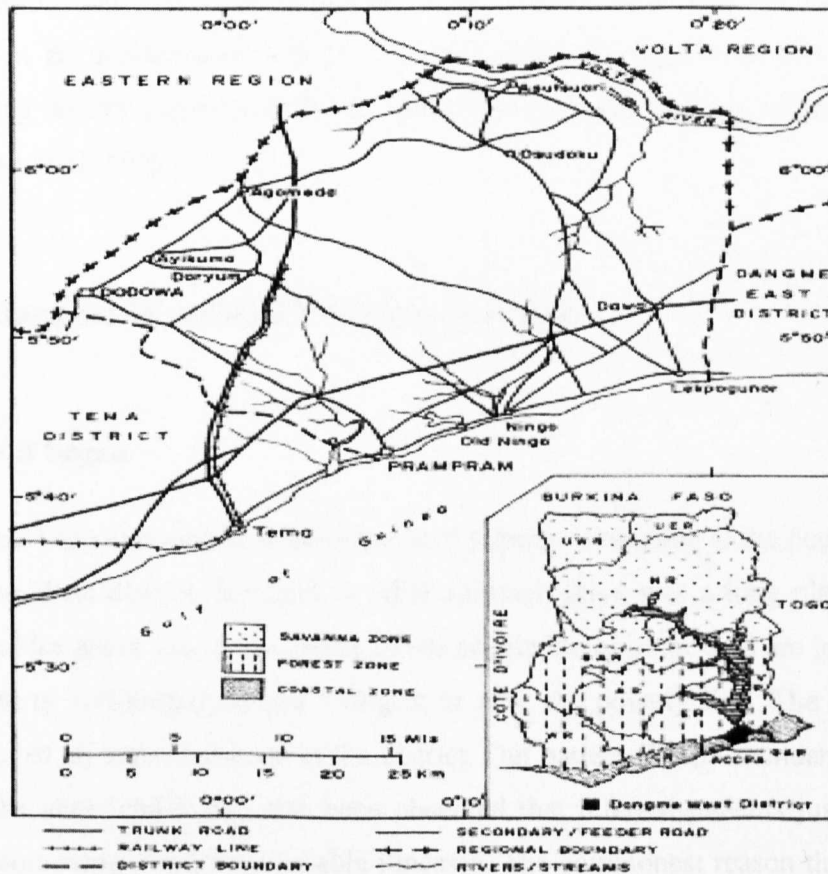
The use of insecticide treated nets is being promoted all over the country, including the study area, and some subsidized, treated nets were on sale at public sector health facilities to pregnant women and children less than five years during the period of the trial. Malaria accounts for over 50% of reported cases at the outpatient department. There are no reliable recent estimates of infant or childhood mortality for the area. There are two main seasons; a rainy season from May to October and a dry season from November to April. Malaria transmission is highest during the rainy season. The district is made up of two different ecological zones: a coastal savannah and a forest zone.

The coastal savanna area is mesoendemic whilst the forest area is hyperendemic for malaria. Home visit data suggest that the yearly incidence rate of malaria in the

hyperendemic area is fairly constant at approximately 107 cases per 1000 population compared to 59 cases per 1000 population in the mesoendemic area. The average man-biting rate in the former area is 0.79 bites per person per night with parasite rates of 61.3% during the dry season and 68.3% during the wet season among children 2-9 years of age (Afari et al. 1995).

3.3 The Dangme West health insurance scheme

3.3.1 How it began

The Dangme West community health insurance scheme is targeted at the people living in the Dangme West district. It began in 2000 although there was a long planning phase which lasted for about four years. Many of the people living in the area are in non-formal employment or self-employed and living at or near the poverty line. The scheme was initiated out of an identified need in the district. Out patient (OPD) attendance had been low over the years and it had also been observed that referred patients just went back home and sometimes died from curable illnesses. The commonest reason they gave was that they were unable to pay out of pocket fees.

In a survey carried out in the district ten years ago, community members indicated their willingness to participate in a scheme which would enable them to access health care whenever they needed it without having to worry about payment for services (Arhin 1995). Their participation was, however, conditional on a) the scheme giving access to health care in which drugs and basic laboratory investigations would be available, b) health staff being professionally qualified and respectful and c) a local solidarity association having a role in administering the participating health facilities and managing the scheme. The scheme was therefore designed together with community members through community durbars and the District assembly. The District Assembly is the local administrative authority for the district and is composed of elected representatives of the people.

3.3.2 Characteristics of the scheme

The scheme is non profit making and has democratic accountability to the members. It currently covers predominantly the use of health services, mainly in the public sector. These services are subsidized by government, which bears about 80% of the costs. The users, therefore, have to pay the remaining 20% or so out of pocket at the point of service use under a system known as cash and carry. Payment of health care costs out of pocket at point of service use appears to be a significant barrier to access to services especially for the poorest of the generally poor population of this district. The aim of the scheme is to replace the need to pay out of pocket at point of service use with insurance.

Insurance thus represents a form of pre-payment. However, it is a form of prepayment in which the whole group involved is showing solidarity by cross subsidizing each other. The insurance year, which was initially October to the end of September of the following year, is now running from January to December of each year based on feedback from members. Collection of premiums still begins in August of the previous year, which is the time of the harvest. Review of premiums is carried out with the elected representatives of enrolled members who seek the views of members they represent.

In 2004, when the study was carried out, the premium and benefits offered by the scheme were different from what pertains currently. Beginning from the year 2005 when the National Health Insurance came into being, some changes were instituted in line with the National Health Insurance guidelines. Changes were made to both the premium and the benefit package whilst the administration of the scheme remained largely the same, although staff positions were made permanent.

At the time of the study, each member of the household between 5 and 69 years paid a contribution of 20,000 Ghanaian cedis∗ (1.25 British pounds) whilst children less than 5years old as well as elderly people 70years and above paid 10,000 Ghanaian cedis (0.63 British pounds) as their premium for a year. In addition, a flat administrative cost of 10,0000 Ghanaian cedis (0.63 British pounds) was paid by each person.

∗ The exchange rate for one British pound and one United States dollars at the time of the study were 16,000 and 9,000 Ghanaian cedis respectively.

The benefits provided by the scheme at the time were as outlined below.

- Primary outpatient clinical care.
- Basic laboratory tests requested as part of primary outpatient clinical care namely, Hb, sickle cell test, full blood count as well as routine examination of stool and urine.
- Antenatal care.
- Delivery and postnatal care.
- Family planning.
- Child welfare and immunization.

  In theory, this was free but, in practice, mothers had to pay a "voluntary contribution" to cover some costs such as cotton wool etc.

- Referral to a participating hospital provided the patient consulted a primary outpatient facility first and was referred by the prescriber there. Clients who self referred to hospital were not reimbursed. This system of gate keeping was necessary to prevent the administrative and financial complications that are likely to be associated with allowing patients to self refer to hospitals outside the district.

  Whenever a client was referred to a hospital, all fees were paid by the scheme up to a maximum of four hundred thousand cedis (25 British pounds). Thereafter the client had to pay any amount over and above this.

Membership of the scheme is voluntary with mandatory household registration to avoid adverse selection. The members are allowed to use any of the ten (10) primary care clinics whenever they fall ill and a referral hospital of their choice when referred. All enrolled households receive individual picture ID cards for each member of the household each of whom is given a unique identification number (Figure 3.2). Enrolled members who fall ill are only required to present their ID cards at primary health care facilities in the district to receive free health services. Households not enrolled in the scheme pay for their services out of pocket. Administration of the scheme is carried out by a group of Area Council executives elected by the enrolled households.

Figure 3.2: The Dangme West Health Insurance Scheme picture identity card ("green card)
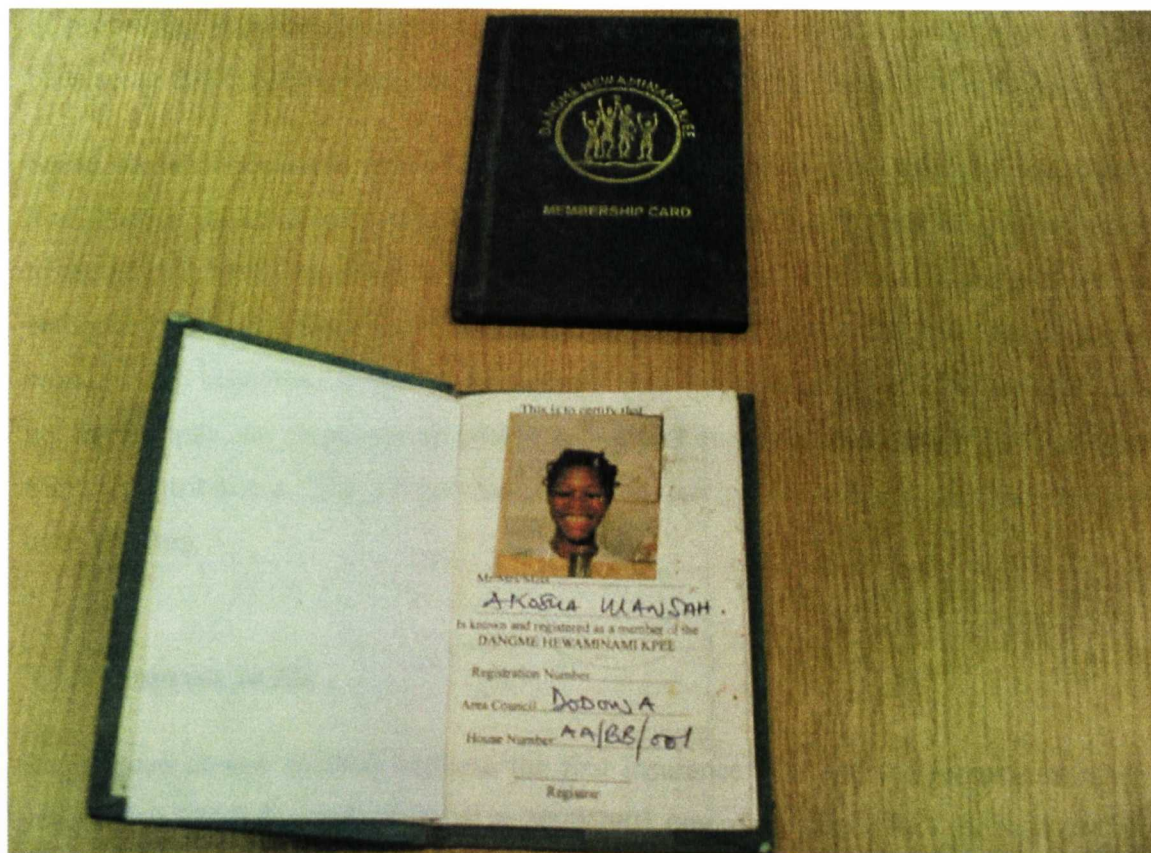
A the time of the study, day to day management was by the District Health Insurance Management Team (DHIMT) which had representation from the district assembly and the District Health Management Team (DHMT). Both groups were overseen by a District Advisory Board, made up of traditional, political, religious, and administrative leaders in the district (DHIMT 2002).

Since the year 2005, with the coming into force of the National Health Insurance Act 650, the day to day management has been taken over by a scheme management team comprising a scheme administrator, a claims officer, a public relations officer and a data manager. These are employed as permanent staff of the scheme. The premium per adult over 18 years per annum has now been set to a minimum of 72,000 Ghanaian cedis (4.50

British Pounds) whilst all children under 18years and those aged over 70 years in that household pay nothing. There is an additional payment to cover the administrative cost of processing individual picture ID cards. This varies from scheme to scheme and has been set at 10,000 Ghanaian cedis (0.63 British Pounds) in the Dangme West District.

Some households classified as indigent are covered by a special dispensation in the Act. The District Mutual Health Insurance Schemes, as they are now called, receive subsidies to provide the benefit package to the indigent free of charge. The subsidy is raised from a National Health Insurance Levy on goods and services. Under the Act, formal sector workers who contribute to the Social Security and National Insurance Trust (SSNIT) do not have to pay any premiums since this is deducted at source by means of 2.5% of their SSNIT contributions. The amount deducted does not cover their spouses and children over 18 years.

3.3.3 Progress so far

Registration almost doubled between the first insurance year and the second insurance year from 3,081 individuals enrolled in 2000/2001 (approximately 3% of the total district population) to 7,473 individuals enrolled in 2001/2002 (a little over 7% of the district population). A total of 2103 households made up of 8108 individuals were enrolled in the third year. This increased to 3031 households comprising 12,372 individuals who themselves enrolled in the fourth registration year.

Data from the first year of operation of the scheme (2000/2001) compares utilization rates in primary facilities among the enrolled and non-enrolled. The enrolled group appeared to utilize the primary care facilities approximately four times more than the non-enrolled group. This indicates that the scheme has been successful in increasing access among enrolled members (Figure 3.3).

Figure 3.3: A comparison of utilization of health services by members of the pre-payment scheme and the non-enrolled Oct 2000 to Sept 2001

OPD Utilization: October 2000–September 2001
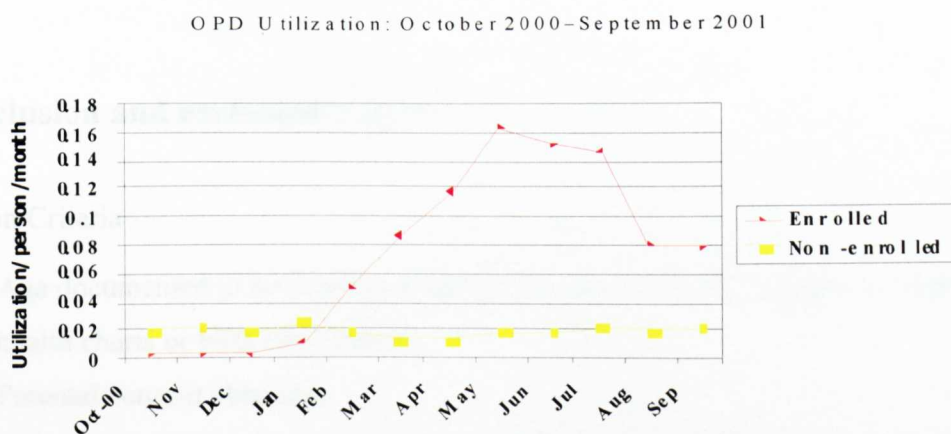
Source: Dangme West District Health Insurance Management Team Report (2002)

This scheme was therefore utilized as a means to reduce the direct cost of care and thereby improve access to health care for half of the households recruited into this study.

3.4 Study population

All households in the Dodowa and Prampram sub-districts with at least one child aged 6 to 59 months who had not already enrolled in the pre-payment scheme for the year were eligible to participate in the study. This information was obtained from a data base of households at the District Health Directorate. The two subdistricts were randomly selected from the two fishing and the two farming sudistricts in the district. The total number of households with children less than five in these two sub districts was estimated to be about 8700. One hundred and thirty-eight of these households had enrolled themselves in the scheme when the registration window was open for the year.

2194 households with 2592 children were randomly selected from among the households who had not enrolled for participation in the study. All the 138 self enrolled households were invited to participate as a subsidiary arm.

3.5 Inclusion and exclusion criteria

Inclusion Criteria

- o Age documented to be between 6 and 59 months (verified by means of road to health charts or birth certificates).
- o Parental consent obtained.
- o Parents or guardians intend to remain in the study area for the next two years.
- o Household not already enrolled in pre-payment scheme.

Exclusion Criteria

- o Parental consent refused.
- o Household due to emigrate from study area within two years.
- o Household currently enrolled.

3.6 The intervention

There were two main trial arms. Households belonging to the intervention arm were enrolled into a pre-payment scheme operating in the area. Each member of the household received an individual picture ID card which allowed them free access to primary care, including diagnosis and drugs whenever they were ill with no limit as well as limited access to secondary health care. The control arm paid user fees for their health care as pertained normally.

3.7 Trial end-point

Existing data from previous studies have shown that in areas where transmission of malaria is high and intense, malaria is the major contributor to anaemia (Kahigwa *et al.* 2002; Koram *et al.* 2000; Menendez *et al.* 1997; Murphy and Breman 2001; Newton *et al.* 1997; Slutsker *et al.* 1994a; Snow *et al.* 1994; Stoltzfus *et al.* 2000). The anaemia is known to result from repeated acute episodes or from prolonged illness due to inadequate treatment. Delay in seeking health care could also contribute to anaemia. The main mechanisms by which *P. falciparum* infection is known to contribute to the aetiology and severity of anaemia include the direct destruction of parasitized red blood cells, immune mechanisms (including the direct destruction of non-parasitized red blood cells), and dyserythropoiesis (Facer 1980; Facer and Brown 1979; Weatherall and Abdalla 1982)

The hypothesis on which this study was based was that reducing the financial barrier to formal health care would lead to presentation to formal healthcare where it would not have occurred and/or earlier presentation. This would result in earlier treatment with an effective drug and avoid a situation where the illness takes a chronic course or becomes more severe. The development of anaemia in the infected child would then be halted.

The trial end-point of prevalence of anaemia (Hb<8g/dl) among the study children was selected to enable comparison with several previous studies involving interventions for the control of malaria which have used a similar end-point as an outcome measure.

3.8 Sample size

The primary end point for the trial was the proportion of children with anaemia (Hb<8g/dl) in the intervention and control arms at the end of the malaria transmission season. The prevalence of severe anaemia (Hb < 6g/dl) among children 6-24 months of age in northern Ghana was found to be 22.1% at the end of the malaria transmission season (Koram *et al.* 2000). The prevalence of anaemia in Dangme West in Southern Ghana is likely to be lower. Therefore, an assumption was made that the prevalence of anaemia among the control group would be 10% at the end of the 24-week period of

follow-up. In order to detect an absolute difference of 4% in the prevalence of anaemia between the two groups, the sample size required to give a study with a power of 90% at a significance level of 5%, was a total of 2028 children with 1014 in each arm. This sample size would also be able to detect a 0.3 g/dl difference in mean haemoglobin between the two groups.

To allow for loss to follow up of approximately 10%, and to cater for the clustering effect of more than one child in approximately 20% of households, the aim was to recruit at least 2500 children. Finally, a total of 2524 children from 2151 households participated in the trial, a number substantially higher than the sample size required.
In addition, 165 children from 138 households who themselves enrolled in the pre-payment scheme were studied to document the difference between them and the children from randomly allocated households.

3.9 Screening and enrolment procedure

Initial visits were paid to all randomly selected households to explain the rationale for the study, and to seek their consent for participation. Consenting heads of households were then invited to the relevant community ballot meeting, depending on the distance of their residence from the nearest health facility. Colour coded invitation slips were used to make it easy to identify any head of household who turned up at the wrong meeting. Those agreeing to participate provided written consent and were enrolled at the meeting prior to randomization.

3.10 Randomization and allocation of intervention

A stratified randomization procedure was used (Smith and Morrow 1996). Households were divided into three strata based on residence being ≤5km, 5-10km, and >10km from the nearest health facility respectively since distance from a health facility is known to be

a major determinant of its use. The aim was to address any confounding that distance would introduce.

At the meeting, all heads of households or their representatives were allocated serial numbers. An equal number of folded papers with "Yes" or "No" written on them, totalling the number present, were dropped into a rotating barrel and mixed up thoroughly in the view of all. Each household head was then invited to pick a paper by calling out their numbers. Those who picked "Yes" were assigned to the intervention group and those who picked "No" to control. This process was used to make the trial more acceptable to community members by showing them the lack of favouritism and randomness of the allocation (Smith and Morrow 1996). Households were unable to change their group until the study ended in December of that year. Households belonging to control arm were supported subsequently the following year together with those who enrolled of their own volition.

3.11 Initial cross-sectional survey

Visits to all households enrolled in the study were carried out in May prior to the peak malaria transmission season. Characteristics of each household, including known risk factors for malaria such as the type of housing, use of insecticide treated materials, use of other preventive measures for malaria and some indicators of household wealth as well as income were documented. Each study child was examined and a brief medical history obtained. The temperature of each child was also recorded.

Similar data were collected from eligible children of the households who voluntarily enrolled in the pre-payment scheme in order to document the differences between them and the study participants in terms of health service utilization, health status, household wealth and other variables, as a subsidiary part of the study

Anthropometric measurements

All children were weighed naked using infant weighing scales for children unable to stand alone and a mechanical stand-on scale for those who could stand alone. The recumbent length of children <24 months was recorded using an infantometer; and a stadiometer was used to measure the standing height of children >24 months of age. The mid upper arm circumference (MUAC) of each child was measured using Shakir's strip. Measurements were carried out twice and the mean used for analysis. In case of discrepancies a third reading was carried out and the outlier discarded. Measuring devices were calibrated daily.

Figure 3.4: Field workers taking anthropometric measurements of study child during household cross-sectional survey

Haematological measurements

A finger-prick sample of blood was obtained for haemoglobin concentration determination using a battery-powered Haemocue haemoglobinometer and Haemocue® microcuvette (*Haemocue AB, Angelholm, Sweden*). The performance of the haemoglobinometers was assessed everyday using standards provided by the manufacturer. If the results showed that the machine was not functioning optimally, it was not used.

Parasitological measurements

Thick and thin blood films were obtained from the same finger prick sample for parasitological measurements. They were labeled with a unique study number for the index child, the community and date. The same study number was also recorded on the child's record form. Both films were then air dried and packed in slide boxes. These were stained with Giemsa and examined by two independent microscopists at the Noguchi Memorial Institute for Medical Research and the Parasitology unit of the Ministry of Health in Ghana. One hundred optical fields under 100 x oil immersion magnification were examined before a film was recorded as negative. Counts of parasites in the thick film were based on the number of asexual parasites per 200 white blood cells (WBCs). This number was converted to the number of parasites per microlitre of whole blood using a conversion multiple of 40 (this assumes 8,000 WBCs per microlitre) (Cheesbrough 2005).

The presence of parasitaemia was rapidly assessed in the field by means of a dipstick antigen capture test for all children with fever or reported fever in the past week. Children found during the baseline cross-sectional survey to have haemoglobin concentration less than 8g/dl, fever or a history of fever and parasitaemia were treated according to local guidelines and were retained in the study.

3.12 Passive surveillance for malaria

Following the baseline cross-sectional survey, morbidity monitoring was carried out using a household, passive case detection system. The monitoring was carried out from June to the end of November. Mothers/principal carers were trained and provided with picture log sheets for each child 6 to 59 months to enable them to indicate both illness episodes and sources of health care for each month. The picture log sheets were left with the mothers at the beginning of each month by a trained fieldworker. They were collected in the first week of the following month and replaced with new sheets. Before collection, the fieldworker went over the completed sheets with the mother/carer to be sure that the entries were correct.

Study participants who visited any of the primary care facilities were treated by the health workers in accordance with the current standard treatment guidelines except for cases of uncomplicated malaria less than five years of age for whom a combination of amodiaquine and artesunate was prescribed in the district.

In the case of mortality, at a culturally appropriate time within a month after the death of the child, a trained research assistant visited the home and a standard post-mortem questionnaire was administered to the child's mother or caretaker. The results were reviewed by three independent physicians to arrive at a possible diagnosis. If two out of three agreed on a diagnosis, that diagnosis was accepted. For children who visited hospital or died in the hospital, hospital case notes were reviewed when available and the attending physician interviewed for more complete information on the child's illness.

3.13 Final cross-sectional survey

A second, cross-sectional, household survey was undertaken at the end of the peak malaria transmission season in December during which interviews, haematological, parasitological and anthropometric assessments relating to the children were repeated. Data relating to the household were not collected in this round.

Rapid diagnostic test (RDT) for malaria

Children whose mothers or principal carers reported a history of fever during the preceding week or who were found to have fever on the day of examination had a rapid diagnostic test carried out to identify those infected with malaria. Whole blood samples obtained from a finger-prick sample from the children who satisfied the inclusion criteria were tested using the OptiMAL-IT (*Flow Incorporated, USA*) assay.

This test utilizes a dipstick coated with monoclonal antibodies against the intracellular metabolic enzyme pLDH. The pLDH antigen is present in and released from parasite-infected erythrocytes. Differentiation of malaria parasites is based on antigenic differences between the pLDH isoforms. Since pLDH is produced only by live *Plasmodium* parasites, this test has the ability to differentiate live from dead organisms. The pLDH assay also turns negative quickly after treatment as compared with assays which are based on histidine-rich protein (HRP-2), which has been shown to persist and is detectable after clinical symptoms of malaria have disappeared and parasites apparently cleared from host (Moody 2002). This is an advantage in areas with a high prevalence of parasitaemia.

Each test kit contains a dipstick and a small tray with two wash wells. The kit also contains an ampoule of buffer, a pipette, a disinfecting swab and a lancet (Figure 3.5).

The procedure for the test is as follows. The device is placed on a flat surface. A drop of the buffer is added to the first well (conjugate well) and 4 drops to the second well (wash well). A drop of whole blood (about 10 micro litre of blood) from a finger-prick is drawn using a pipette and added to the conjugate well, stirred gently with the pipette and allowed to stand for a minute. The dipstick is then inserted into the conjugate well and allowed to stand for 10 minutes allowing the conjugate mixture to be completely soaked up. The dipstick is then transferred to the wash well and allowed to stand for another 10 minutes resulting in a complete clearing of the reaction field. The dipstick is then removed and inserted into a clear plastic piece for reading and interpretation of results.

Figure 3.5 Picture of OptiMAL-IT (*Flow Incorporated, USA*) Test kit used in the study

The dipstick has a control band "C" and two potential diagnostic bands "P" and "Pf". When both "P" and "C" bands are present then the sample is positive for *P. vivax, P. malariae, or P. ovale.* The monoclonal antibody attached at the "P" area of the strip is an enzyme common to all four target *Plasmodium* species. When "Pf", "P" and "C" bands are present, the sample is positive for *P. falciparum.* The monoclonal antibody attached at the "Pf" area of the strip is specific for *P. falciparum* only. One control band only at the top of the test trip means a negative result. (Figure 3.6)

Figure 3.6: Reaction bands of the Opti-MAL-IT (*Flow Incorporated, USA*) Test

Negative	**P. vivax/P. ovale/P .malariae present. No P. falciparum**	**P .falciparum present +/-P.vivax/P.ovale/P. malariae**	**Invalid**	**Invalid**
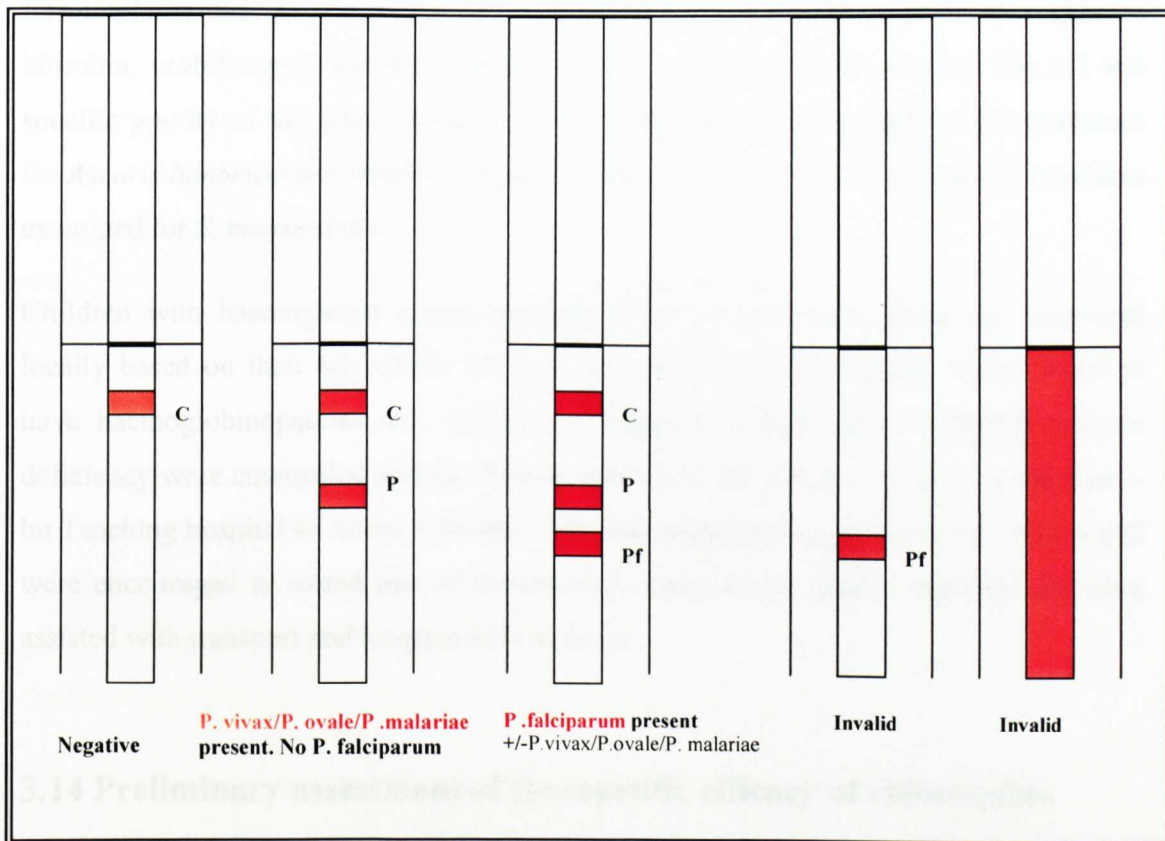
Haematological investigations

Children found to have anaemia during the final cross-sectional survey were investigated further. Hb electrophoresis, glucose-6-phosphate dehydrogenase (G6PD) testing, full blood count, stool and urine examinations were done.

For the full blood count and G6PD tests, approximately 3 millilitres of whole blood was taken from either the dorsum of the hand or the ante-cubital fossa by a trained laboratory technician. This was then put in a EDTA tube and transported to the Noguchi Memorial Institute for Medical Research as quickly as possible. Filter paper samples were taken for Hb electrophoresis assay at the same institute.

Urine samples were examined for the presence of red blood cells as well as *Schistosoma haematobium* ova. In addition, a multi-dipstick was used to test for the prescence of bilirubin, urobilinogen, ketones, glucose, protein, nitrites, and leucocytes. The pH and specific gravity of the urine samples were also assessed. Stool samples were examined for *Ascaris lumbricoides,* Hookworm and *Trichuris trichuria* ova. The samples were also examined for *S. mansoni* ova.

Children with haemoglobin counts between 6 and 8 g/dl were given free treatment locally based on their lab results for both anaemia and helminthiasis. Those found to have haemoglobinopathies and Glucose-6-Phosphate dehydrogenase (G6PD) enzyme deficiency were counselled and the former referred to the sickle cell clinic at the Korle-bu Teaching hospital in Accra. Children with haemoglobin concentration less than 6 g/dl were encouraged to attend one of the hospitals close to the district urgently and were assisted with transport and hospital bills to do so.

3.14 Preliminary assessment of therapeutic efficacy of chloroquine

An assessment of the therapeutic efficacy of chloroquine was carried out prior to the main study in order to ascertain the efficacy of chloroquine in the study area since the use of an ineffective drug would confound the impact of the intervention on the primary outcome, haemoglobin concentration. Previous studies carried out in other sites in the country had revealed that chloroquine was no longer efficacious.

The methods of this preliminary assessment are described in much greater detail in chapter five of the thesis.

3.15 Background descriptive studies

An ethnographic study was done and was conducted in three phases. The first phase was a document review of current knowledge on malaria and its complications both in the country in general and in the district specifically. This information was used to guide the

selection of communities and the design of questionnaires. The second phase elicited community perceptions on various issues including their recognition of the signs and symptoms of severe malaria and resulting actions, user fees, exemptions, the existing pre-payment scheme and indicators of poverty. Part three involved the collection of case histories of children admitted in the district referral hospitals with severe malaria. These case studies were conducted with mothers of children less than 5 years of age who had been admitted to the children's ward at any of the referral hospitals. This study is described in more detail in chapter 4 of the thesis.

3.16 Other ancillary studies

Three additional sub studies were carried out to collect information on factors that might act as confounders to the results of the main trial. They are described in greater detail in chapter six of this thesis.

3.17 Measurement of study end points

Primary

- Prevalence of anaemia (Hb<8g/dl) at the end of the peak malaria transmission season in each group.

Secondary

- Prevalence of severe anaemia (Hb<6g/dl) at the end of the peak malaria transmission season in each group.
- Mean haemoglobin concentration at the end of the peak malaria transmission season in each group.
- Change in mean haemoglobin concentration in each group over the peak malaria transmission season.
- Mean number of outpatient visits to primary care and referral health facilities per child in each group.

- Change in mean anthropometric indicators in each group.
- Proportion of parasitaemic children in each group at both the baseline and final cross-sectional surveys.
- All cause mortality among children in each group.

3.18 Field operations

Training for field work

The training of field staff took about ten days. Trainees, who were mainly secondary school leavers, were taken through:

- The objectives of the study.
- Community entry skills.
- Collection of good quality data.
- Interviewing techniques.
- Laboratory and anthropometric measurement techniques.

Questionnaires were translated into the local languages and back into English to ensure that the understanding of the questions was the same among all interviewers. The tools were pre-tested on two occasions and in two areas outside the area where the actual study was to take place. After pre-testing, the data collection tools were finalized and an instruction manual was produced for interviewers. The best twelve among the trainees for laboratory and anthropometry were selected and given more detailed training in laboratory and anthropometry techniques related to taking a good finger-prick sample, measuring haemoglobin using a haemocue machine (*Haemocue AB, Angelholm, Sweden)*, making of thick and thin blood films and collecting good quality blood samples for other haematological assessments. They focused on this during the baseline cross-sectional survey, whilst the 22 other fieldworkers focused on questionnaire administration.

During the final cross-sectional survey, the strategy was changed for a variety of reasons including the fact that some of the fieldworkers trained earlier had left for the university

and other tertiary institutions and a few new ones had to be trained in addition to the old fieldworkers who were re-trained. They were then put into seven teams of two who carried out all the measurements and the questionnaire administration once they reached a household. Every 4 fieldworkers had one supervisor with the overall management of the fieldwork carried out by the Principal Investigator (PI).

The Principal Investigator moderated most of the focus group discussions and individual in-depth interviews herself except a few which were moderated either by the social scientist or by an experienced research assistant due to language barrier. The FGD involving the problem tree technique was moderated by the social scientist whilst the PI was the notetaker. Data analysis was assisted by the social scientist and formed a learning process for the PI who learnt by doing.

3.19 Data management and analysis

Field data were collected by means of standard pre-coded questionnaires administered to heads of households and mothers/principal carers of the children. Quantitative data were recorded on pre-coded questionnaires and record forms for anthropometric and haematological data whilst qualitative data were recorded both on a tape recorder and in small notebooks. Data were checked daily for accuracy and consistency, correctly labeled, and stored for data entry. For quantitative data, data entry clerks carried out double entry of the raw data from questionnaires and record forms into EPI Info version 6, except in the case of data from the *in vivo* assessment of the efficacy of chloroquine where data were entered into Excel. After data entry, data cleaning was carried out to identify errors and inconsistencies for correction. The data were then imported into Stata version 8 which was used for the analysis.

Analysis of qualitative data

For the qualitative data, analysis was an ongoing process and started whilst in the field. For any group discussion or interview that was held, the team discussed the findings and

clarified issues where necessary. Once a phase of fieldwork was completed, the recorded interviews were transcribed verbatim, a second person listened to the tape and filled in the missing gaps after the transcript had been typed. A matrix was constructed, based on the main issues arising from the various data collection techniques. Any further gaps were identified and filled in during the next phase of data collection. Once this was completed, all segments of group discussions were coded. The information was then put into themes.

The data were analyzed using Textbase Alpha after converting the transcribed text file into an ASCII file.

Analysis of quantitative data

Quantitative data were analyzed using STATA Version 8 after data had been exported into it from EPI Info Version 6. Summary statistics, odds ratios, confidence limits and p-values were calculated to compare outcomes between the two groups for the primary and secondary endpoints. Stratified analysis was carried out based on distance of household residence from a health facility and household wealth. Means of continuous variables such as rise in haemoglobin concentration were compared using the Student t-test.

The primary analyses were performed on the two randomly allocated groups. A major secondary analysis was performed comparing those who had enrolled and paid voluntarily with the other groups. Further secondary analyses were performed repeating the primary and main secondary analyses by wealth quintile.

For binary categorical outcomes, odds ratios were calculated and presented with 95% confidence levels, whilst for the primary and key secondary outcomes they were calculated and presented both unadjusted and adjusted for pre-defined potential confounding factors. For the primary and main secondary outcomes the pre-defined potential confounding factors were age, sex, distance of household residence from a health facility and socioeconomic status defined by wealth quintile. A secondary analysis was also undertaken based on distance between place of residence and a health facility. This was to elicit a gradient of effect, if any, by distance. Finally, an analysis was

undertaken to assess whether children for whom there were missing data differed in terms of anaemia and other key indicators from children who completed follow-up.

To allow for clustering within households, the primary and main analyses were repeated using the svy command in STATA setting households as the primary sampling unit (psu). For the primary analysis $p<0.05$ (two-sided test) was taken to be significant.

Anthropometric data were analyzed initially by calculating anthropometric indices (weight-for-age, weight-for-height, height-for-age). Weight-for-age, weight-for-height, height-for-age z-scores were computed with reference to the standards of the United States National Centre for Health Statistics by use of the EPINUT module of EPI-Info version 6.0. The z-score measures the degree of dispersion of a series of observations such as the weight-for age (WAZ), the height-for-age (HAZ), and the weight-for height(WHZ) in relation to the median of the series (Chevassus-Agnes and Marcoux 1999; Cogill 2001; WHO 1995). Low weight for height (wasting), weight for age (underweight) and height for age (stunting) were defined respectively as z-scores of less than -2. The data were then transferred into STATA version 8 for further analysis.

3.19.1 Assessment of household socio-economic status

Household socio-economic status (SES) was assessed by constructing a household 'wealth index' based on household dwelling conditions and asset ownership applying principal components analysis as proposed and validated by Filmer and Pritchett in 2001 (Filmer and Pritchett 2001). Some data were, however, still collected on income as part of this study knowing full well the limitations involved in order to compare the data with that which is based on household ownership of certain key assets.

Data on a total of 26 indicators were collected at baseline and used to derive the asset-based wealth index. A variety of indicators of household living standards were divided into three groups as follows: access to utilities (lighting fuel, cooking fuel, pipe-borne water, telephone and sanitation), ownership of durable assets (radio, television, bicycle, motor-bike, tractor, fishing vessel, private car, commercial vehicle, subsistence farm, commercial farm, land, cattle, and house for rent) and housing characteristics (home

ownership, floor material, wall material, roof material, number of rooms available to household and number of households sharing a compound). These assets were selected based on work carried out in similar settings in Ghana and elsewhere and were modified using some information from focus group discussion and knowledge of the study site.

All household variables, except the number of rooms available to the household were coded into dichotomous variables, distinguishing between households owning a particular asset and those that did not. The coded variables also sorted the households into those that had access to a particular utility and those that did not. The number of rooms available to the household remained as the only continuous variable. The value of the household asset-based index was then calculated by summing the score on each variable across all the variables included in the principal component analysis (Booysen 2002). The scores of the first principal component were used to derive the asset-based index (Filmer and Pritchett 2001). Separate indices were constructed for access to utilities, ownership of durable assets, housing characteristics and subsequently all indicators. This was done to find out which index was statistically better with regards to less clumping and less truncation.

The weights used were the first component from a principal components analysis of the wealth indicators and this gave the greatest weights to the following in order of importance:

- Having cement/brick/terrazzo walls for the house.
- Use of electricity or gas as lighting fuel.
- Ownership of a refrigerator.
- Water source reached within ten minutes or less.
- Access to potable water.
- Ownership of a television.
- Ownership of a telephone.
- Use of electricity or gas for cooking.

Table 3.1: Principal components and summary statistics for asset indicators

Variable	Scoring Factor for 1st Principal Component			Summary Statistics		
	Utilities only	Housing Only	Durable Assets only	All indicators	Mean	Std Dev.
Utilities						
Has telephone				0.172	0.078	0.269
Use electricity/gas for lighting	0.366			0.335	0.445	0.497
Use electricity/gas for cooking	0.392			0.164	0.046	0.210
Pipe-borne water	0.449			0.254	0.877	0.329
Time to water source ≤10 mins	0.450			0.265	0.878	0.327
Toilet facilities in house	0.328			0.058	0.113	0.317
Housing Characteristics						
Home owner		0.418		-0.222	0.571	0.495
House has cement/terrazzo/tiled floor		-0.347		0.191	0.659	0.474
House has cement/terrazzo/brick walls		-0.471		0.369	0.540	0.498
House has block/terrazzo/brick tiled roof		0.043		-0.036	0.006	0.077
Household does not share compound		0.554		-0.295	0.330	0.470
Number of rooms		0.418		-0.151	1.757	1.241
Durable assets						
Owns Radio			0.287	0.050	0.758	0.429
Owns Television			0.339	0.246	0.329	0.470
Owns fridge			0.314	0.272	0.173	0.378
Owns a bicycle			0.339	-0.102	0.274	0.446
Owns a motor-bike			0.188	0.050	0.017	0.130
Owns a tractor			0.181	0.042	0.007	0.084
Owns a fishing vessel			0.050	0.041	0.022	0.147
Owns a private car			0.276	0.092	0.035	0.183
Owns a commercial vehicle			0.247	0.056	0.042	0.200
Owns a subsistence farm			0.257	-0.300	0.531	0.499
Owns a commercial farm			0.270	-0.270	0.295	0.456
Owns land			0.339	-0.092	0.231	0.422
Owns cattle			0.270	-0.151	0.077	0.267
Owns house/s for renting			0.234	0.031	0.036	0.187
Utilities Index					0.000	1.328
Housing Index					0.000	1.362
Durable asset index					0.000	1.539
All indicators					0.000	1.872
Eigenvalue[1]	1.764	2.191	2.368	3.460		
% variance[2]	0.29	0.27	0.17	0.14		
Number of variables used	6	8	14	26		

Notes: 1. Eigenvalue associated with first component
2. Share of variance associated with first component

Both the housing and utilities indices showed some evidence of clumping (Figures 3.7 1 and 3.7.3). Athough there was less clumping in the housing index, there was evidence of truncation at the lower part which may make it less useful for determining inequality amongst the poor (Figure 3.7.1). The durable assets index also showed evidence of truncation at the bottom which means that it may not be able to distinguish clearly among the poor in terms of inequality (Figure 3.7.2).

The overall index which was reasonably smooth, with little evidence of clumping and truncation appeared to make for a better, more robust, and internally coherent index (Figure 3.7.4). This means that the index consistently produces sharp distinctions across socio-economic groups on almost all assets.

Figure 3.7 Distribution of the various indices
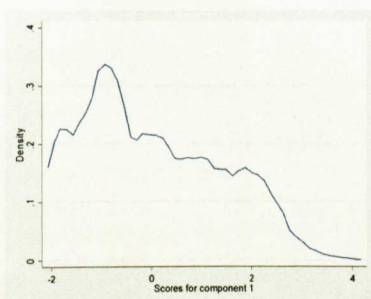
Figure 3.7.1 Distribution of housing index   **Figure 3.7.2 Distribution of durable assets index**
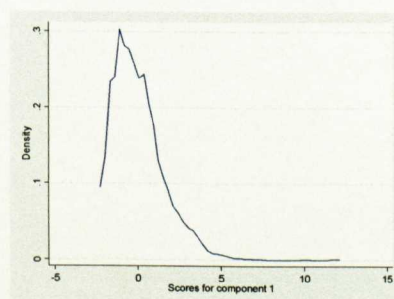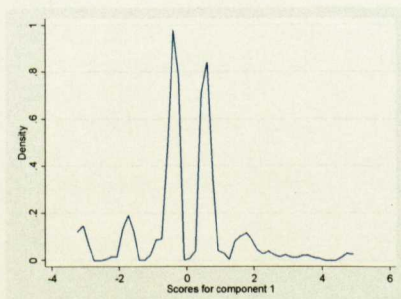
Figure 3.7.3 Distribution of utilities index   **Figure 3.7.4 Distribution of overall index**
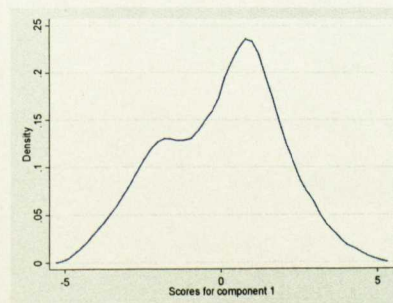
We then divided the households into "wealth quintiles" categorized as poorest, very poor, poor, less poor and least poor. We chose to use quintiles in this study for ease of comparability with several previous studies which have used them. We use these labels because essentially most people in this area are poor and very few can really be categorized as rich (Table 3.2).

Table 3.2 Socioeconomic differences in household asset ownership.

Variable	n	Socioeconomic status quintiles				
		Most poor	**Very Poor**	**Poor**	**Less Poor**	**Least Poor**
Utilities						
Has telephone	2689	7 (1.3%)	19 (3.5%)	18 (3.3%)	24 (4.5%)	43 (26.6%)
Use of electricity/gas for lighting	2689	29 (5.4%)	96 (17.8%)	220 (40.9%)	348 (64.7%)	504 (93.9%)
Use of electricity/gas for cooking	2689	5 (0.9%)	1 (0.2%)	8 (1.5%)	8 (1.5%)	102 (19.0%)
Pipe-borne water	2689	301 (56.0%)	478 (88.9%)	517 (96.1%)	529 (98.3%)	532 (99.1%)
Time to water source ≤10 mins	2689	288 (53.5%)	492 (91.5%)	518 (96.3%)	533 (99.1%)	530 (98.7%)
Toilet facilities in house	2689	50 (9.3%)	57 (10.6%)	56 (10.4%)	43 (8.0%)	304 (11.3%)
Housing Characteristics						
Home owner	2689	481 (89.4%)	351 (65.2%)	294 (54.7%)	260 (48.3%)	150 (27.9%)
House has cement/terrazzo/tiled floor	2689	225 (41.8%)	258 (48.0%)	384 (71.4%)	437 (81.4%)	469 (87.3%)
House has cement/terrazzo/brick walls	2689	21 (3.9%)	125 (23.2%)	330 (61.3%)	472 (87.7%)	504 (93.9%)
House has block/terrazzo/brick tiled roof	2689	7 (1.3%)	7 (1.3%)	2 (0.4%)	0 (0%)	0 (0%)
Household does not share compound	2689	434 (80.7%)	233 (43.3%)	115 (21.4%)	61 (11.3%)	44 (8.2%)
Durable assets						
Owns Radio	2689	401 (74.5%)	393 (73.1%)	355 (66.0%)	411 (76.4%)	477 (88.8%)
Owns Television	2689	68 (12.6%)	82 (15.2%)	138 (25.7%)	173 (32.2%)	424 (79.0%)
Owns refrigerator	2689	5 (0.9%)	8 (1.5%)	53 (9.9%)	89 (16.5%)	310 (17.3%)
Owns a bicycle	2689	253 (47.0%)	153 (28.4%)	114 (21.2%)	85 (15.8%)	132 (24.6%)
Owns a motor-bike	2689	1 (0.2%)	9 (1.7%)	10 (1.9%)	3 (0.6%)	23 (4.3%)
Owns a tractor	2689	0 (0%)	3 (0.6%)	3 (0.6%)	1 (0.2%)	12 (2.2%)
Owns a fishing vessel	2689	2 (0.4%)	14 (2.6%)	10 (1.9%)	11 (2.0%)	22 (4.1%)
Owns a private car	2689	11 (2.0%)	6 (1.1%)	13 (2.4%)	8 (1.5%)	55 (10.2%)
Owns a commercial vehicle	2689	15 (2.8%)	15 (2.8%)	15 (2.8%)	22 (4.1%)	45 (8.4%)
Owns a subsistence farm	2689	505 (93.8%)	417 (77.5%)	250 (46.5%)	159 (29.6%)	97 (18.1%)
Owns a commercial farm	2689	369 (68.6%)	217 (40.3%)	118 (21.9%)	60 (11.2%)	28 (5.2%)
Owns land	2689	205 (38.1%)	123 (22.9%)	112 (20.8%)	87 (16.2%)	95 (17.7%)
Owns cattle	2689	128 (23.8%)	35 (6.5%)	27 (5.0%)	6 (1.1%)	12 (2.2%)
Owns house/s for renting	2689	12 (2.2%)	20 (3.7%)	11 (2.0%)	26 (4.8%)	28 (5.2%)
Income						
Median monthly income [1]		300,000	325,000	315,000	400,000	500,000

Note: All amounts in Ghanaian cedis. Exchange rate for £1.00 and $1.00 at time of study was C16,000 and C9,000respectively

3.20 Ethical issues

3.20.1 Ethical approval

Ethical approval was obtained from the Ethics committees of both the Ministry of Health/Ghana Health Service in Ghana and the London School of Hygiene and Tropical Medicine. Prior discussions were held with the members of the Traditional Council and the District Assembly to explain the purpose of the study and to seek their consent. At community level, consent was sought from the chiefs and elders as well as the opinion leaders of the specific communities where the work was to be carried out. Individual heads of households also gave written informed consent during the randomization meetings before participating in the randomization. The heads of households who had enrolled themselves gave informed consent during visits to their homes.

3.20.2 Ethical considerations

Laboratory results were communicated to the parents/guardians of the children concerned. All children who had clinical malaria, severe anaemia or severe malaria during the two cross-sectional surveys were treated immediately at no cost in accordance with the Standard Treatment Guidelines of Ghana. All households agreeing to take part received one year of pre-payment; the intervention group in year 1, and the control group in year 2. Additionally, those who had already elected to enrol had a year paid for in year 2 to prevent any feeling of unfairness in the community. It had been made clear at the outset that the one year of payment was one-off, and would not be repeated.

Households were given the option to withdraw at any time during the study with the assurance that this would not affect their normal care and management at the health facility nor their enrolment status. The results of the study will be communicated to the communities in which the data were collected.

3.20.3 Informed consent

Written informed consent was obtained from parents or guardians of all study participants before their inclusion in the study. The rationale for the study, procedures, anticipated benefits and potential risks of the trial were explained to them in their preferred language. Permission was obtained from the chiefs and elders as well as other local authorities.

3.20.4 Confidentiality

Study records were identified using study numbers of the participating children. All records of study participants were kept in a manner that concealed their identity but will be available for inspection by the supervisory panel and the District Health Directorate.

3.21 Protocol amendments

There were no amendments to the protocol.

3.22 Timelines and Milestones

Activity	Year 2003				Year 2004				Year 2005			
	QI	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Initial Preparations			■									
Assessment of therapeutic efficacy of chloroquine				■								
Community interviews					■							
Baseline cross-sectional survey						■						
Randomization & enrolment of households						■						
Passive surveillance						■	■	■				
Final cross-sectional survey								■	■			
Enrolment of households not enrolled in the first year									■			
Data cleaning									■	■		
Data Analysis and Report Writing											■	■

Q 1 – First Quarter; Q2 – Second Quarter; Q3 – Third Quarter; Q4 – Fourth Quarter

CHAPTER 4 CONTEXT OF STUDY

4.1 Perceptions of community members on malaria and treatment seeking behaviour

Prior to the main trial, a qualitative study was carried out in the study area. Its aim was to document the context in which the trial was to be carried out in order to assist in the explanation of the results that would be obtained. In addition, the results of the qualitative study were designed to assist in the fine tuning of the data collection tools developed for the main trial. The study explored the perceptions of community members with regards to both uncomplicated and severe malaria and the sources of care for each type of malaria. It was important to find out where health care for malaria was sought most frequently as this had a direct bearing on the expected change in behaviour from the intervention.

In addition, the factors influencing treatment seeking behaviour and the decision making process for seeking care were explored. Documentation of the barriers to accessing care was important as well to confirm the premise on which the trial was based. Determining the perceptions of community members on health care financing, and especially the existing pre-payment scheme was important as very negative perceptions would influence the results of the study. Community perceptions on poverty were also explored, since the main target for improvement of financial access would be the poor who stand to benefit most from such an intervention. Community indicators of poverty were elucidated.

4.1.1 Methods

For the qualitative studies, communities in the two sub-districts were put into three groups. The first group comprised communities less than 5 kilometres away from any of the primary care facilities in the district. The other two groups were made up of communities 5 to 10 km and greater than 10 kilometres away from a primary care facility respectively. From each of these groups two communities each were selected randomly.

Data collection involved focus group discussions, and key informant interviews in the various communities using a discussion guide.

Non-participant observation and problem tree techniques were also used to explore the issues of interest. The problem tree is a visual problem-analysis tool that can be used by both field development staff and the community to specify and investigate the causes and effects of a problem and to highlight the relationships between them. It is a tool for the identification and analysis of the relevant causes of the main problems, which will later form the bases for formulating solutions. As the name implies, this tool resembles a tree. The roots of the tree metaphorically represent the causes of the main problem. The tree trunk represents the main problem and the tree branches, provide a visual representation of the effects of the main problem.

In each community, discussions were held with one mens group and one womens group. These were men and women with children less than five years of age. A minimum of one key informant was also selected purposively from each community.

Selection and recruitment of participants

The Principal Investigator, a social scientist and a research assistant lived in the field for a period of one week at a time to conduct the interviews. Prior discussions were held with the chiefs and elders to explain the purpose of the study and to seek permission to conduct the interviews. For the first two focus group discussions, the mothers were recruited with the help of community health nurses and other community members. They were asked to identify 8-12 men and women with children less than five years who could meet for the discussion on an agreed date. On arrival of the study team on the appointed date, the contact person in the community gathered the groups for the discussion. For the rest of the interviews, however, the research team carried out the recruitment themselves with the assistance of a contact person in the community. Each focus group discussion group comprised a moderator, a note-taker/observer and between 8 and 12 discussants. Key informants were identified with the help of community leaders. Once interviewed, the key informant gave ideas as to other people who could be interviewed.

The same issues were explored during the baseline cross-sectional surveys using structured questionnaires which were administered to either the head of household or the principal carer of the study child. The findings from the household survey on the issues are set out in section 4.1.2 whilst those from the qualitative studies are found in section 4.1.3.

4.1.2 Main findings from household interviews

Malaria was said to be the most common illness. Over 87% of respondents spontaneously mentioned malaria as the commonest illness affecting children in the area. About 42 respondents (1.6%) mentioned convulsion. Other diseases mentioned were worm infestation (0.5%), diarrhoeal diseases (2.5%), measles (3.5%) and stomach pain (2.0%). Many of the others mentioned, except asthma, could actually be classified as symptoms rather than diseases.

The cause of malaria appeared to be known to the majority of respondents. Approximately 1940 (72.2%) mentioned mosquitoes as the cause of malaria. The next most frequently mentioned causes were too much sun (18.7%), poor nutrition (1%) and oily foods (0.65%) in that order. When asked whether malaria could become severe and cause death in children, 1197 (44.6%) of respondents said that could never happen. About 17% said this happened commonly, 28% said it happened sometimes whilst 10% said the occurrence was infrequent (Table 4.1).

Table 4.1: Household perceptions of malaria

	Responses N=2689	
	n	Proportion (%)
Cause of malaria		
Mosquito bite	1940	72.2%
Too much sun	503	18.7%
Poor nutrition	27	1.0%
Oily foods	16	0.6%
Don't know	140	5.2%
Others	63	2.4%
Does malaria ever become severe and cause death in children?		
Commonly	461	17.2%
Sometimes	757	28.2%
Infrequently	272	10.1%
Never	1197	44.6%

The decision to seek health care was taken in 87% of cases by which ever one parent of the child was available or both at the time of illness. Other members of the family, especially the grandparents, also made the decision on some occasions. For most (93.6%) of respondents the closest health facility to their home was a public sector one in the district. About 2113 (78.6%) respondents sought health care from the health facility closest to their home. The rest tended to seek health care from other health facilities further away.

To access the health facility, 1054 (39.2%) of all respondents walked whilst approximately 1572 (58.5%) did so travelling by public transport. Only 27 (1%) travelled by private car and 1 person who was disabled mentioned that he travelled by wheelchair to reach the health facility he used. The time it took to reach the health facility in respondents' estimation ranged from a minute to about three hours. It took 509 (18.9%) of respondents 5 minutes to reach the health facility whilst 580 (21.6%) took 10 minutes.

About 39.6% of respondents said there were no transportation costs in order for them to access the health facility which they usually utilized. Transportation costs for the rest ranged between 200 and 80,000 Ghanaian cedis∗.

A total of 1067 (39.7%) children were reported to have been ill within the last two weeks before the survey. The last time 982 (36.5%) of the children had been ill was more than a month ago. About 243 (9%) of children less than five years of age had been admitted to hospital at least once during the previous year and 197 of these children had been admitted because of malaria. Most of the admissions had occurred more than two weeks ago. Less than 1% (n=24) had been admitted over the previous two weeks.

The source of care that was utilized most during the most recent illness of the child was one of the primary care clinics in the district. Altogether, 1415 (52.6%) of respondents reported that they sought care there when the children were last ill. Chemical sellers were the next most common source of care. One hundred and ninety-one (7.1%) respondents used home treatment whilst a few others sought prayer from some prophetesses or prayed for the child themselves. Overall, 1634 (60.8%) sought care from formal health care sources. There were several reasons why care was not sought from formal sources when the child was last ill. The most common reason for not seeking care from formal sources during the last illness of the child was the fact that it was too expensive. Other reasons specified were mainly that the illness was not severe or there were left over drugs at home (Table 4.2).

∗ The exchange rate at the time of the study for the British pound and United States dollars was approximately 16,000 and 9,000 Ghanaian cedis respectively.

Table 4.2 Reasons given for not seeking care from formal sources when the study child was last ill.

Reasons	Responses	
	No	Proportion (%)
Too expensive; could not afford health care costs	508	35.5
Transport costs too high	55	3.8
Difficult to obtain transport	21	1.5
Staff are not technically competent	28	2.0
Staff are not nice to patients	18	1.3
Can treat the illness myself at home	294	20.5
Prefer to use herbal drugs	47	3.3
Chemical seller closer	214	14.9
Traditional healer/TBA closer	5	0.3
Other reasons	243	16.9
Total number of responses	**1433**	**100%**

For the last illness, direct cost of health care ranged between 200 and 1 million cedis whilst transport costs ranged from 100 cedis to 1 million cedis. Other costs related to the illness ranged from 1000 cedis to 1 million cedis. Overall, 1936 (72.1%) respondents said they had enough money at home to pay for their health care costs at the time of illness whilst 389 (14.5%) did not. Those who did not, mostly borrowed from friends, neighbours or relatives. They also had money contributed by relatives and friends to settle their bills, provided paid labour or sold agricultural produce for money in that order. A few bought drugs on credit.

4.1.3 Main findings from qualitative studies

A total of six communities were randomly selected from communities less than 5km, 5 to 10km and greater than 10 km respectively away from the primary care facilities in the two sub-districts. Twelve focus group discussions were conducted with 5 groups of men and 7 groups of women with children less than five years of age from the selected communities. Individual in depth interviews were held with 2 traditional healers, 2 traditional birth attendants (TBAs), 5 community leaders and 2 owners of chemical shops (Table 4.3).

Additionally, five hospitals were visited during the period and a total of 12 mothers/carers whose children had been admitted to the hospital with severe malaria according to the nurse in charge of the ward were interviewed. These case studies were conducted to elucidate the carers' perception of their child's ill health and their course of action prior to hospital admission. The hospital records were also reviewed to document how this narrative compared with the diagnosis made by the health staff at the time the child was admitted. The background descriptive studies were therefore carried out both at community and health facility level.

Table 4.3: Study communities and number of interviews conducted.

No.	Community	Key Informant (In-depth Interviews)	Male FGD	Female FGD	Case Studies	Problem Tree
1	Agomeda	3	1	2		
2	Dodowa	2		1		
3	Apese	1	1	1		1
4	Lardowayo	2	1	1		
5	Abonya	2	1	1		
6	Luom	1	1	1		1
	Total	**11**	**5**	**7**	12	2

Background of respondents

Focus Group Discussions (FGDs)

Over 80 percent of the discussants had some formal education. It was only in one group discussion in Lardowayo that over 50% of the women had had no formal education. Their main occupation was farming but there were a few civil servants, traders and fisher folk. Their ages ranged between 20 and 60 years and over 90% of them were married with between 1-8 children.

Individual in-depth interviews (IDIs)

All except three of the key informants were male. The female key informants comprised two TBAs at Lardowayo and Agomeda respectively and the owner of the only chemical shop in Agomeda. They were aged between 45 and 60 years.

Case studies

All except one of the twelve carers interviewed were females and the mothers of the children. The only exception was the father of one child. The ages of the children ranged from 6 months to 6 years and there were equal numbers of male and females. The youngest carer was 19 years whilst the oldest was 43 years old. Eight out of the 12 had had some form of formal education. All the women were traders and the man was a mechanic. All except 2 of the children had other siblings.

Key issues arising from FGDs and individual in-depth interviews (IDIs)

Words used locally for signs and symptoms of uncomplicated and severe malaria

In all the study communities, there were well-defined local terms for symptoms of malaria and severe malaria. The three main terms *"Asra"*, *"Atridii"* and *"Fever"* used to describe malaria were the same whether the person was an adult or a child, male or female and were used interchangeably depending on the dialect. Two types of malaria were mentioned *"Asra Eyoo"* and *"Asra Eku"*, typically translated as "female" and "male" malaria respectively. *"Asra Eyoo"* had a description close to the case definition used in biomedical diagnosis of uncomplicated malaria.

Perceived cause of uncomplicated malaria

Mosquitoes were mentioned spontaneously as a cause of malaria in almost all the group discussions. Other causes included over feeding, roaming or working too hard in the sun, eating without washing hands, worm infestation, playing on the rubbish dump and drinking unclean water. Some also believed that malaria was related to all childhood illnesses.

> *"Malaria is under every sickness. This is what we can say. Every sickness has malaria under it. Because if the child says "my stomach" and you go to the hospital, they will also treat malaria first before they treat other things so we detected that this is the cause of our children's problems."* **(Dodowa Women)**

Signs of uncomplicated/female malaria

In all group discussions and interviews, the signs of uncomplicated malaria were easily described and were linked to severe malaria if not treated properly.

> *"The child's body will be hot and then she will start to vomit and lose appetite. The urine will be hot and sometimes the child will even have diarrhea. There are times when the stomach will become big and the child will grow lean. When the "asra" is serious, the eyes will start to even become very yellow and if you don't take care the doctor will "declare you."* **(Apese Men)**

(The doctor will "declare you" in this context means the doctor will decide that your condition is very severe and the chances of recovery low).

> *R: "When you get malaria, you become weak and cannot walk; you have body and joint pains, and chills. Even if the sun is shining, you feel cold. Your mouth becomes sour and sore and you cannot eat. It is the same with children. If it happens frequently the pupils become yellow-like."*
>
> *Q: " Is that the malaria? "*
>
> *R: "Yes. "*
>
> *Q: "What about the "asra? "*
>
> *R: "It is the same thing as malaria but we have the "eku" and the "eyoo"* (male and female)."
> **(Agomeda Women)**

> *"When it starts the body becomes hot then the child will say "my head" and " my stomach" then sometimes there will be vomiting. The urine can become yellowish and the vomit too. "* **(Luom Women)**

> *"Recently, my child had "asra". His body was hot and his blood became small. I know because when I pressed his palms it was white. His urine was yellow and his vomit was also yellow. Even the vomit did not come out properly maybe because he had lost appetite. "* **(Agomeda Woman)**

Signs of severe malaria

"Asra eku", typically translated as "male" malaria, was perceived to be a very serious condition which could kill. Generally, community members recognized *"asra eku"* as a progression from *"asra eyoo"* or uncomplicated malaria.

"Fever" causes the convulsion. When "fever" strikes and the body becomes too hot, it leads to convulsion. The convulsion also leads to epilepsy." (**Lardowayo Traditional healer**)

A group of pre schoolteachers indicated that severe malaria is the result of simple malaria that has not been treated properly

"Some of the mothers do not take good care of their children. When they are given drugs for "white fever" at the hospital, they do not complete the dose and if this happens several times, the child's condition can go to "yellow fever" and even move to "high fever" if the mother is not careful." (**Pre School Teacher, Dodowa**)

The disease is thought to present in various forms, some of which are a progression of others. Most of its perceived presentations tie in closely with biomedical definition of severe malaria. The presentations include: convulsions (*"Hiowe"*, *"Sediblim"*), very hot body (*"Hedola wawee"*), dirty stomach (*"Mimi semu"*), sore in the stomach (*"Mimi pa"*, *"Musu fla"*, *"Yamkuro"*), lump in the stomach (*"Mimi kpo"*), lack of blood (*"Muo be ehe"*), inability to eat, drink, sit or stand, excessive vomiting, and change in mental status or child behaving strangely. They explained the development of some of these conditions as follows:

Lack of blood/Anaemia (*"Muo be ehe"*)

The local term for anaemia is translated to mean the child does not have blood. This is thought to be due to a number of reasons:

- Children lose blood when they are ill and this is because they lose appetite and do not eat properly. Some conditions like fever, measles and sore in the stomach could lead to loss of blood.

"In some cases when you already do not have enough blood, when the malaria attacks you, it becomes serious." (**Agomeda Women**)

"Malaria too can lead to shortage of blood. If it were to be food alone, then the child should make use of it for blood gain." (**Agomeda Men**)

- Poor nutrition; for instance giving a child a meal without fish could cause anaemia.

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- Sitting in the sun and always sitting by the fire. The heat from the sun and the fire dry the blood up.

Signs of anaemia ("*lack of blood*") were easily recognized by all categories of people interviewed. The fingertips are pale, and when pressed, blood does not rush to the tip. In addition, the face, under the eyelids, inside the palms, the sole of the feet and the tongue all become pale.

> *Q: "How do you detect that a child is short of blood?"*
>
> *R: "What I normally see them do at the hospital which we also imitate is that, when they say the child is not having blood, they look under the eyelid or they look at the fingertips and when it is white then the child is short of blood."* **(Agomeda Men)**

The child also loses weight. The treatment is mainly herbal with proper nutrition. In addition, the children are sometimes given a concoction prepared by mixing a malt drink with tomato puree and milk for a whole day and repeating the dose after three to four days.

Convulsions ("*Hiowe*", "*Sediblim*")

Carers seemed to be very much concerned about this particular condition which would make them rush for help usually at the nearest health facility. This was confirmed through group discussions and in case histories conducted at the hospitals.

The terms "*hiowe*" and "*sediblim*" used to describe convulsion means "heaven sickness" and depending on how it occurred may either be spiritual or as a result of a physical condition. A key informant in Dodowa explained that convulsion from spiritual sources may occur in two main ways which all relate to occurrences in the skies.

The first "*spiritual*" convulsion resulted from the child coming in contact with evil forces in the sky when carried on an adult's shoulder whilst the second occurred as a result of thunder and lightening during rain. Evil forces worked through these natural occurrences to attack people who walked in the rain. The "confusion" in the skies is manifest in the way a person behaves when he/she is convulsing. Discussants gave a vivid description of convulsion as follows:

"The child will become very very hot, then the child will start struggling with air then the head will go up and look into the sky. The eyes will roll so that you cannot see the black one again then the child will become stiff like a dead fowl during harmattan." **(Agomeda Women)**

Carers treat children with convulsions in a variety of ways.

- Pour water on the child continuously till the body becomes cool and rush to the nearest health facility.

- Rub the child with mud from the bathroom drain.
  (In typical rural areas in Ghana, bathrooms are usually makeshift structures at the back of the compound with no roof. Water from the bathroom drains into a small dug-out pit behind the structure).

- Use water from a pot in which a maize meal has been prepared and the crust left overnight with water.
  (In Ghanaian culture, there are certain meals that get slightly burnt during preparation, usually maize. After preparation of the meal, water is put in the pot to soften the crust for easy cleaning. The water is usually left in the pot overnight. The water from the pot is what is poured over the convulsing child).

All these actions are actually meant to cool the child down (before sending the child to a health facility) since the water in the pot and water from the bathroom drain are all cool.

There were other forms of home treatment which included putting pepper in fire and holding the child close to the fumes so that she breathes it in and sneezes, saying incantations and praying for the child, smearing of garlic and honey on the body of the child, giving enema of cold water (usually three syringes full), or liquid from a particular thorny shrub and once the child passes stool, the body cools down, or inducing vomiting by giving the child the liquid from the shell of a snail mixed with salt to drink.

It is worth mentioning that even though one of the commonest conditions seen by traditional healers in a census conducted on traditional healers in 1999 in the district was convulsions, both traditional healers interviewed mentioned that in recent times many

mothers send their children who have either convulsed or show signs of convulsion directly to the health facility, although they have the treatment for the disease.

> *"These days the mothers do not bring the children to us. Aunti Ceci (Community Health Nurse) is just here so they send the children there. The nurses also tell people to bring their children straight to them when they are convulsing and the mothers listen to them."* **(Traditional Healer Agomeda)**

Actions taken in event of illness in a child

The first action is usually to observe for a while followed by sponging at home with administration of an analgesic. If the child does not improve, the carer would then either go to a nearby chemical seller, community clinic or health centre. Generally, the nearby chemical store is visited when a presumptive diagnosis of the illness is made by the carer. The hospital is the last resort, either through self referral or referral from the primary care facility. Some community members also use the hospital for their primary health care because of their perception of the lower quality of care at some of the primary care facilities. Carers sometimes decide on how severe an illness is and, based on this, select the appropriate source of health care.

Decision making in health care seeking

Decision making on health care seeking in the district was said to be a democratic process and either one of the child's parents who was present at the time of the child's ill health could send the child for treatment. This, however, depended on the availability of funds. The Apese women confirmed this by adding that they either discussed with their husbands if they were available, their neighbours or used their own discretion.

> *"Sometimes when the child is ill, we treat the child at home. If it works we save money and do not go to the hospital. Sometimes the father is not here but then when it happens like that you can run to someone you know in the town and tell him that your child is ill. He will bring what ever treatment he also knows and then we cure the sickness or send the child to hospital if it fails."* **(Apese Women)**

With the 12 case studies, in over half of the cases, a discussion was held with relatives or friends before a decision was taken on where to send the child for health care. Most of the caretakers (8/12) indicated that they sought advice from someone before sending the child to seek care. In half of the cases, it was the mother who sent the child to the hospital. In three of the cases it was both parents. Two children were brought by their fathers and one by his grandmother. In most cases (10/12) it was the father who paid for the cost of care. Three of the 12 cases had to borrow money in order to seek health care.

Causes of delay in seeking care at health facilities

A number of factors were brought up as causes of delay in seeking care from health facilities. These included:

- Direct cost of health care

> *"..................... what is even worse is when the person's child is sick and needs to be taken to the clinic. There you can see that after the first day, instead of going, the second day he goes to buy paracetamol at a drug store. You can also see time is going and the sickness is at a standstill. But if he is able to get something and send the child to the health facility it becomes clear that the sickness has become worse so he should be taken to Atua (a referral hospital) then it becomes a problem. Those who have money, in times of sickness they don't knock on anybody's door. Before you realize, they have gone to the health facility and come back."* **(Agomeda Men)**

> *Q: "What hinders you from getting to the health centres on time when your children are ill?"*
> *R: "Money and Transportation"*
> *Q: "What do you do if you do not have money?"*
> *R1: "We borrow from neighbours."*
> *R2: "We keep them in the house and give them Paracetamol and "M & B."*
> **(Lardowayo Women)**

> *Q: "What are the hindrances you face with respect to health care for your children?"*
> *R: "Money. When our children attract illness suddenly, we try to give them herbal treatment first because whenever we borrow money to send our children to a clinic, we pay back that money with interest. So we rather turn to herbal treatment until we work and get the money to send them to a clinic or health centre."*

Q: "Assume there is money available. What else hinders you?"
R: "Lack of vehicle may hinder us but we will walk if necessary."
(Abonya Women)

Abonya is a community which is less than 5 km away from the health centre in the district capital, Dodowa.

When the child is ill and we send the child to the health facility and maybe we have only C30,000.00 on us, and the doctor writes a prescription, that amount is not able to solve the problem for the child. This then creates a problem for we the parents. On the other hand if you don't send the child early then it turns into another thing." **(Agomeda Men)**

"What brings about the delay is money and without money when you take him to the health facility he will not be taken care of. So to get money, you must go round and search for some, sometimes for three days before you will get the money." **(Apese Men)**

Lack of finances to pay for health care seemed to be a very important factor and was invariably mentioned first. The discussion brought up the fact that even the very low premiums of C25,000 (£1.65) per person per year required for membership of the district pre-payment scheme appeared to be problem.

- Transport costs and distance from health facility. This problem was mostly brought up by those who lived more than ten kilometres away from the nearest health facility.

Q: "What are some of the things that hinder you from getting to the health facility early when your children are ill?"

R1: "Transportation difficulties-we sometimes do not get vehicles on time."

R2: "Lack of money."

R3: "The distance from this village to the health facility is too far."

R4: "Due to lack of work we do not have enough money to send our children to the health facility." **(Lardowayo Men)**

"We take the children to the herbalist for first aid when the illness occurs in the night and no vehicle is available. And then take them to the clinic later." **(Abonya Men)**

- Trying other options nearer home to see if they will work first or simply staying at home and hoping for the best. These included the following:

Left over medication/prayers

They used either orthodox medication left over from previous visits to health facilities or from previous purchases from the chemical seller. They sometimes also prayed themselves in addition or sought for prayer from a "pastor" nearby.

"When the child gets fever today and for 3 days you give the child chloroquine or paracetamol and it still doesn't get better, you tell your husband you have given the child some drugs and prayers but still there is no improvement. Therefore you want to send the child to the health facility for them to diagnose the child." **(Agomeda Women)**

"When the child's temperature is high, it may be malaria or just a new tooth coming up. When you give the child paracetamol, in the case of the new tooth, you will see that it subsides. But for malaria, you see the temperature is on and off. When the temperature is high and does not stop then we send the child to the health facility." *(***Agomeda Men)**

"We wait for about three days before going to the health facility. If it is the stomach, you can give enema. If it is high temperature and you have any syrup, you can give it to him to bring it down if it doesn't come down, then you have to visit the health facility." **(Luom Women***)*

Herbal preparations

There appeared to be knowledge of some specific herbs thought to be efficacious in the treatment of febrile illnesses. This information was usually passed down through the generations or through consultation from other community members. And the information was shared among community members who were always happy to contribute to the health of the sick person by sharing whatever knowledge they had.

"The women know some of these leaves so that when they see the symptoms they sometimes grind some leaves and give it to the child to drink and then when it becomes necessary before they take him to the health facility." **(Apese men)**

"We prepare herbal medicines for them at home. My mother normally goes for some leaves to prepare this. We normally take them to the health facility after the herbal medicine has failed." **(Lardowayo Men)**

Chemical sellers

Medication was also purchased from near-by chemical sellers. The parent usually described the symptoms to the chemical seller who was trusted as someone who was knowledgeable about the drugs because he had been handling them over a long period of time. They were usually trusted and respected members of the community as well.

"We buy drugs from the chemical shop including ampicillin and paracetamol for the children. We give them the medicines for about four days. Some children recover after this. If they do not, we take them to the clinic." **(Abonya Women)**

Drug peddlers

There were some itinerant drug peddlers who moved from community to community and over a long period of time had become accepted. Their credibility was usually based on their previous "successes" in the "curing" of ailments and were recommended mainly by other community members. They usually were not members of the community but came in from bigger cities and towns. Their addresses were often not known and they kept to a known schedule. Community members often cover up for these drug peddlers when their activities are being investigated.

"There are some people who have some knowledge of medicine and so come over here to visit us and sell drugs to us." **(Lardowayo Men)**

Hoping for the best

Some households who do not have the means to seek health care sometimes stay at home and hope for the best.

"....there are sometimes that we say the mother should stay in the house for us to see whether it will be well but before you realize the child is dead." **(Apese Men)**

Payment for health care services

Ability to pay for health services and perception of the size of the bill was said to depend mainly on the financial situation of the family. Whilst some are able to pay outright from funds available in the home, others resort to various coping mechanisms which include the following:

- **Borrowing from relatives or friends.**

"We borrow money if we do not have any." **(Lardowayo Men)**

"We are all a large extended family with one grandfather, so we meet together as a group and finance a member who is ill for treatment. And later meet again to settle that debt." **(Abonya Men)**

"I borrow money from my sisters to pay the bills if I do not have the money." **(Abonya Woman)**

- **Working on other people's farms for money.**

"We sometimes work partly for others in order to get advances on the work to settle the medical bill." **(Lardowayo Women)**

"The husband may do any labourer work to raise the money, for example, weeding someone's farm. We sometimes weed people's farms for money in times of need. Half a pole takes two weeks to weed and the payment for that is C90,000.00 (£5.60)." **(Abonya Women)**

- **Arranging to pay in instalments.**

- **Credit facilities (commonly with traditional service providers).**

- **Selling farm produce quickly to raise the funds.**

"We sometimes sell our domestic animals like sheep, goats or fowls to settle the medical bills." **(Lardowayo men)**

- **Falling on savings.**

- **Some mothers waited for the father to return home before obtaining money for healthcare.**

- **Others relied on their enrolment in the existing scheme.**

Perceptions of the district pre-payment scheme and government exemptions policy

Almost everybody admitted to having heard about the pre-payment scheme. However, very few had enrolled for the year, most citing lack of money.

> *Q: "Have you heard about the health Insurance scheme?"*
> *R: "Yes." (in unison)*
> *Q: "Have you enrolled in it?"*
> *R: "Those of us here have done so but those at the centre over there have not done it." (laughter)*
> *Q: "Why have you not enrolled?"*
> *R: "We are now gathering money. We did not have money to join earlier."*
> *Q: "What is your experience with the scheme?"*
> *R1: "Those of us who have done it know it is good. We know ourselves that it is good."*
> *R2: "We know it is good but just that there is no money."* **(Agomeda Women)**

> *"Yes they have been saying it. At first I did not bother but a friend of mine who is a nurse advised me to enrol. Just after a few days my child fell sick and I had nothing on me but when I took him to the hospital I paid nothing. It is very good and profitable."* **(Apese Man)**

> *"My experience is that when your child is sick and you do not have money, it will be a big problem. But with the insurance, if the child gets a fever you take the child to the clinic for free medical care and free drugs. Even if the sickness is serious and you are referred to Agomanya or Atua it helps you a lot, because there they do not collect anything from you."* **(Agomeda Women)**.

Others referred to reports by some enrolled members of the quality of care offered to members of the scheme as their reason for not enrolling, even though they still utilized the facility. It appeared that those who enrolled in the scheme expected to be given new and different drugs whenever they were ill. For instance if they had malaria and were given chloroquine, the first line anti-malarial drug at the time, they were displeased and felt they were not receiving the level of care they should have. Some also had misconceptions and misunderstanding about the operation of the scheme.

"When I heard about the scheme at first, I thought it would not materialise. But we were told again the other day so we decided to enrol." **(Abonya woman)**

"People complain that it is the same old paracetamol and chloroquine they are given. So I feel at peace rather for me to care for my child than to go and collect that drug." **(Agomeda Men)**

"We were told some time ago that we will have to deposit an amount of money, so that in case we go to the health facility we will be given a card for medication. When we took that into consideration, we felt that if one should pay C200,000.00 and another C1 million then it implies that the one who paid more will be given more attention so it is better we don't pay..(laughter)." **(Lardowayo Men)**

"I was enrolled in the scheme and paid my premium. But once, I took my sick child to the clinic and was given drugs that made me unhappy-paracetamol. She did not recover and was later cured by our herbalist. This made me annoyed and I decided to stop. But one of my relatives advised me to be patient. I later decided to look for money to pay the premium this year." **(Abonya Man)**

Several discussants mentioned that they were waiting to enrol in the new National Health Insurance scheme which they had heard would not require any payment of premiums, even though this was a misconception.

Very few had heard about the government of Ghana exemptions scheme for the elderly (over 70years of age), children less than five years and antenatal care for pregnant women. Some mentioned that they knew it existed in the past. Those who said they knew about it, were unable to say who the beneficiaries were and did not seem to know of any one who had benefited from it. Some presumed that the beneficiaries were health workers.

Perceptions of poverty

Community members came up with a variety of indicators by which they identified the poor in their midst. These were:

- **Clothing** – tattered, usually dirty, or the same clothing worn at all times without washing them (*"they wear trousers with a hole at the bottom"*).

- **Food** – Poor people eat an unbalanced diet e.g food without meat or fish

  "...one piece of fish dancing and going round in the soup for the family all alone." *(Apese men)*

  "When the poor person is visited one could see that he/she will be eating banku or 'face the wall' with pepper without fish or meat." **(Lardowayo Men).**

  The family may not eat the whole day or purchase food on credit.

- **Money for various obligations**– The poor always borrow money and are unable to make family contributions. They are unable to take their children to the clinic when ill because they have no money to pay for the services. They are also unable to pay the school fees of their children.

- **Societal Conduct** – They walk with their heads down, and easily shed tears whenever someone asks them for money. When they attend functions or gatherings they always sit at the back. They show a lack of confidence in the midst of people and do not like attending functions.

- **Housing and Property** – They have no property or livestock and their houses are not well furnished or in a state of disrepair.

The poor were said to survive by searching for firewood and selling it to buy food. They sometimes sold or pawned their possessions for money.

They also borrowed from other community members or worked on other people's farms for money. They sometimes washed and carried loads for others for which they received payment. They mostly depended on the sympathy of friends and relations or on the "Grace of God". Those who belonged to churches sometimes received assistance from

church members. However, there were no known formal structures in any of the communities to assist the poor.

Attitudes and perceptions on treated nets

All discussants from the two different groups said they owned nets and used them. They were quite knowledgeable about bed nets and also about treated nets which were being promoted.

Their main reason for sleeping under mosquito nets was to avoid being bitten by mosquitoes. Two women had other reasons and these were to prevent the lizards and other insects from falling on them from the roof which had no ceiling and another was to keep warm during the cold weather. According to discussants, people who owned nets sometimes did not sleep under them or slept under them with their heads outside the net for several reasons. They felt too hot and sweated when they slept under the nets. Some complained of difficulty in breathing and a feeling of suffocation under the net. Others simply felt uncomfortable under the net. It must be mentioned that some mosquito "nets" used in the area were actually made of pieces of calico joined together and had no net component.

Almost all the women linked mosquito bites with malaria and explained further that if they slept under the mosquito nets and were not bitten by mosquitoes then they would not get malaria.

> *"It prevents us from getting malaria due to the inability of mosquitoes to bite us when we use it."* **(Asebi Woman not enrolled)**

> *We know that mosquito bites give malaria, so we sleep under bed nets."* **(Hiowe Gblaka woman not enrolled)**

> *"We sleep under them so that the children will not be bitten by mosquitoes in order to prevent malaria."* **(Agomeda Woman enrolled)**

A few seemed to have an idea that in the dry season, there were no mosquitoes at all so that if one did not like heat, one could decide not to sleep under a net during that period.

The women said there were different kinds of nets available in the community. They said there were different colours available such as green, blue, pink, brown and white ones, there were nets made from grey baft or polyester and others from cotton or nylon net. There were also very big nets and smaller ones. They had also heard about the treated nets (*"the net with medicine it"*) but only few of them had one at home.

> *"There is a type they say they have put medicine in and when you use it, a mosquito will not even stand on it."* **(Asutuare junction woman enrolled)**

When asked where one could obtain nets, the women indicated that untreated nets could be obtained from the big markets, usually from second hand clothes dealers, whilst the treated nets were mostly sold at the public health facilities and child welfare clinics in the district at a subsidized cost for children less than five and pregnant women. They mentioned, however, that one could obtain some treated nets at full cost at some Pharmacy shops in Accra. The subsidized, treated nets were said to cost about C20,000 (£1.25) whilst those that were not subsidized cost between C75,000 (£4.69) and C120,000 (£7.50). They usually bought the untreated ones on the open market at a price ranging between C25,0000 (£1.56) and C50,000(£3.13).

They were not sure and had varying opinions on how often one needed to re-treat a treated net. The period before re-treatment ranged from about 3 days to a number of weeks (1 week to 3 weeks). Most said the nets could last for months before needing re-treatment. When pressed for exactly how many months the treated nets lasted, some said 3 months, whilst others said they were certain the period was 6 months. Others thought that the nets lasted for at least one year or 4 years before re-treatment would be required.

Finally when asked who they thought should be given preference in terms of sleeping under the net, some thought the child should sleep under the net because as one woman put it:

> *"..the child is young and the blood is not strong but that of the adult is strong. The adult can receive many mosquito bites before attracting illness but a child can be bitten today and attract the illness tomorrow."* **(Howe Gblaka Woman enrolled)**

Most of the discussants, however, thought the mother should share the net with the children for various reasons. Most interesting and frequently mentioned among these reasons was the fact that malaria infection in the mother could be passed to the child through breast milk.

> *"You the mother if you don't sleep under the net and you are bitten by mosquito, and you get malaria, the child is breastfeeding and will get malaria too."*
> **(Asutuare Junction woman enrolled)**

Other reasons why the mother should sleep under the net with her young children included the fact that the mother could also be infected by malaria from the child because she was the one who cooks and does everything for the child. A few others said if there was a pregnant woman in the house she should sleep under the net because when one gets pregnant, one gets weaker so adding illness to the weakness was dangerous. Two people said the father should sleep under the net.

4.1.4 Summary

The study showed that community members were familiar with both uncomplicated and severe malaria and could clearly differentiate between the two by means of a set of signs and symptoms. They sought care for these conditions mainly from the health facilities nearby except in the case of convulsions, which they sometimes attributed to spiritual causes. Decisions on whether to seek care and where to do so appeared to lie mainly with whoever was present when the child fell ill, in most cases, the mother. And she usually either took the decision herself or consulted with nearby neighbours and relatives if she so wished.

The main barrier to seeking formal health care was the direct cost of care according to community members. However, distance and travel costs also appeared to be a barrier which community members thought was largely surmountable. Some community members did not seek care from the primary care facility because the chemical seller was closer.

Community members were familiar with the pre-payment scheme operating in the area and although many of them had not yet enrolled, they said they had not done so mainly because of cost. A few members, however, had heard some negative rumours about the scheme from others and had therefore decided not to enrol based on that. Community members came up with clear indicators of poverty and coping mechanisms but indicated that there were no formal structures in the community to support the poor.

Although a lot seemed to be known about treated nets, very few were using them. Untreated net usage appeared to be still high traditionally in this area, as has been found in previous studies. Contrary to what was found in previous studies, however, community members do link up sleeping in a net with prevention of malaria and think that young children need to sleep under the nets preferably with their mothers.

The results of these studies are therefore consistent with the premise on which the trial was based and supported the carrying out of the study.

CHAPTER 5 RESULTS OF AN *IN VIVO* THERAPEUTIC ASSESSMENT OF THE EFFICACY OF CHLOROQUINE

5.1 Introduction

The results of a preliminary study to assess the therapeutic efficacy of chloroquine in the study area are presented in the following sections.

The study was carried out in from October 2003 to January 2004. At the time of the study, chloroquine was still the first line drug for the treatment of uncomplicated malaria in the study area as well as the whole country. In principle, the National Malaria Control Programme had taken a decision for a change to an artesunate-amodiaquine combination. The modalities for implementing this new policy were still being worked out. It was critical to the study that the drug in use at the time was effective. Therefore a study was undertaken to determine the efficacy of chloroquine in the study area.

5.2 Methods

It was a longitudinal study involving the collection of data using quantitative methods. The standard World Health Organization (WHO) 14-day follow-up assessment of therapeutic efficacy of anti-malarial drugs was followed (WHO 2001).

Sample size

The level of chloroquine resistance was expected to be slightly lower than that found at Hohoe in the southern part of Ghana. In a previous study by Koram and others, Hohoe was found to have a chloroquine resistance of about 13% comprising 6.5% and 6.0% early and late treatment failures respectively (Koram 2003a). It was assumed, therefore that the level of resistance in Dangme West would be approximately 10% with a maximum variance of 5%. The sample size required to give the study a power of 90% at a significance level of 5% was therefore 97.

Inclusion criteria

- Age between 6 and 59 months of age.

- Absence of severe malnutrition.
- Single infection with *P. falciparum*, with parasitaemia in the range of 2000 to 200,000 asexual parasites per μl.
- Absence of general danger signs or signs of severe *falciparum* malaria according to the definition given by WHO.
- Presence of axillary temperature ≥ 37.5°C or a history of fever at the visit.
- Absence of febrile conditions caused by diseases other than malaria.
- Ability to come for the stipulated follow-up visits and easy access to the health facility.
- Informed consent of parent/guardian.

Exclusion criteria

- Children who required parenteral treatment.
- Severe or complicated malaria based on a parasite count >250,000/μl of blood or as judged by the attending Medical Officer using clinical criteria.
- Hb < 5g/dl.
- Evidence of another disease condition apart from malaria, signs of severe malaria or chronic disease.
- Withdrawal of consent.
- Movement far away from the study area.

Screening, treatment and follow-up

Children 6 to 59 months of age who reported to the outpatients department with uncomplicated malaria were recruited based on a set of inclusion criteria. Informed consent was obtained from mothers/guardians for their participation in the study. They were assured of their freedom to withdraw their consent at any time during the study if they so wished without it affecting their management at the health facility. Following parental consent, the child was enrolled into the study. Demographic and other background data on the child were collected and baseline haematological and

parasitological assessments were carried out. Thorough physical examination was undertaken to rule out other causes of fever in the child.

The first dose of chloroquine based on the child's weight was administered to the child under direct supervision of a project nurse. The child was observed at the clinic for a minimum of thirty minutes to ensure that he/she did not vomit. If the child vomited during this period of observation, the dose was re-administered. Over the subsequent 14 days, the child was given the rest of the three-day dose under supervision and closely followed up clinically and parasitologically according to the WHO 14-day therapeutic efficacy protocol. Any child who failed to report on a scheduled day was followed up at home on the same day.

Mothers/principal carers were encouraged to bring their children back on non-scheduled days if they had any concerns about the child's condition. Any of the children who did not respond to treatment with chloroquine were treated with sulphadoxine-pyrimethamine, which was the second line anti-malarial drug at the time of the study. Children who still did not improve on the second line drug or who developed any complications were referred to a hospital. Children who developed concomitant infections were excluded from the study. Transport to a referral hospital was borne by the study. Children found to be anaemic on day 14 were treated as per the Standard Treatment Guidelines of Ghana at the study's cost. Data were collected according to the schedule in Table 5.1.

Table 5.1: Study time-table

	Clinical examin-ation	Temperature recorded	Parasitaemia determined	Haemoglobin measured	Treatment Given
Day 0	X	X	X	X	*X*
Day 1	X	X			*X*
Day 2	X	X	X		*X*
Day 3	X	X	X		
Day 7	X	X	X		
Day 14	X	X	X	X	
Any other day	*X*	*X*			

Treatment doses

- Chloroquine – 10mg/kg body weight daily for the first two days followed by 5 mg/kg body weight on the third day
- Sulphadoxine-pyrimethamine – ¼ tablet per 5kg body weight stat (one tablet contains 25 mg pyrimethamine and 500 mg sulphadoxine)

Laboratory methods

Haemoglobin concentrations were assessed using haemocue cuvettes (*Haemocue AB, Angelholm, Sweden*). Thin and thick blood films were stained with Giemsa reagents and read by experienced malaria microscopists.

Classification of outcomes

Therapeutic responses over the 14 days were classified according to the WHO protocol for assessment of therapeutic efficacy of anti-malarial drugs for uncomplicated *falciparum* malaria for areas with intense malaria transmission (WHO 2001). Patients were classified as follows:

- *Early Treatment Failure (ETF)*

  o Development of danger signs or severe malaria on or before day 3 in the presence of parasitaemia, or

  o Day 2 parasite density exceeding that on day 0 irrespective of axillary temperature, or

  o Day 3 parasite density $\geq$ 25% of that on day 0 or

  o Fever and parasitaemia on day 3.

- *Late Clinical Failure(LCF)*

  o Development of danger signs or severe malaria in the presence of parasitaemia after day 3 or

o   Fever in the presence of parasitaemia after day 3 without previously meeting any of the ETF criteria.

- *Late Parasitological Failure (LPF)*

o   Presence of parasitaemia without fever on day 14 without previously meeting any of the ETF or LCF criteria.

- *Adequate Clinical and Parasitological Response (ACPR)*

Absence of parasitaemia on day 14 irrespective of axillary temperature without previously meeting any of the criteria for the afore-mentioned classification.

5.3 Main findings

A total of 504 children with fever or histories of fever were screened over a period of four months at the Dodowa Health Centre. They were recruited from that facility and another primary care facility nearby, the Agomeda Community Clinic. Four hundred and sixty-seven were microscopically positive for *P. falciparum,* showing a slide positivity rate of 92.7%. Of the 467 patients, 344 (73.7%) were excluded due to low initial parasitaemia, 2 (0.4%) were excluded because they had a haemoglobin concentration less than 5g/dl and 3 (0.6%) because their guardians refused consent. One other patient whose age was found to be above 59 months when re-checked was also excluded.

Altogether 117 children met the inclusion criteria and were enrolled in the study. Seven (6%) patients were excluded after enrolment because they developed febrile illnesses other than malaria during the follow-up period. One other patient was excluded because she refused to swallow the medication after several tries whilst 3 (2.6%) were lost to follow-up because their mothers travelled with them far away from the study area and did not return. For analysis therefore, 106 patients who completed follow-up were taken into account (Figure 5.1).

Figure 5.1 Trial profile for the assessment of therapeutic efficacy of chloroquine

504
Chn with fever screened

37
Excluded. Slide negative

467
Slide Positive

344
Excluded. Parasite count <2000/µl

3
Excluded. Refused consent

2
Excluded. Hb<5g/dl

1
Excluded. Age >59 mths

117
Met inclusion criteria

7
Excluded. Other febrile illness

1
Excluded. Child refused medication

3
Lost to follow-up

106
Completed follow-up
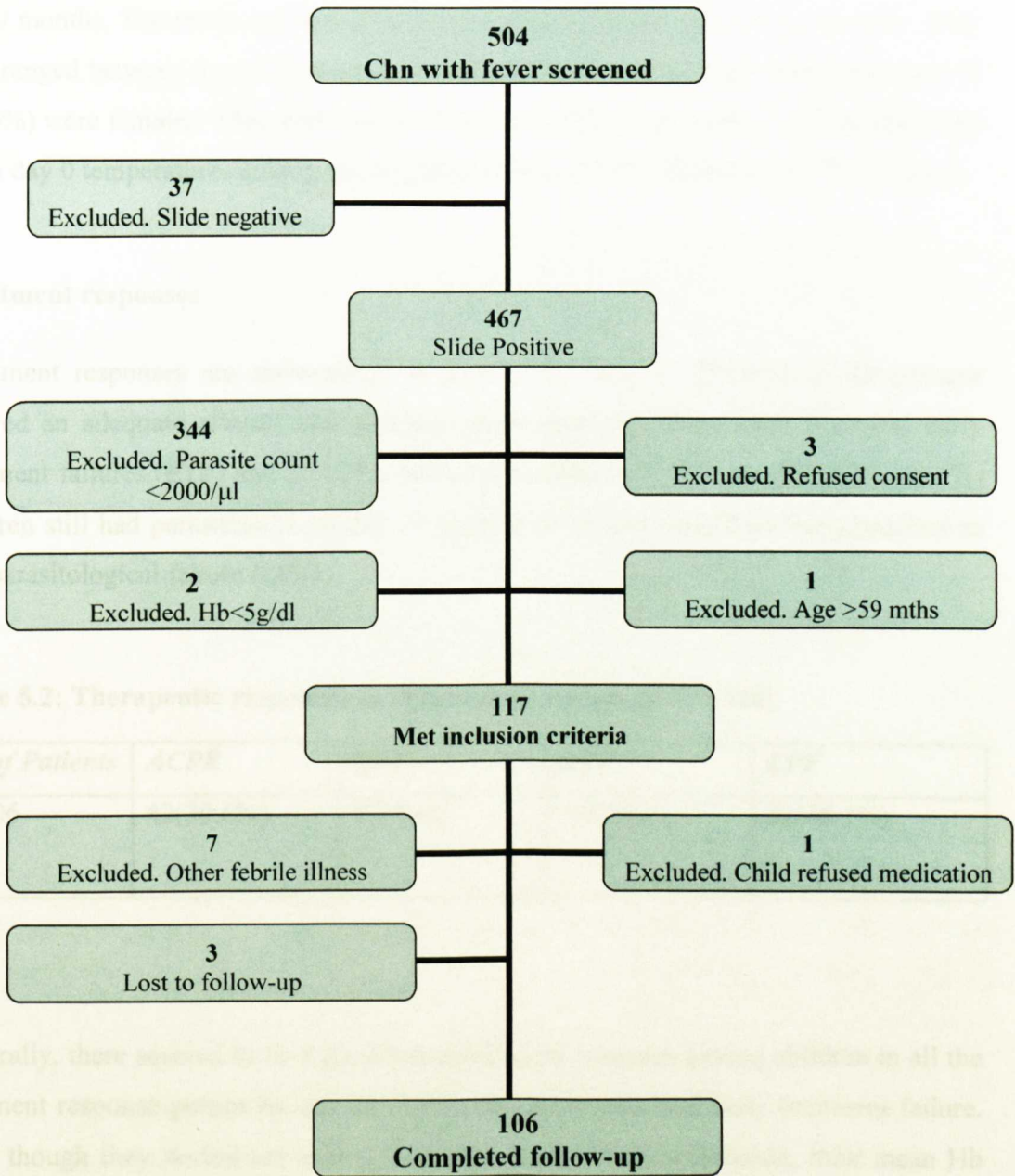
Demographic data

There were 14 (13.2%) children aged 6-11 months whilst 92 (86.8%) were aged between 12-59 months. The mean age was 27.9 months with a median age of 25.5 months. Their ages ranged between 6 and 59 months. A total of 63 (59.4%) patients were males and 43 (40.6%) were females. They had a mean weight of 11.7kg with a range of 7 to 28kg. The mean day 0 temperatures among the 106 patients was 38.1°C falling to 36.6°C by day 2.

Treatment responses

Treatment responses are summarized in Table 5.2. Only 42 (39.6%) of the patients showed an adequate clinical and parasitological response. There were 8 (7.6%) early treatment failures (ETF) and 5 (4.7%) late clinical failures (LCF). A total of 51 (48.1%) children still had parasitaemia on day 14 without fever and were therefore classified as late parasitological failure (LPF).

Table 5.2: Therapeutic responses to chloroquine treatment (N=106)

No. of Patients	ACPR	ETF	LCF	LPF
N=106	42(39.6%)	8(7.6%)	5(4.7%)	51(48.1%)

Generally, there seemed to be a good haematological response among children in all the treatment response groups by day 14 except the group who had early treatment failure. Even though they started out with a very high mean Hb concentration, their mean Hb dropped to a level much lower than those who achieved an adequate clinical and parasitological response. Of the three other groups, even though their mean Hbs at day 0 were very similar, improvement in Hb was highest among the ACPR treatment outcome group followed by the LPF, and LCF in that order (Figure 5.2). The differences in mean

haemoglobin concentrations of the four groups were not significant both on day 0 ($\chi^2=5.32$ p=0.15) and day 14 ($\chi^2=0.81$ p=0.85) of follow-up.

Figure 5.2 Comparison of mean Hb by treatment outcome at the end of follow-up
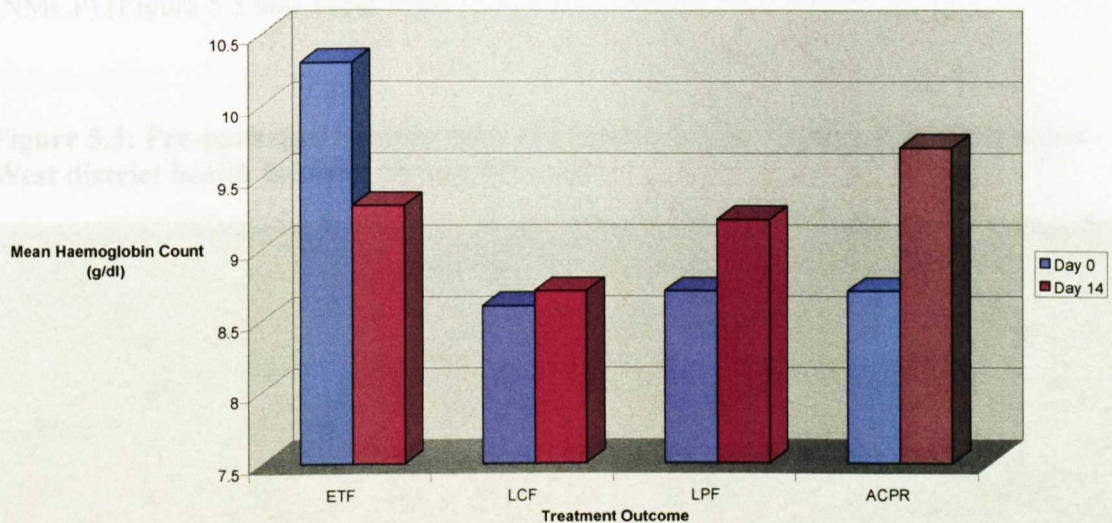
5.4 Consequences of the *in vivo* assessment of the therapeutic efficacy of chloroquine

The study demonstrated that chloroquine was no longer efficacious for the treatment of malaria in the study area. Therefore, permission was sought from the national authorities to change the first line anti-malarial in use at health facilities in the district for children aged less than five years.

An initial meeting was held at the District Health Administration with heads of both public and private sector health facilities during which the results of the study were presented. Subsequent meetings were held with heads of facilities during which ways for

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effecting the change of anti-malarial from chloroquine to amodiaquine-artesunate were discussed. The change was carried out prior to the onset of the main trial.

Artesunate and amodiaquine tablets were purchased and co-packaged at the District Medical Store for purchase by health facilities using the existing system for procurement of drugs in the district. There were two packages based on weight for children aged less than five years as proposed by the Ghana National Malaria Control Programme (NMCP).(Figure 5.3 and Table 5.3).

Figure 5.3: Pre-packaged amodiaquine artesunate tablets dispensed in all Dangme West district health facilities during the trial.

During the entire period of the study, therefore, all children less than five years of age who visited any of the health facilities in the district and were diagnosed with malaria received the amodiaquine-artesunate combination. In total, over the six month period of

the study, a total of 3493 packages for infants and 6036 packages for children were packaged and distributed by the district medical store to health facilities (public and private) who dispensed them to patients.

Table 5.3Dosage schedule for treatment of uncomplicated malaria with amodaquine-artesunate combination for children less than five years of age.

Weight (kg)	Age (Years)	Number of Tablets					
		Artesunate 50 mg Tablets			Amodiaquine 150 mg base		
		Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
5-10	Infants	1/2	1/2	1/2	1/2	1/2	1/2
11-24	1-6	1	1	1	1	1	1

CHAPTER 6 RESULTS OF MAIN TRIAL

6.1 Introduction

The following section sets out the results of the main trial. It was an open, two-arm, randomized controlled trial with a subsidiary observational arm. Where the discussion involves the intervention, control and the subsidiary (self-enrolled) arms, they are referred to in the plural form as "study arms". The intervention and control arms are referred to either by name, as "randomly allocated group" or "trial arms".

6.2 Recruitment and randomization

A total of 2332 households in the Dodowa and Prampram sub districts with 2757 children aged 6 to 59 months were randomly selected from a district database for enrolment into the study. The households comprised all of the 138 households with 165 children aged 6 to 59 months who had already voluntarily enrolled in the pre-payment scheme at the time of closure of the registration window and 2194 households with 2592 children aged 6 to 59 months of age who had not. The total number of households with children less than five years old in these two sub districts was estimated to be about 8700.

The 2194 households who were randomly selected from the database were invited for randomization by open ballot within the three distance strata. Meetings to carry out random allocation of the two study arms were held at separate locations on separate days for three distance groups as follows: residence less than 5km, 5-10km and more than 10 km from a public sector health facility respectively. Heads of households were given colour coded invitation cards to attend the meetings. It was therefore very easy to spot a household head who had attended the wrong meeting and re-direct him/her to the right one. The slips of paper were collected and individual informed consent sought for enrolment into the study before the consenting household heads were allowed to ballot.

At the meetings, consenting heads of households were informed about the baseline cross-sectional survey which was due to begin two weeks later. Informed consent was sought

at household level from the 138 households who had themselves enrolled in the existing district pre-payment scheme. They were recruited into the study in order to document the differences between them and the randomly allocated arms as a subsidiary part of the study.

6.3 Baseline cross-sectional survey

The baseline cross-sectional survey involved visits to all households enrolled in the study. Forty-three households containing 68 children from the randomly allocated arms were unavailable during the baseline cross-sectional survey. Most had travelled far away from the study area and were not going to be back for a long period. A few households were not located on account of inaccurate addresses provided at the randomization meetings. Finally a total of 2151 households out of those randomly allocated containing 2524 children remained in the study and participated in the baseline cross-sectional survey. The achieved sample size at baseline was, therefore, more than what had been planned. See page 133. The trial profile in shown in figure 6.1.

6.3.1 Overall characteristics

Overall, 947 (37.5%) households in the group that was randomly allocated had more than one child aged less than five years. A total of 490 (37.8%) of the households in the control arm had more than one child aged less than five years as compared to 457 (37.3%) of the households who belonged to the intervention arm. Of the 138 self-enrolled households, 74 (44.8%) had more than one child aged less than five years. The mean number of children aged less than five years in households belonging to all three study arms was 1.5.

Most of the respondents were the mothers (72.6%) or the fathers (17.0%) of the study children and their main occupations were traders (38.3%), farmers (26.3%) and artisans (14.4%) in both arms. The overall reported unemployment rate was about 9.6%; being less in the self-enrolled group (8.5%). Over 80% of respondents in all arms said they

belonged to the Christian Faith whilst the rest were Muslim or practised African Traditional Religion, with a few agnostics (Table 6.1).

The households resided in a total of 150 communities scattered over the two sub-districts. Overall there are a total of 381 communities in the whole district. The distribution of the study participants by distance strata is set out in Table 6.2.

Table 6.1: Comparison of the background characteristics of the three study arms at baseline.

	Control N=1297	Intervention N=1227	Self-enrolled N=165
Sex			
Male	639(49.3%)	614 (50.0%)	87(52.7%)
Female	658(50.7%)	613(50.0%)	78(47.3%)
Median age in months (IQR)	32 (18-46)	33 (18-46)	32(19-45)
Christian religion	1124 (86.7%)	1082 (88.2%)	154 (93.3%)
Married respondent	1078 (83.1%)	1016 (82.8%)	144 (87.3%)
Mean SES Score (SD)	-0.067 (1.87)	-0.053 (1.86)	0.924 (1.75)
Mean monthly income [1] (in cedis)	459,031	470,485	553,788

Overall, 1745 (64.9%) of the children lived within five kilometres from a health facility whilst 417 (15.5%) lived more than 10km away. The rest lived 5-10km away from a health facility. None of the self-enrolled group lived more than 10km away from a health facility. Most (87.3%) of them lived within 5 km of a health facility. Place of residence in relation to a health facility was similar in the two randomly allocated arms since the randomization took this into consideration. See Table 6.2.

Table 6.2: The number of study children belonging to the different trial arms by place of residence.

| | Distance of residence from health facility | | | Total |
	<5km	5-10 km	>10km	
Control	829 (63.9%)	253 (19.5%)	215 (16.6%)	**1297**
Intervention	772 (62.9%)	259 (21.1%)	196 (16.0%)	**1227**
Self-enrolled	144 (87.3%)	21 (12.7%)	0(0%)	**165**
TOTAL	**1745**	**533**	**417**	**2689**

Figure 6.1 Trial profile

```
┌─────────────────────────────┐
│ Eligible HH with Chn <5yrs   │
│ 2332 HH (2757 Chn)           │
└─────────────────────────────┘
            │                        ┌─────────────────────────┐
            ├───────────────────────▶│ Self-enrolled           │
            │                        │ 138 HH (165 Chn)        │
            ▼                        └─────────────────────────┘
┌─────────────────────────────┐                 │
│ Randomization of            │                 │
│ 2194 HH (2592 Chn)          │                 │
└─────────────────────────────┘                 │
            │                                    │
┌─────────────────────────────────────────────────────────────┐
│ Baseline cross sectional survey at the beginning of the      │
│ malaria transmission season                                  │
└─────────────────────────────────────────────────────────────┘
            │                                    │
            │            ┌──────────────────┐    │
            ├───────────▶│ Not found at     │    │
            │            │ Baseline 43 HH   │    │
            │            │ (68 Chn)         │    │
            │            └──────────────────┘    │
    ┌───────┴───────┐                            │
    ▼               ▼                            │
┌──────────────┐ ┌──────────────┐                │
│ INTERVENTION │ │ CONTROL      │                │
│ 1057 HH      │ │ 1094 HH      │                │
│ (1227 Chn)   │ │ (1297 Chn)   │                │
└──────────────┘ └──────────────┘                │
       │              │                          │
┌─────────────────────────────────────────────────────────────┐
│ Passive morbidity monitoring throughout the malaria          │
│ transmission season (24 weeks)                               │
└─────────────────────────────────────────────────────────────┘
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| LTFU 7.9% 88 HH (98 Chn lost + 5 dead) | LTFU 7.4% 82 HH (96 Chn lost + 4 dead) | LTFU 2.4% 4 HH (4 Chn) |

```
┌─────────────────────────────────────────────────────────────┐
│ Final cross sectional survey at end of the malaria           │
│ transmission season                                          │
└─────────────────────────────────────────────────────────────┘
```

| INTERVENTION 969 HH (1124 Chn) | CONTROL 1012 HH (1197 Chn) | SELF-ENROLLED 134 HH (161 Chn) |

*HH=Household, Chn=Children, LTFU=Loss to follow-up

6.3.2 Comparison of the base-line characteristics of randomly allocated intervention and control arms

The households that were randomly allocated to the intervention and control arms were very similar at baseline in terms of their background characteristics, the main outcome variables and their socio-economic status.

The mean number of household members in each trial arm was 5.6. The mean numbers of children aged less than five years in households in the control and intervention arms were 1.5 and 1.4 respectively and the difference between groups was not statistically significant (p=0.54). The median ages of the study subjects in each trial arm were 32 and 33 months respectively. The proportion of households who belonged to the major ethnic group in the area, Dangme, was 65.9% in the intervention arm and 62.6% in the control arm (χ^2=3.04 p=0.08). The next major ethnic group in each arm was Ewe and the proportion of households who belonged to this ethnic group was similar in both trial arms. There were 1124 (86.7%) households professing Christianity among the control arm compared to 1082 (88.2%) in the intervention arm (χ^2=1.32 p=0.25).

Most of the respondents in the control and intervention arms were mothers (73.4% and 71.6%) or fathers (16.4% and 17.7%) of the study children respectively (χ^2=4.54 p=0.60). Over 80% of them in each arm were married with a little over 2% of single status (χ^2=1.38 p=0.85). Although there was no significant difference between the mean number of years of formal education completed by the principal carer or mother of the child (p=0.12), the heads of households in the intervention group appeared to have had slightly more years of formal education than those in the control group (p=0.04).

The main occupations of the heads of households in the two arms were traders, farmers and artisans but the proportion of heads of households who indicated any of these three occupations as their main occupation was higher in the control than in the intervention arm. There were more civil servants in the intervention arm than in the control arm and the difference in main occupation between the two arms was significant (χ^2=17.27 p<0.01). The reported unemployment rates in the control and intervention arms were 126 (9.7%) and 118 (9.6%) respectively.

Table 6.3: Comparison of the background characteristics of control and intervention arms at baseline.

	Control N=1297	Intervention N=1227	P-value
Median age in months (IQR)	32(18-46)	32.5 (18-46)	0.51
Major ethnic group (%)	812 (62.6%)	809 (65.9%)	0.08
Household profess Christianity (%)	1124(86.7%)	1082 (88.2%)	0.25
Mean number of household members	5.6	5.6	-
Mean number of household members less than 5 yrs of age	1.5	1.4	0.54
Mean number of years of formal education completed by mother	5.0	5.3	0.12
Mean number of years of formal education completed by Head of Household	6.9	7.4	0.04

The two trial arms were similar at baseline with regards to the trial end-point, anaemia (χ^2=0.14 p=0.71). The proportions of children anaemic and severely anaemic were quite low at baseline. Approximately 7% of children were anaemic and 1% severely anaemic in each arm. The two arms were also similar in nutritional status with similar proportions of children being wasted (χ^2=0.46 p=0.50).

Similar proportions of households in the two arms indicated that they used some method to prevent malaria. Levels of reported use of treated and untreated nets to protect children under five years as well as screening for doors and windows among households in the two arms were not significantly different between groups at baseline. Bed net ownership was much higher than actual use by children less than five years of age in households in each arm. Consistent use of any net by the child occurred in about half of the households who owned nets. There was no significant difference in the two arms with regards to this (χ^2=0.42 p=0.52) (Table 6.4 and Figure 6.2).

Table 6.4: Comparison at baseline of the control and intervention arms in terms of the main outcome variables and malaria related indicators.

	Control N=1297	Intervention N=1227	P-value
Mean Hb (g/dl) at baseline	10.3	10.3	-
Hb < 8g/dl	97 (7.5%)	87 (7.1%)	0.71
Hb <6g/dl	17 (1.3%)	12 (1.0%)	0.43
Prevalence of parasitaemia	312 (26.0%)	325 (29.1%)	0.19
Proportion wasted (WHZ) %	60 (4.6%)	64 (5.2%)	0.50
Use of preventive measures for malaria by household	1206 (93.0%)	1154 (94.1%)	0.28
Household ownership of any net	691 (53.3%)	667 (54.4%)	0.59
Use of treated bed nets by child <5yrs	107 (8.3%)	104 (8.5%)	0.84
Use of untreated bed nets by child <5yrs	608 (46.9%)	577 (47.0%)	0.94
Child slept under bed net during the past 7 nights	444 (34.2%)	405 (33.0%)	0.52
Use of screening on windows or doors	709 (54.7%)	662 (54.0%)	0.72
Use of mosquito coils and sprays by household	634 (48.9%))	594 (48.4%)	0.81
Use of herbal preparations for malaria prevention	60 (4.6%)	71 (5.8%)	0.19

Figure 6.2 Comparison of the use of preventive methods for malaria between the control and intervention households.
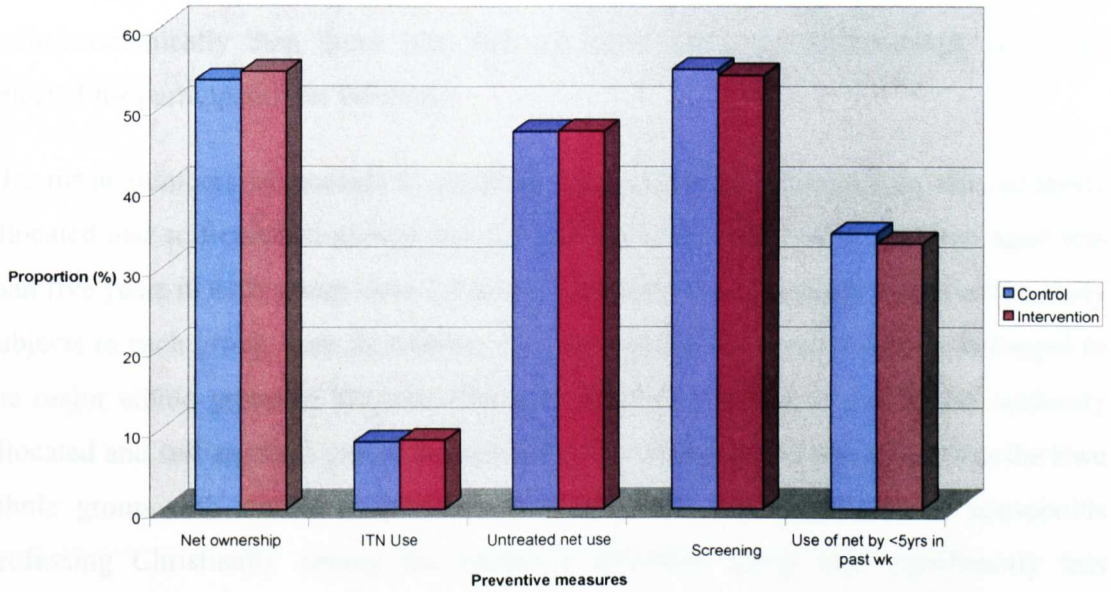
The two randomly allocated arms were very similar at baseline in terms of their place of residence in relation to the nearest health facility ($\chi^2=1.02$ p=0.60). Approximately 63% of households in each trial arm lived less than five kilometres away from the nearest health facility with about 16% living more than ten kilometres away from a health facility (Figure 6.3).

6.3.3 Comparison of base-line characteristics of randomly allocated and self-enrolled groups

The randomly allocated group was significantly different from the group who self-enrolled in the pre-payment scheme. The self-enrolled group appeared to be better off socio-economically than those who did not enrol and were subsequently randomly selected for participation in the study.

The mean numbers of household members in households belonging to the randomly allocated and self-enrolled groups was 5.6 and the mean numbers of children aged less than five years in each group were 1.4 and 1.5 respectively. The median ages of the study subjects in each group were 32 months. The proportions of households who belonged to the major ethnic group in the area, Dangme, were 64.2% and 64.9% in the randomly allocated and self enrolled groups respectively. The next major ethnic group was the Ewe ethnic group with similar proportions in each group. The proportion of households professing Christianity among the randomly allocated group was significantly less (n=1621 87.4%) than among those in the self-enrolled group (n=107 93.3%) (χ^2=5.08 p=0.02).

There were about four times more civil servants among the self-enrolled group as there were in the randomly allocated group as a whole. Their main occupations were traders and artisans as compared to the randomly allocated group who were mainly traders and farmers. Reported unemployment rates were lower among the self-enrolled (8.5%) than the randomly allocated group (9.7%) but the difference was not statistically significant (χ^2=0.25 p=0.62). The principal carer or mother and head of household in the self-enrolled group had had significantly more years of formal education than their counterparts in the randomly allocated group (p<0.001). See Table 6.5.

Table 6.5: Comparison of baseline characteristics of the randomly allocated and self-enrolled groups.

	Randomized N=2524	Self-enrolled N=165	P-value
Median age in months (IQR)	32 (18-46)	32 (19-45)	-
Major ethnic group (%)	1621 (64.2%)	107 (64.9%)	0.87
Households profess Christianity (%)	2206 (87.4%)	154 (93.3%)	0.02
Mean number of household members	5.6	5.6	-
Mean number of household members less than 5 yrs of age	1.5	1.4	0.10
Mean number of years of formal education completed by mother	5.1	7.6	<0.001
Mean number of years of formal education completed by head of household	7.1	9.7	<0.001

The self-enrolled group had a mean haemoglobin concentration of 10.7g/dl at baseline as compared to a value of 10.3g/dl among the randomly allocated group (p<0.01). Overall, 184 (7.3%) of the children in the latter group were anaemic at baseline compared to 8 (4.8%) in the self-enrolled group but the difference was not significant (χ^2=1.39 p=0.24). None of the children in the self-enrolled group was severely anaemic at baseline as compared to 29 (1.2%) in the randomly allocated group. The proportion malnourished at baseline was not significantly different in the two groups (χ^2=3.22 p=0.07) even although a higher proportion of children belonging to the randomly allocated group were wasted.

Table 6.6: Comparison of the randomly allocated and self-enrolled groups in terms of the main outcome variables and malaria related indicators at baseline.

Baseline Indicators	Randomized Group N=2524	Self-enrolled N=165	P-value (chi-square)
Mean Hb (g/dl) at baseline	10.3	10.7	<0.01
Hb < 8g/dl	184 (7.3%)	8 (4.8%)	0.24
Hb <6g/dl	29 (1.2%)	0	-
Prevalence of parasitaemia	637 (27.5%)	36 (26.5%)	0.59
Proportion wasted (WHZ) %	124 (4.9%)	3 (1.8%)	0.06
Use of preventive measures for malaria by household	2360 (93.5%)	158 (95.8%)	0.25
Household ownership of any net	1358 (53.8%)	86 (52.1%)	0.68
Use of treated bed nets by child <5yrs	211 (8.4%)	37 (22.4%)	<0.001
Use of untreated bed nets by child <5yrs	1193 (47.3%)	55 (33.3%)	0.001
Child slept under bed net during the past 7 nights	849 (33.6%)	39 (23.6%)	<0.01
Use of mosquito netting on windows and doors	1371 (53.3%)	117 (70.9%)	<0.001
Use of mosquito coils and sprays by household	1228 (48.7%)	85 (51.5%)	0.48
Use of herbal preparations for malaria prevention	131 (5.2%)	5 (3.0%)	0.22

Although similar proportions of the two groups indicated that they used preventive measures for malaria and owned at least one bed net, the households who belonged to the self enrolled group were more likely use a treated bed net to protect their child less than five years of age than those belonging to the randomly allocated group (χ^2=36.59 p<0.001). In contrast, a household belonging to the randomly allocated group was more likely to use a net that was not treated as a means of protecting the child under five

(χ^2=12.09 p=0.001). The self-enrolled group used screening on their doors and windows more often than the randomly allocated group (χ^2=17.15 p<0.001).

Consistent use of any bed net by the child less than five in the household during the previous 7 days was significantly higher among the randomly allocated group than the self-enrolled group (χ^2=7.00 p<0.01) (Figure 6.4). Use of mosquito coils and sprays as well as herbal preparations for preventing malaria was not different between the two groups.

Figure 6.3: Comparison of the use of preventive methods for malaria between the randomly allocated and self-enrolled groups.
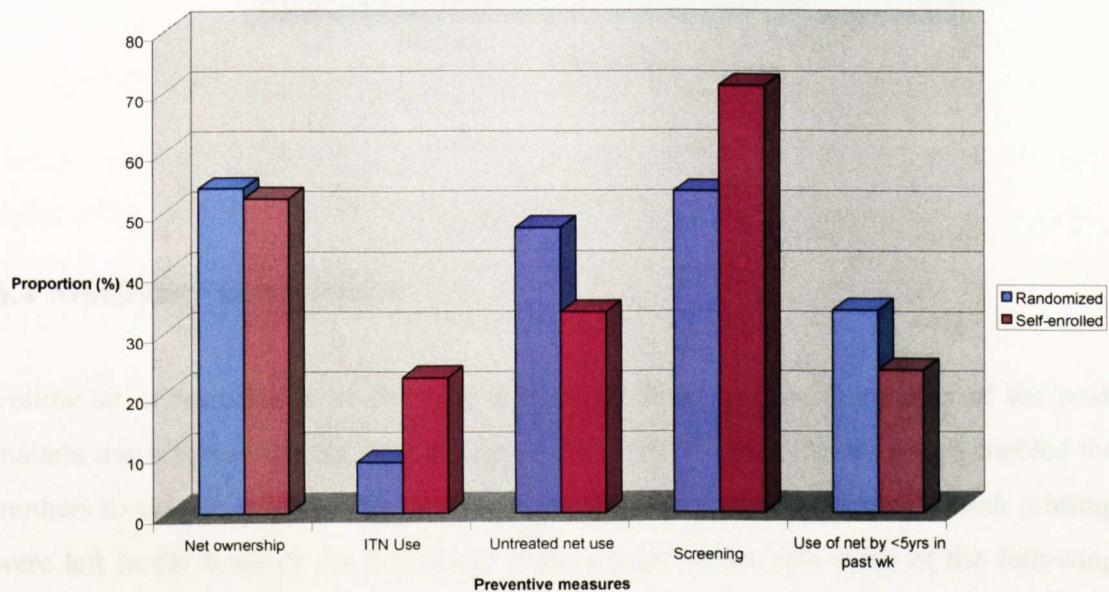
The self enrolled group lived near a health facility significantly more than the randomly allocated group (χ^2=44.78 p<0.001). A total of 144 (87.3%) of households in this group lived within 5 km from a health facility and none of them lived more than 10km away. On the contrary, 1602 (63.5%) of children belonging to the randomly allocated group, lived within 5km of a health facility, with 410 (16.2%) of them living more than 10km away (Figure 6.5).

Figure 6.4: Comparison of the distribution of the self-enrolled and randomly allocated groups by distance of residence from a health facility.
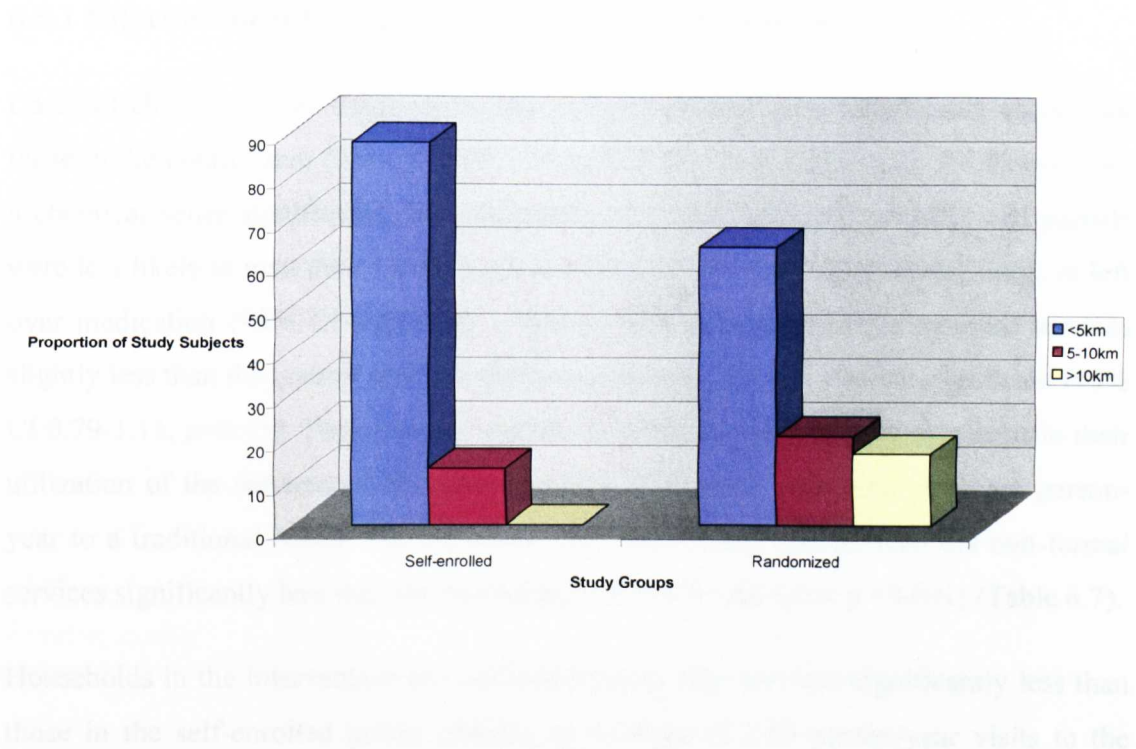
6.4 Morbidity surveillance

Follow-up of households in all three arms took place for the six months of the peak malaria transmission season, May to November 2004. Pictorial diaries which enabled the mothers to keep a record of all episodes of illness and sources of care by thumb printing were left in the home at the beginning of the month. In the first week of the following month, a trained fieldworker went to the household to collect the completed diary. He/she went through the diary with the mother to ensure that all entries had been made and then left a fresh diary for the next month. This process continued throughout the peak malaria transmission season.

Loss to follow-up was low in each study arm. Eighty-eight households with 98 children (7.9%) were lost to follow-up from the intervention arm compared to 82 households with 96 children (7.4%) in the control arm. In the self-enrolled arm, loss to follow-up was even less; 4 households with 4 children (2.4%).

6.5 Effect of the intervention

6.5.1 Effect of the intervention on utilization of health services

Cases of children in the intervention arm utilized primary care significantly more than those in the control arm (95% CI 1.04-1.20; p=0.001). They sought care for illness from a chemical seller significantly less frequently (95% CI 0.85-0.97; p<0.01) and parents were less likely to treat their children at home themselves using either herbal drugs or left over medication (95% CI 0.82-0.96; p<0.01). Although they utilized hospital services slightly less than the control arm, the difference between groups was not significant (95% CI 0.79-1.11; p=0.43). There was no significant difference between the two arms in their utilization of the services of traditional healers. Both arms paid 0.12 visits per person-year to a traditional healer. On the whole, the intervention arm utilized the non-formal services significantly less than the control arm (95% CI 0.86-0.95; p <0.001) (Table 6.7).

Households in the intervention arm utilized primary care services significantly less than those in the self-enrolled group, making an average of 2.80 person-year visits to the primary care provider as compared to 4.32 visits by the self-enrolled group (95% CI 0.58-0.73; p<0.001). Households in the intervention arm were also more likely to seek care from a chemical seller (95% CI 1.20-1.68; p<0.001) and, surprisingly, less likely from a traditional healer (95% CI 0.26-0.71; p<0.001) than the self-enrolled group. They also resorted to home treatment less often than households in the self-enrolled group, although this difference did not achieve statistical significance.

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Table 6.7: Comparison of the utilization of health care by households in the control and intervention arms.

Visits/person-yr to	Control N=1297	Intervention N=1227	Rate Ratio	(95% CI)	2-sided p-value
Primary care clinic	2.50	2.80	1.12	(1.04-1.20)	0.001
Hospital	0.47	0.44	0.93	(0.79-1.11)	0.43
Chemical seller	2.97	2.69	0.90	(0.85-0.97)	<0.01
Home treatment	2.01	1.79	0.89	(0.82-0.96)	<0.01
Traditional healer	0.12	0.12	1.02	(0.72-1.43)	0.92
Non formal health care services	5.10	4.59	0.90	(0.86-0.95)	<0.001
Fever episodes	5.72	5.53	0.97	(0.92-1.01)	0.17

Overall, there was no significant difference between the intervention and self-enrolled group in their use of non-formal sources of health care although households in the intervention arm used the latter services slightly more than those in the self enrolled arm (Table 6.8).

There was no significant difference in the number of fever episodes per person-year among all three study arms although the children in the intervention arm appeared to have had slightly fewer fever episodes as compared to those who belonged to the other two study arms. Removal of the barrier due to the direct cost of health care had a significant impact on utilization of health services.

Table 6.8: Comparison of the utilization of health care by households in the intervention and self-enrolled arms.

Visits/person-yr to	Intervention N=1227	Self-enrolled N=165	Rate Ratio	(95% CI)	2-sided p-value
Primary care clinic	2.80	4.32	0.65	(0.58-0.73)	<0.001
Hospital	0.44	0.42	1.06	(0.74 -1.56)	0.77
Chemical seller	2.69	1.90	1.42	(1.20-1.68)	<0.001
Home treatment	1.79	1.98	0.90	(0.76-1.07)	0.22
Traditional healer	0.12	0.28	0.42	(0.26-0.71)	<0.001
Non formal health services	4.59	4.16	1.10	(0.99-1.24)	0.08
Fever episodes	5.53	5.83	0.95	(0.86-1.050	0.28

6.5.1.1 Effect of distance on utilization of health services by trial arms

Utilization of health services by households from the control and intervention arms was compared with regards to how far they lived from the nearest health facility. Generally, utilization of primary care services decreased with distance from a health facility whilst utilization of non formal sources of health care increased correspondingly in each arm.

Although households in the intervention arm living within 5 km of a health facility utilized primary care services more than the control households in the same vicinity, this was of borderline statistical significance. In contrast, the difference in use of non formal sources of care among these households living very close to a health facility was significant (p<0.001) with households in the intervention arm using the latter services much less than control households.

At distances 5 to 10 km away from the nearest health facility, the intervention households utilized primary care services significantly more than the control (p<0.01) and although they tended to use non formal sources of care less, the difference between groups was not statistically significant. There was no significant difference in the use of primary care services and non-formal sources of care among intervention and control households who lived more than 10 km away from a health facility. However, the intervention households tended to use primary care services more and non-formal sources of care less than the control households in this sub group as well (Table 6.9).

Table 6.9: A comparison of the utilization of primary and non-formal care services between households in intervention and control arms by distance of residence from the nearest health facility.

Distance from HF	IR Control	IR Intervention	RR	95% CI	2 sided p-value
Utilization of Primary Care (visits/person-yr)					
<5km	2.71	2.93	1.08	(0.99-1.18)	0.06
5 to 10 km	2.22	2.79	1.25	(1.07-1.48)	<0.01
>10 km	2.06	2.32	1.12	(0.93-1.37)	0.21
Utilization of informal care (visits/person-yr)					
<5km	4.92	4.10	0.83	(0.78-0.89)	<0.001
5 to 10 km	5.39	5.33	0.99	(0.89-1.10)	0.85
>10 km	5.46	5.59	1.02	(0.91-1.15)	0.72

Households in the self-enrolled group living within 5 km of a health facility utilized primary care services significantly more than the intervention households in the same vicinity (95% CI 0.58-0.75 p<0.001). In contrast, the use of non formal sources of care was similar in the two groups (95% CI 0.90-1.16 p=0.73). Among households who lived 5 to 10 km away from a health facility, there was no significant difference in both the use of primary and informal sources of care between the intervention and self-enrolled

groups. It was not possible to compare those who lived more than 10 km away in the two groups as none of the households in the self-enrolled group lived that far away from a health facility (Table 6.10).

Table 6.10: A comparison of the utilization of primary and non-formal care services between households in intervention and self-enrolled arms by distance of residence from the nearest health facility

Distance from HF	IR Intervention	IR Self-enrolled	RR	95% CI	2 sided p-value
Utilization of Primary Care (visits/person-yr)					
<5km	2.93	4.46	0.66	(0.58-0.75)	<0.001
5 to 10 km	2.79	3.39	0.82	(0.58-1.20)	0.28
>10 km*	-	-	-	-	-
Utilization of informal care (visits/person-yr)					
<5km	4.10	4.01	1.02	(0.90-1.16)	0.73
5 to 10 km	5.33	5.23	1.02	(0.77-1.37)	0.90
>10 km*	-	-	-	-	-

*None of the self-enrolled group lived more than 10km from a health facility. Comparison was therefore not possible in this sub group

6.5.2 Effect of the intervention on anaemia

At the end of the peak malaria transmission season, the intervention appeared to have had very little impact on anaemia (Hb<8g/dl). Thirty-six (3.2%) of children in the intervention arm were anaemic at the end of the transmission season compared to 37 (3.1%) in the control arm ($\chi^2=0.24$; p=0.88).

The mean haemoglobin concentration among children in the intervention arm was 11.1 g/dl whilst that of those in the control arm was 11.0g/dl (p=0.47). The self-enrolled group had a mean haemoglobin concentration of 11.4 g/dl. Overall there was a modest increase in mean haemoglobin concentration in all three study arms at the end of the peak malaria transmission season. The mean change in haemoglobin concentration among children

who belonged to the intervention arm was higher (+0.75) than that of those in the control arm (+0.71) although this did not achieve statistical significance (p=0.69) (Table 6.11)

Table 6.11: Effect of the intervention on the prevalence of anaemia

	Control N=1197	Intervention N=1124	P-value (chi-square)
Hb<8g/dl (%)	37 (3.1%)	36 (3.2%)	0.88 (0.02)
Hb<6g/dl (%)	3 (0.3%)	2(0.2%)	0.71 (0.14)
Mean Hb (g/dl)	11.0	11.1	0.47
Mean change in Hb (g/dl)	+0.71	+0.75	0.69

The odds of being anaemic were the same whether a child was in the control or intervention arm. When the odds was adjusted for pre-defined potential confounding factors such as age, sex, distance from health facility, socioeconomic status (defined by an asset-based wealth index) and clustering of study subjects in a household, the results were not changed (Table 6.12).

Table 6.12: Odds ratios for the effect of the intervention on anaemia

	OR (95% CI)	p-value
Crude	1.04 (0.65-1.65)	0.88
Adjusted for age, sex, distance, poverty and clustering	1.05 (0.66-1.67)	0.84

When the intervention arm was compared to the self-enrolled arm with regard to the trial end-point, prevalence of anaemia (Hb <8g/dl), there was no statistical difference between the groups, both of who had improved financial access to healthcare (χ^2=3.32 p=0.07). The statistical difference between them with regards to their mean Hb concentration was probably due to baseline effects. Although the mean change in Hb concentration was higher among children in the self-enrolled group (+0.78) than those in the intervention arm (+0.75), this did not achieve statistical significance (p=0.82) (Table 6.13).

Table 6.13: Effect of intervention on the prevalence of anaemia: comparison of the intervention and self-enrolled arms

Outcome Indicators	Intervention N=1124	Self enrolled N=161	P-value (chi-square)
Hb<8g/dl (%)	36 (3.2%)	1 (0.6%)	0.07 (3.36)
Hb<6g/dl (%)	2 (0.2%)	0	-
Mean Hb (g/dl)	11.1	11.4	<0.01
Mean change in Hb (g/dl)	+0.75	+0.78	0.82

The impact of the intervention was analyzed by household socio-economic status and distance of residence from the nearest health facility. The results of the analysis of trial outcomes by household socio-economic status, are described in more detail in Chapter 7. The impact of the intervention on anaemia by distance of household residence from health facility is set out below. Distance of household residence from a health facility did not affect the outcome of the intervention when the control and intervention arms were compared (Table 6.14).

Table 6.14 Effect of the intervention on anaemia by distance of household residence from a health facility.

Distance of household residence from a health facility	Control N=1197	Intervention N=1124	P-value (chi-square)
<5km	21 (2.7%)	23 (3.2%)	0.58 (0.31)
5-10km	9 (4.0%)	9 (3.9%)	0.98 (0.001)
>10km	7 (3.5%)	4 (2.2%)	0.46 (0.54)

A comparison of the self-enrolled and intervention arm did not show any clear pattern. The prevalence of anaemia among all groups was generally very low, resulting in very small numbers (Table 6.15).

Table 6.15 Effect of the intervention on anaemia by distance of household residence from a health facility: a comparison of the intervention and self-enrolled arms.

Distance of household residence from a health facility	Intervention N=1124	Self enrolled N=161	P-value (chi-square)
<5km	23 (3.2%)	1 (0.7%)	0.10 (2.72)
5-10km	9 (3.9%)	0	0.37 (0.82)
>10km	4 (2.2%)	-	-

Results of an investigation into the causes of anaemia at the end of malaria transmission season

Seventy-three children had anaemia (Hb <8g/dl) at the final cross-sectional survey. One of these children died and another moved away from the study area before the next level of haematological investigations were carried out. Further investigations were carried out into the causes of anaemia among the sub sample of 71 remaining children.

Blood samples from 57 (80.3%) of the 71 study children examined showed signs of microcytic anaemia using an MCV cut-off of 78 femtoliters (10^{-15} liters). The rest had an MCV greater than 78 femtoliters. Of the children with signs of microcytic anaemia, 27 (79.4%) belonged to the control arm while 29 (80.6%) were from households in the intervention arm. The difference in proportions was not statistically significant ($\chi^2=0.01$ p=0.91). The only case of anaemia that belonged to the self-enrolled arm also showed signs of microcytic anaemia.

Overall, 28 (39.4%) of the stool samples from the children examined were positive for helminths. Eighteen (25.4%) contained *A. lumbricoides* ova whilst 10 (14.1%) contained hookworm ova. The geometric mean *ascaris* ova density was 84.5 whilst that of hookworm was 52.1. No stool sample contained both *ascaris* and hookworm ova concurrently and none contained ova of *S. mansoni*. There was no significant difference in the prevalence of hookworm ova between the children belonging to the intervention and control arms ($\chi^2==0.34$; p=0.56).

Twenty of the anaemic children (28.2%) were found to have various haemoglobinopathies. The haemoglobinopathies detected included AS, SS, SC, AC, and CC. Three (8.8%) of the children from the control arm and 4 (11.1%) from the intervention arm were homozygous for sickle cell anaemia. Twenty-five (73.5%) children from households in the control arm and 25 (69.4%) from intervention households had normal haemoglobins. One male child had G6PD enzyme deficiency.

Four (5.6%) children had blood in their urine. There were two each from each trial arm. None of the children, however, was infected with *S. haematobium*. One child who was

homozygous for sickle cell disease (SS) had G6PD deficiency and *ascaris* ova in his stool.

6.5.3 Effect of the intervention on parasitaemia

There was no association between the intervention and the prevalence of parasitaemia among the study subjects at the end of the peak malaria transmission season. At the beginning of the peak malaria transmission season, the prevalence of parasitaemia was slightly higher among the subjects in the intervention arm than in the control arm. At the end of the season, both arms saw a reduction in the prevalence of parasitaemia. This was consistent with the increase in mean Hb concentration. The reduction in the prevalence was very similar (10%) in each of the trial arms. The self-enrolled group had the biggest reduction in prevalence of parasitaemia at the end of the period (18.7%).

The median parasite density was lower at the end of the period among children in the intervention arm perhaps accounting for the slightly bigger increase in mean Hb among this group. Whilst the intervention group had a reduction in baseline levels of mean parasite density, the control had an increase over the baseline levels at the end of the period (Table 6.16).

Table 6.16: A comparison of the parasite prevalence between control and intervention arms before and at the end of the peak transmission season.

	Control	Intervention	p-value (chi-square)
Prevalence of Parasitaemia			
Baseline (%)	306 (25.5%)	315 (28.2%)	0.14 (2.19)
Final (%)	174 (15.9%)	193 (18.9%)	0.08 (3.13)
Median Parasite Density			
Baseline (IQR)	460 (160-1440)	520 (160-2200)	0.09
Final (IQR)	580 (160-1920)	480 (112-1760)	0.09

The parasites identified in positive blood films among all study subjects at baseline included *P. falciparum* (93%), *P. malariae* (4.8%) and a mix of *P. falciparum and malariae* (2.2%). During the final cross-sectional survey at the end of the malaria transmission season, *P. falciparum* comprised 83.9% of the parasites identified. The parasites identified also included *P. malariae* (1.9%) and a mix of *P. falciparum* and *malariae* (0.5%). *P. ovale* was identified alone in 10.6% of positive slides and also mixed with *P. falciparum* (2.6%) and with *P. malariae* (0.5%). Gametocyte prevalence was low both at baseline (1.1%) and after the malaria transmission season (0.7%).

The odds of being parasitaemic at the end of the peak malaria transmission season were slightly higher in the intervention arm although this was not significant (p=0.08). The odds did not change much when adjusted for age sex, distance, poverty and clustering effect of more than one child in a household (Table 6.17).

Comparing the intervention and self-enrolled groups, the unadjusted odds of a child being parasitaemic at the end of the peak malaria transmission season if he/she belonged to the intervention arm were approximately three times the odds if he/she belonged to the self-enrolled arm (OR=3.00 95% CI 1.59-5.65; p=0.001). Adjusting for confounders reduced the odds slightly (OR=2.34 95% CI 1.23-4.42; p=0.009).

Table 6.17: Odds Ratio for the effect of the intervention on the prevalence of parasitaemia.

	OR (95% CI)	p-value
Crude	1.23 (0.98-1.54)	0.08
Adjusted for age, sex, distance, poverty and clustering	1.23 (0.96-1.56)	0.10

6.5.4 Effect of the intervention on anthropometric indicators

The effect of the intervention on nutritional indicators was assessed first by comparing the means of the basic anthropometric indicators such as the mid upper arm circumference (MUAC), the height and the weight; and subsequently by looking at the prevalence of wasting (z-score of weight-for-height below -2), underweight (z-score of weight-for-age below -2) and stunting (z-score of height-for-age below -2) among children in the three study arms at baseline and the end of the study period.

At baseline, there were no significant differences in the mean MUAC (95% CI 15.00-15.14; p=0.28), mean weight (95% CI 12.07-12.39; p=0.70) and mean height (95% CI 87.23-88.48; p=0.49) of children belonging to the control and intervention arms. There was very little change in this situation at the end of the peak malaria transmission season. Generally, there were increases in the mean MUACs, mean weights, and mean heights of children in all the three study arms. This was consistent with the increase in haemoglobin concentration and reduction in prevalence of parasitaemia at the end of the peak malaria transmission season.

There was no significant statistical difference in the mean heights (95% CI 92.62-95.65 p=0.93) or mean weights (95% CI 13.41-14.35; p=0.22) of the intervention and self enrolled arms when they were compared at the end of the peak transmission season. Children belonging to the self-enrolled arm had a significantly higher mean MUAC than children belonging to the intervention arm at the end of the period (95% CI 15.39-15.76; p=0.04). This may have been due to persistence of baseline effects (Table 6.18).

Table 6.18: A comparison of the mean anthropometric indices of study children at baseline and final cross-sectional surveys.

	Control		Intervention		Self-enrolled	
	Baseline	**Final**	**Baseline**	**Final**	**Baseline**	**Final**
Weight-for-height (wasting)						
Mean (SD)	-0.35	-0.53	-0.37	-0.56	-0.21	-0.36
	(1.39)	(0.99)	(1.45)	(0.96)	(1.50)	(0.99)
Weight-for-age (underweight)						
Mean (SD)	-0.89	-0.97	-0.88	-0.97	-0.70	-0.71
	(1.41)	(1.03)	(1.47)	(1.04)	(1.45)	(1.27)
Height-for- age (stunting)						
Mean (SD)	-0.87	-0.85	-0.84	-0.81	-0.77	-0.63
	(1.55)	(1.30)	(1.68)	(1.38)	(1.47)	(1.58)
MUAC (cm)						
Mean (SD)	15.07	15.30	15.01	15.34	15.21	15.58
	(1.27)	(1.18)	(1.25)	(1.38)	(1.26)	(1.19)
Weight (kg)						
Mean (SD)	12.23	13.51	12.28	13.58	12.54	13.88
	(2.96)	(2.92)	(2.96)	(2.91)	(3.04)	(3.03)
Height/length (cm)						
Mean (SD)	87.85	93.64	88.17	94.06	88.38	94.14
	(11.55)	(10.45)	(11.65)	(10.27)	(10.71)	(9.75)

Though the mean change in individual weights of the study subjects over the six-month period was slightly higher for the intervention than the control arm (1.26kg vrs 1.24kg), the difference not statistically significant ($p=0.81$). The same picture was found when the mean of the change in individual heights was compared (5.86 cm vrs 5.67cm; $p=0.56$).

Assessment of nutritional status was then carried using the prevalence of indicators such as wasting, underweight and stunting among children in the three groups. Of these indicators the most sensitive for the purposes of this study is wasting.

Table 6.19: The prevalence of indicators of malnutrition by study arm and stage of intervention

	% Weight-for-height (WHZ) <-2 /Wasting		% Weight-for-age (WAZ) <-2 /Underweight		% Height-for-age (HAZ) <-2 /Stunting	
	Baseline	**Final**	**Baseline**	**Final**	**Baseline**	**Final**
Control	60	79	205	188	237	197
	(4.6%)	(6.6%)	(15.8%)	(15.7%)	(18.3%)	(16.5%)
Intervention	64	72	189	174	213	190
	(5.2%)	(6.4%)	(15.4%)	(15.5%)	(17.4%)	(16.9%)
Self-enrolled	3	3	20	20	24	26
	(1.8%)	(1.9%)	(12.3%)	(12.4%)	(14.7%)	(16.2%)

There was a small increase in the prevalence of wasting among the children in the three arms. At baseline, the control and intervention arms were similar (χ^2=0.46 p=0.50) and were not significantly different from the self-enrolled arm (χ^2=3.22 p=0.07) although the prevalence of wasting among the latter was about half that of the randomly allocated group. At the end of the transmission season there were increases in the prevalence of wasting among the children in both the intervention and control arms and although the difference between them at the end of the peak transmission season was still not significant, (χ^2=0.04 p=0.85) the prevalence in the control arm increased by 1.2 percentage points compared to 0.96 percentage points among the intervention. Baseline effects appeared to have persisted with the difference between the intervention and self-enrolled arms becoming statistically significant (χ^2=5.29 p=0.02).

The differences between all study arms at the end of the period with regards to underweight and stunting were all not significant.

6.5.5 Effect of the intervention on household all cause mortality

There were 9 deaths among study children during the six-month period of the study. These deaths were in the intervention and control arms only; there were no deaths among the smaller number of children in the self-enrolled group. Four of the deaths were from the control arm with 5 from the intervention arm. There was no significant difference between the two arms in this respect.

Results of the household baseline cross-sectional survey showed no significant difference in reported child mortality over the previous year between households belonging to the randomly allocated arms (χ^2=2.90 p=0.41) or between the self-enrolled and randomly allocated arms (χ^2=4.08 p=0.25).

Results of the final cross-sectional survey showed that eleven (0.4%) of the children who completed follow-up, lost one parent over the period. Eight out of the 11 parents who died were fathers of the study children. Twenty-three (22.8%) of all those who had died were the siblings of the study children. There was no significant difference in mean number of people who died in the households of the randomly allocated arms (p=0.13) or between the intervention and self-enrolled arms (p=0.06).

Results of verbal post mortem

Verbal autopsies were carried on the 9 study subjects less than five years of age who died during the course of the study. These were given to three independent physicians to review. In all of the cases the physicians came up with similar diagnoses. In 6 out of the 9 deaths, the immediate cause of death was related to malaria. There were 2 cases of severe anaemia secondary to malaria and 3 cases of cerebral malaria. The last of the 6 cases was a febrile convulsion probably due to malaria. However, the immediate cause of this child's death was the administration of a herbal concoction which caused a severe osmotic diarrhoea leading to death within less than 12 hours.

Two of the others were deaths due to immuno-suppression, most probably vertically transmitted HIV/AIDS, whilst the final one was a case of severe dehydration due to severe diarrhoea with underlying malnutrition.

Table 6.20: Cause of death by intervention arm

Diagnoses	Control	Intervention
Severe dehydration secondary to malnutrition	0	1
Severe malarial anaemia	2	1
Pneumonia secondary to HIV/AIDS	0	1
Severe dehydration secondary to HIV/AIDS	0	1
Cerebral malaria	2	0
Severe dehydration secondary to severe diarrhoea(ingestion of herbal concoction)	0	1
TOTAL	**4**	**5**

6.6 Summary

A total of 2524 children from 2151 households participated in the study. Included in this were 165 children from 138 households who had themselves enrolled in the pre-payment scheme operating in the study area.

At baseline, the households that were randomly allocated to the intervention and control arms were very similar in terms of their background characteristics, the main outcome variables and their socio-economic status but the group who self-enrolled were significantly less poor and had better health outcome measures.

Introducing free primary healthcare significantly altered the healthcare seeking behaviour of households, with those randomly allocated to the intervention arm using formal healthcare more (95% CI 1.04-1.20; p=0.001) and home treatment and chemical sellers less than those in the control group. This did not, however, lead to any measurable difference in any of the health outcomes at the end of the six-month trial period. For the primary outcome of moderate anaemia there was no difference seen OR 1.05 (0.66-1.67).

CHAPTER 7 HOUSEHOLD SOCIO-ECONOMIC STATUS AND TRIAL OUTCOMES

7.1 Overview

The relationship between household socio-economic status and the use of preventive methods for malaria in the district was assessed at baseline. For an overview of these household characteristics, baseline data from all the households participating in the study were pooled and households categorized into wealth quintiles based on the asset index developed. The households were labelled as poorest (Q1), very poor (Q2), poor (Q3), less poor (Q4) and least poor (Q5).

Subsequently, the two main trial arms were compared with regards to household socio-economic status. The self-enrolled group was also compared with the randomly allocated group. Comparison of health service utilization and health outcomes between wealth quintiles in the two trial arms on one hand, and the self-enrolled and intervention arm on the other were also carried out. The main aim was to bring out any obvious trends by wealth quintile. Household socio-economic status and distance of residence from a health facility are known to be potential confounders for outcomes such as health service utilization and health outcomes. As such, the trial design took this into consideration and ensured that the trial arms were similar in terms of these two factors. Though the study was not designed to be powered to look at the effect of the intervention on sub groups, within the intervention arm, the modifying effect of these two factors on the outcome of the intervention was assessed by comparing wealth quintiles and looking at the outcomes within the three distance groups of the intervention arm. The results are discussed in the following sections.

The distribution of wealth quintiles was similar in the two randomly allocated trial arms. The self-enrolled group had a completely different distribution of wealth quintiles with over 60% of them belonging to the two least poor quintiles and 7% belonging to the poorest quintile (χ^2=36.11 p<0.001) (Figure 7.1). It is unlikely that differences in household socio-economic status could have affected the outcome of this randomized trial since the two trial arms were very similar in socio-economic terms (χ^2=2.78 p=0.69).

The distribution of households by wealth quintiles and distance of residence from primary care facility within the randomly allocated arms varied significantly (χ^2=380.03 p<0.001). There was a significant difference between the poorest and the least poor quintile (χ^2=231.39 p<0.001) with regards to the proportion of households living at various distances away from a primary care facility. Approximately 30% each of the households who belonged to the poorest quintile lived less than 5km and 5-10km away with almost 40% of them living more than 10 km away respectively from a health facility. In contrast, almost 80% of the least poor households lived less than 5km away from a health facility with just about 8% of them living more than 10 km away from a health facility (Table 7.1).

Figure 7.1 Distribution of wealth quintiles in the study arms
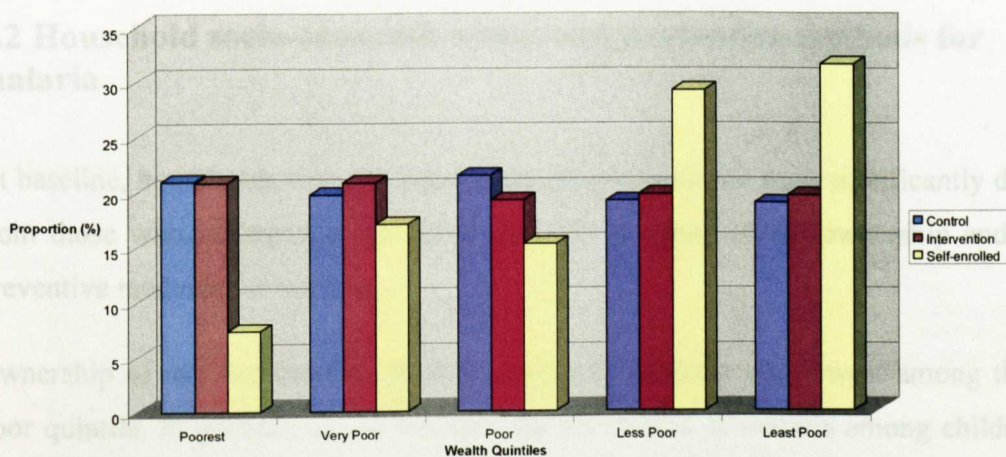
In the self-enrolled group, although there was some variation in the distribution of the wealth quintiles, this was minimal and the difference between the poorest and least poor quintile in this regard was not significant (χ^2= 0.44 p=0.51) (Table 7.1).

Since distance is a major factor affecting utilization, this distribution is likely to influence utilization patterns by wealth quintile.

Table 7.1 A comparison of the distribution of wealth quintiles by distance of residence from a health facility among the study arms

	Percentage distribution by wealth quintiles (%)				
	Q1	Q2	Q3	Q4	Q5
Intervention arm					
<5km	28.2	60.8	77.9	72.3	77.9
5-10km	33.7	22.4	12.8	22.3	13.3
>10km	38.0	16.9	9.4	5.4	8.8
Control arm					
<5km	34.0	60.0	72.3	76.6	79.2
5-10km	31.4	20.4	14.8	18.2	12.2
>10km	34.7	19.6	13.0	5.2	8.6
Self-enrolled arm					
<5km	91.7	85.7	92.0	75.0	96.2
5-10km	8.3	14.3	8.0	25.0	3.9
>10km	0	0	0	0	0

7.2 Household socio-economic status and preventive methods for malaria

At baseline, households who belonged to the poorest quintile were significantly different from those who belonged to the other quintiles in terms of the ownership and use of preventive methods for malaria.

Ownership of any bed net was highest among the poorest and lowest among the least poor quintile. In general, use of bed nets for prevention of malaria among children less than five years of age was highest among the poorest whilst use of screening on doors and windows was highest among the least poor. Most of the bed nets owned and in use by the poorest were untreated. Four hundred and twenty-one (78.3%) households in the poorest quintile indicated that they used untreated nets to prevent malaria in their child aged less than five years as compared to 160 (29.8%) of the least poor (χ^2=254.09 p<0.001).

In contrast, the least poor households were more likely to be using treated nets (16.0%) than the poorest (6.3%) to protect their child less than five years of age from malaria

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($\chi^2=25.47$ p<0.001). The condition of the nets in use whether treated or untreated was not assessed during this study. Most of the least poor households (81.8%) used screening on their windows and doors as compared to just 36.4% of the poorest ($\chi^2=328.51$ p<0.001). They also used mosquito coils more (60.5%) than the poorest (30.9%) ($\chi^2=95.32$ p<0.001).

Three hundred and forty (63.2%) children aged less than five years from households belonging to the poorest quintile had slept under a net every night over the previous one week whilst only 105 (19.6%) of the children belonging to households in the least poor quintile had done so ($\chi^2=211.01$ p>0.001). The distribution was the same for children who had slept under a net at least once over the previous week (Figure 7.2).

Figure 7.2: Ownership and use of net at baseline by wealth quintiles
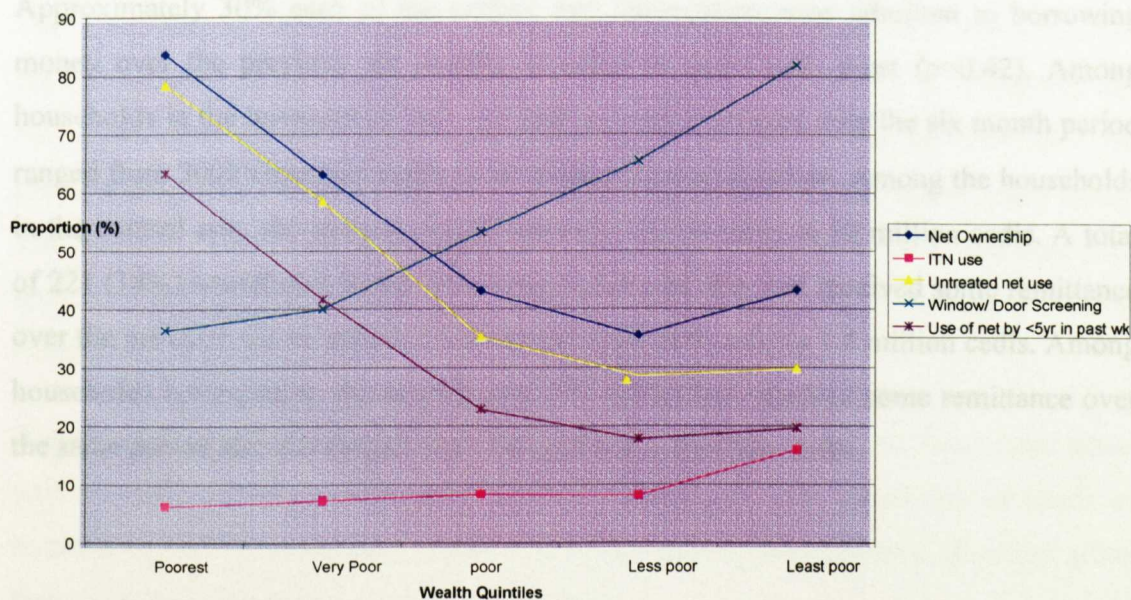
7.3 Comparison of household wealth between the intervention and control arms

The wealth quintiles were similarly distributed between the two trial arms (χ=2.28 p=0.69). The poorest in both arms comprised approximately 21% whilst the least poor quintile comprised about 19% of the study subjects. The randomly allocated arms were very similar when key indicators of socio-economic status were used to compare them. They were also similar in terms of the proportion of heads of household with no formal education (χ=5.62 p=0.13) (Table 7.2).

However, households in the control arm had better access to potable water (χ^2=8.56 p<0.01) and a shorter time to their water source (χ^2=4.38; p=0.04) than the intervention arm. They also had a lower motorbike ownership than the intervention arm (χ^2=6.87 p<0.01).

Approximately 30% each of the control and intervention arms admitted to borrowing money over the previous six months in order to make ends meet (p=0.42). Among households in the intervention arm, the total amount borrowed over the six month period ranged from 3000 Ghanaian cedis to 10 million Ghanaian cedis*. Among the households in the control arm, the amount ranged between 10,000 cedis to 10 million cedis. A total of 221 (18%) households in the intervention arm said they had received some remittance over the previous six months and this ranged from 500 cedis to 1.8 million cedis. Among households belonging to the control arm, 247 (19%) had received some remittance over the same period and this ranged from 106 cedis to 1.5 million cedis.

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* Exchange rate for British pound and one United States dollar at the time of the study were 16,000 and 9,000 Ghanaian cedis respectively.

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Table 7.2 A comparison of intervention and control arms in terms of some indicators of socio-economic status at baseline.

	Control N=1297	Intervention N=1227	P-value (chi-square)
Poorest Quintile (%)	271 (20.9%)	255(20.8%)	0.95 (0.00)
Very Poor Quintile (%)	255 (19.7%)	255 (20.8%)	0.48 (0.49)
Poor Quintile (%)	278 (21.4%)	235 (19.2%)	0.16 (2.03)
Less Poor Quintile (%)	248 (19.1%)	242 (19.7%)	0.70 (0.15)
Least poor Quintile (%)	245 (18.9%)	240(19.6%)	0.67 (0.18)
Household heads with no education	363 (28%)	313 (25.5%)	0.13 (5.62)
Income			
Mean monthly income [1]	459,031	470,485	0.51

Note: 1 All amounts in Ghanaian cedis. Exchange rate for £1.00 at time of study was C16,000

7.4 Comparison of household wealth between the randomly allocated and self-enrolled groups

The distribution of wealth quintiles between the randomly allocated group as a whole and the self-enrolled group was significantly different (χ^2=36.11 p<0.001). Five hundred and twenty-six (20.8%) children from households which belonged to the randomly allocated group belonged to the poorest quintile compared to 12 (7.3%) of the self-enrolled group. The majority of the study subjects in the self-enrolled group belonged to the least poor quintile which showed that they were much better off socially and economically than the other group (Table 7.3).

The two groups differed significantly in most of the indicators of socio-economic status with the self-enrolled arm being consistently better off. The proportion of heads of households with no formal education was higher among the randomly allocated group than the self-enrolled group (χ^2=73.20 p<0.001).

With regards to some major assets such as ownership of land, subsistence farms, houses for rental purposes, vehicles for commercial purposes, and motorbike, tractor and fishing vessel, there were no significant differences between the two groups. This was not surprising in view of the fact that most of the people in this area are poor.

The ownership of cattle or a farm for commercial purposes was higher among households who belonged to the randomly allocated group. Again this was not inconsistent with fact that this group was made up of mostly indigenes in contrast to the self-enrolled group which comprised a higher proportion of people who were living in the area because of work. These major assets did not count for much in the determination of wealth in this community using principal component analysis.

Sixty-six (40%) households belonging to the self-enrolled group admitted to borrowing money over the previous six months as compared to 803 (31.8%) of the randomly allocated group (p=0.03). The total amount the former group borrowed over the six month period ranged from 10,000 cedis to 4 million cedis*. They borrowed less over the period than the randomly allocated group as a whole who borrowed between 3,000 cedis and 10 million cedis.

Thirty-four (21%) households in the self-enrolled group said they had received some remittance over the previous six months and this ranged from 10,000 cedis to 1.2 million cedis. They received a lower maximum remittance than the randomly allocated group which was not unexpected because they were probably more self-sufficient.

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* Exchange rate for British pound and one United States dollar at the time of the study were 16,000 and 9,000 Ghanaian cedis respectively.

Table 7.3: A comparison of the randomly allocated and self -enrolled groups in terms of some indicators of socio-economic status at baseline.

	Randomized Group N=2524	Self-enrolled Group N=165	P-value (chi-square)
Poorest Quintile (%)	526 (20.8%)	12 (7.3%)	<0.001(17.81)
Very Poor Quintile (%)	510 (20.2%)	28 (17.0%)	0.31 (1.01)
Poor Quintile (%)	513 (20.3%)	25 (15.2%)	0.11 (2.59)
Less Poor Quintile (%)	490 (19.4%)	52 (31.5%)	<0.01 (9.06)
Least poor Quintile (%)	485(19.2%)	52 (31.5%)	<0.001(14.66)
Household heads with no education	676(26.8%)	28 (17.0%)	<0.001(73.20)
Income			
Mean monthly income [1]	464,599	553,788	<0.01

Note: 1-All amounts in Ghanaian cedis. Exchange rate for £1.00 at time of study was C16,000

7.5 Household socio-economic status and utilization of health services

The poorest and the least poor households who belonged to the intervention arm were compared in terms of their utilization of various sources of health care.

The utilization of primary health care facilities by the poorest intervention households was significantly lower than the least poor intervention households (p=0.03). Although both groups appeared not to utilize hospital care as much as they did primary care, the poorest sought hospital care significantly less than the least poor (p<0.001). Overall utilization of non-formal sources of care such as the chemical seller, the traditional healer and home treatment were highest among the poorest households in the intervention arm (p<0.001) (Table 7.5).

Table 7.4: A comparison of utilization of various sources of health care between the poorest and the least poor intervention households.

Visits/person-yr to	Least Poor N=255	Poorest N=240	Rate Ratio	(95% CI)	2-sided p-value
Primary care clinic	3.11	2.61	1.19	(1.02-1.39)	0.02
Hospital	0.62	0.30	2.08	(1.38-3.18)	<0.001
Chemical seller	2.30	3.07	0.75	(0.64-0.88)	<0.001
Home treatment	1.30	2.25	0.58	(0.47-0.70)	<0.001
Traditional healer	0.07	0.22	0.32	(0.12-0.72)	<0.01
Non-formal health care services	3.67	5.55	0.66	(0.58-0.75)	<0.001
Fever episodes	5.17	5.97	0.87	(0.78-0.97)	<0.01

The difference in utilization between the poorest and the least poor quintile is likely to be due to differences in the distribution of households belonging these quintiles with regards to distance of residence from a health facility. Whilst about 30% of the poorest quintile lived within 5 km away from a health facility, over 80% of the least poor quintile lived within this distance. Utilization of health services has been found both in this study and previous studies to decrease with distance from a health facility (Table 7.6 and 7.7).

Children from the poorest quintile of intervention households experienced significantly more fever episodes than those from the least poor intervention households (p<0.01) (Table 7.4).

7.5.1 Comparison of utilization of health services between the intervention and control households by wealth quintile

A comparison of utilization of primary and non-formal sources of care was carried out across wealth quintiles between the intervention and control arms. The results show that households in the intervention arm tended to use primary care services more than those in

the control arm across the five socio-economic groups. This difference reached significance only among the least poor quintile (95% CI 1.18–1.64; p<0.001).

This difference may again be due to the significant difference (χ^2=59.44 p<0.001) between the least poor and the other quintiles, particularly the poorest quintile, in terms of distribution of households by distance of residence from a health facility.

There was no clear pattern across the five quintiles with regards to utilization of non-formal sources of care between the control and intervention arms. However, apart from the poorest quintile, intervention households belonging to all the other socio-economic groups utilized non-formal health care services less than the control households (Table 7.5).

Table 7.5: A comparison of the utilization of health services between the intervention and control households by wealth quintile

	IR Control	IR Intervention	RR	95% CI	2-sided p value
Utilization of primary care (visits/person-yr)					
Q1	2.50	2.61	1.04	(0.89-1.22)	0.60
Q2	2.65	2.70	1.02	(0.87 -1.19)	0.80
Q3	2.59	2.78	1.07	(0.92 – 1.25)	0.38
Q4	2.52	2.84	1.12	(0.96 – 1.32)	0.13
Q5	2.23	3.11	1.40	(1.18 – 1.64)	<0.001
Utilization of informal care (visits/person-yr)					
Q1	5.37	5.55	1.03	(0.93 – 1.15)	0.56
Q2	6.11	5.00	0.82	(0.73 – 0.91)	<0.001
Q3	4.80	4.45	0.93	(0.82 – 1.04)	0.21
Q4	5.34	4.20	0.79	(0.70 – 0.89)	<0.001
Q5	3.82	3.67	0.96	(0.84 – 1.10)	0.56

Among study subjects who lived less than 5 km away from a health facility, there was little difference in primary care service utilization between the control and intervention arms in the lower four quintiles. Among the least poor households, however, the intervention arm utilized primary care services significantly more than the control (95% CI 1.17-1.68; p<0.001). Overall, among households living within 5 km from a health facility, non-formal sources of health care tended to be used more by the control than the intervention households. This achieved statistical significance among the very poor, the poor and the less poor quintiles (Table 7.6).

Table 7.6: A comparison of the utilization of health services between the intervention and control households living <5km away from a health facility by wealth quintile

	IR Control	IR Intervention	RR	95% CI	2 sided p-value
Utilization of primary care by residents <5km from nearest facility (visits/person-yr)					
Q1	2.89	2.86	0.99	(0.75-1.30)	0.95
Q2	2.78	2.85	1.02	(0.84-1.25)	0.80
Q3	2.95	2.55	0.86	(0.72-1.03)	0.10
Q4	1.89	1.83	0.97	(0.78-1.20)	0.78
Q5	2.29	3.22	1.40	(1.17-1.68)	<0.001
Utilization of informal care by residents <5km from nearest facility (visits/person-yr)					
Q1	4.84	4.82	0.99	(0.81-1.22)	0.96
Q2*	5.79	4.32	0.75	(0.64-0.86)	<0.001
Q3	4.88	4.22	0.87	(0.75-0.99)	0.04
Q4	5.55	4.07	0.73	(0.64-0.84)	<0.001
Q5	3.67	3.57	0.97	(0.83-1.14)	0.73

*Mainly significantly reduced home treatment among the intervention arm in this quintile

Among the households who lived more than 5 km away from the nearest health facility, the intervention arm used primary care services more than the control arm in each

quintile, but this difference did not achieve statistical significance except in the poor (Q3) quintile. Again, there was no clear pattern to the use of non-formal sources of health care (Table 7.7).

Table 7.7: A comparison of the utilization of health services among intervention and control households living >5km away from a health facility by wealth quintile

	IR Control	IR Intervention	RR	95% CI	2 sided p-value
Utilization of Primary Care by residents >5km from nearest facility (visits/person-yr)					
Q1	2.31	2.51	1.09	(0.90-1.33)	0.37
Q2	2.44	2.46	1.01	(0.78-1.31)	0.95
Q3	1.66	3.58	2.16	(1.54-3.04)	<0.001
Q4	1.88	2.10	1.12	(0.76-1.65)	0.56
Q5	2.01	2.67	1.33	(0.90-1.97)	0.14
Utilization of informal care by residents >5km from nearest facility (visits/person-yr)					
Q1	5.65	5.83	1.03	(0.91-1.17)	0.62
Q2	6.60	6.07	0.92	(0.78-1.08)	0.30
Q3	4.59	5.25	1.14	(0.90-1.44)	0.25
Q4	4.63	4.57	0.99	(0.77-1.27)	0.92
Q5	4.39	4.04	0.92	(0.69-1.22)	0.56

7.5.2 Comparison of utilization of health services between the intervention (trial-enrolled) and self-enrolled households

It was interesting to compare households in the intervention arm with those in the self enrolled arm because the difference that was observed with regards to baseline characteristics was also observed with regards to this trial outcome.

Comparison of the intervention and self-enrolled arms across the five socio-economic groups showed differences with regards to the use of primary care services. While an

increase in the level of utilization was observed with improving socio-economic status in the intervention arm, the reverse was found in the self-enrolled arm.

Among the self-enrolled group, the poorest appeared to have benefited most in terms of improved access to health services as they used the primary health care services most with a decrease in the level of utilization up the socio-economic gradient towards the least poor. The difference between the intervention and self-enrolled arms was significant for all the quintiles except among the least poor quintile where utilization appeared to be similar in both groups. It was only among the least poor that the intervention households used primary care services to the level that the self-enrolled households used it (Table 7.8).

Table 7.8: A comparison of utilization of health services among intervention and self-enrolled households by wealth quintile

	IR Self-enrolled	IR Intervention	RR	95% CI	2 sided p-value
Utilization of Primary Care (visits/person-yr)					
Q1	6.67	2.61	0.39	(0.28-0.56)	<0.001
Q2	4.92	2.70	0.55	(0.42-0.72)	<0.001
Q3	4.64	2.78	0.60	(0.45-0.81)	<0.001
Q4	4.35	2.84	0.65	(0.52-0.82)	<0.001
Q5	3.27	3.11	0.95	(0.75-1.22)	0.66
Utilization of informal care (visits/person-yr)					
Q1	5.00	5.55	1.11	(0.77-1.66)	0.59
Q2	5.28	5.00	0.95	(0.74-1.23)	0.66
Q3	5.60	4.45	0.79	(0.62-1.04)	0.08
Q4	4.52	4.20	0.93	(0.75-1.16)	0.49
Q5	2.34	3.67	1.57	(1.20-2.09)	<0.001

Among the households in the intervention arm, the least poor utilized the primary care services most with a gradual reduction in effect towards the poorest. There was no obvious pattern among the socio-economic groups with regards to use of non-formal sources of health care. It must be noted that this picture may probably be due to the fact that almost 80% of the least poor lived within 5km of a primary care facility as compared to just 30% of the poorest households. More than 60% of the poorest households lived more than 5km away from a health facility.

A comparison of intervention and self-enrolled households living within 5 km of a health facility showed that though the least poor intervention households still utilized primary care services more than the poorest intervention households, it was the poor quintile (Q3) that had the lowest utilization rate (Table 7.9).

Table 7.9: A comparison of the utilization of health services between the intervention and self-enrolled households living <5km away from a health facility by wealth quintile.

	IR Self-enrolled	IR Intervention	RR	2 sided p-value	95% CI
Utilization of Primary Care by residents <5km from nearest facility (visits/person-yr)					
Q1	6.40	2.86	0.45	(0.30-0.68)	<0.001
Q2	5.07	2.85	0.56	(0.42-0.76)	<0.001
Q3	4.70	2.55	0.54	(0.40-0.75)	<0.001
Q4	4.82	3.11	0.65	(0.50-0.83)	<0.001
Q5	3.36	3.22	0.96	(0.75-1.24)	0.72
Utilization of informal care by residents <5km from nearest facility (visits/person-yr)					
Q1	4.36	4.82	1.10	(0.72-1.77)	0.67
Q2	4.65	4.32	0.93	(0.70-1.26)	0.60
Q3	5.57	4.22	0.76	(0.58-1.00)	0.05
Q4	4.77	4.07	0.85	(0.67-1.10)	0.20
Q5	2.35	3.57	1.08	(0.72-1.65)	0.72

No obvious pattern was seen when households living more than 5 km away from a health facility among the intervention and self-enrolled arms were compared. Apart from the least poor quintile, the intervention arm utilized primary care services less than the self-enrolled arm among all quintiles. This achieved significance only among households in the poorest quintile (RR=0.25 95% CI 0.11-0.78; p=0.01). This was probably because very few of the self-enrolled households lived that far away; the numbers were as such too small for any meaningful analysis.

7.6 Household socio-economic status and anaemia

The prevalence of anaemia among children in the intervention arm at the end of the transmission season was lowest among the very poor (Q2) (n=5) (2.1%) and highest among the poor (Q3) (n=11) (5.1%). The poorest had the third lowest prevalence (n=7) (2.9%). The prevalence of anaemia was generally very low among study subjects and as such these numbers were small. There was no association between anaemia at the end of the peak malaria transmission period and household socio-economic status (95% CI 80-1.11 p=0.49). This was also the case at baseline.

Table 7.10: Prevalence of anaemia at the end of the malaria transimission season among households in the intervention arm by wealth quintile

	Poorest	Very poor	Poor	Less poor	Least poor
Prevalence of anaemia (Hb<8g/dl)	7 (2.9%)	5 (2.1%)	11 (5.1%)	6 (2.8%)	7 (3.2%)

The odds of being anaemic at the end of the peak malaria transmission season for a child who belonged to the least poor quintile of the intervention arm instead of the poorest quintile were lower; although not significantly so (OR=0.66 95% CI 0.29-1.53; p=0.33). The odds were minimally increased when adjusted for sex, age, distance from health facility and clustering effect of more than one child in a household (OR=0.69 95% CI 0.27-1.79; p=0.45). The level of utilization resulted in an improvement in this health outcome among the least poor quintile, though not significantly so.

7.6.1 Effect of intervention on anaemia among the poorest

The effect of the intervention was greatest among the poorest quintile who lived within 5 km from a health facility. In this group, both the barrier due to direct cost of care and that due to distance are removed (OR=0.32; 95% CI 0.03-2.93) (Table 7.11). Among the poorest who lived more than 5 km away from a health facility, the odds of being anaemic was higher (OR=1.46; 95% CI 0.41-5.28).

Table 7.11 Effect of poverty and distance on the outcome of the intervention

Wealth quintiles		Modifying factors			
		Crude	Distance <5km adjusted	Age sex dist <5km adjusted	Age sex dist >5km adjusted
Poorest	OR	0.93	0.32	0.34	1.40
	(95% CI)	(0.33-2.60)	(0.35-2.93)	(0.04-3.16)	(0.38-5.20)
	p-value	0.89	0.31	0.34	0.62
Very poor	OR	0.55	0.65	0.60	0.33
	(95% CI)	(0.18-1.68)	(0.18-2.36)	(0.16-2.21)	(0.03-3.31)
	p-value	0.30	0.52	0.45	0.33
Poor	OR	1.22	1.34	1.49	0.96
	(95% CI)	(0.52-2.88)	(0.44-4.06)	(0.48-4.62)	(0.23-4.08)
	p-value	0.65	0.61	0.49	0.96
Less poor	OR	0.90	1.08	1.09	0.51
	(95% CI)	(0.30-2.73)	(0.31-3.82)	(0.31-3.85)	(0.04-5.99)
	p-value	0.86	0.90	0.89	0.59
Least poor	OR	3.55	-	1.15	0.47
	(95% CI)	(0.73-17.28)		(0.22-5.86)	(0.04-5.62)
	p-value	0.11	-	0.87	0.55

7.7 Household socio-economic status and parasitaemia

At baseline, the prevalence of parasitaemia decreased across the quintiles from the poorest to the least poor and the trend was statistically significant (p<0.001). The parasite prevalence was highest among households in the poorest quintile (n=191) (39.1%) and lowest among households in the least poor quintile (n=74) (14.9%). This trend was seen again at the end of the peak malaria transmission season with the highest prevalence still among the poorest (n=104) (22.9%) and the lowest among the least poor (n=32) (7.1%).

The odds of being parasitaemic at the end of the malaria transmission season if a child belonged to the least poor quintile of an intervention household instead of the poorest quintile of the same arm was significantly lower (OR 0.32 95% CI 0.18-0.57; p<0.001) and increased slightly when adjusted for sex, age, distance from health facility and clustering effect of more than one child in a household (OR 0.36 95% CI 0.19-0.68; p=0.002).

7.8 Household socio-economic status and anthropometric indicators

At baseline, there was a significant trend (p=0.02) across the wealth quintiles with the highest prevalence of wasting being among households in the poorest quintile (n=36) (6.7%) and the lowest among the least poor (n=22) (4.1%). Baseline prevalence of children who were underweight was highest among the poorest (n=95) (17.7%) and lowest among the least poor (n=59) (11.0%). The trend across the wealth quintiles with regards to wasting was significant at baseline (p=0.001).

At the end of the peak malaria transmission period, the highest prevalence of wasting among children in the intervention arm was among the poorest quintile with the lowest being among the least poor. The odds of a child who belonged to the intervention arm being wasted at the end of the peak transmission season was lower if that child belonged to the least poor quintile instead of the poorest quintile and not significantly so (Table 7.12).

Table 7.12: Association between household socio-economic status and wasting in the intervention arm

	OR (95% CI)	p-value
Crude	0.84 (0.51-1.40)	0.51
Adjusted for age, sex, distance, clustering	0.95 (0.53-1.72)	0.87

7.9 Summary

The results showed that, as expected, the randomly allocated arms were similar in the distribution of wealth quintiles, whilst the self-enrolling arm was very different. There was a marked variation as well in the distribution of households by distance of residence from primary care facility within the three arms. At baseline, poorer households relied more on untreated nets for prevention of malaria whilst the least poor quintile tended to use screening of doors and windows more.

The utilization of primary care facilities was significantly lower and use of non-formal sources of care higher among the poorest intervention households. Children from the poorest intervention households experienced more fever episodes than those from the least poor intervention households. A comparison of the utilization of health services among the wealth quintiles in the intervention and control arms showed that though households in the intervention arm tended to use primary care services more than their counterparts in the control arm across the five socioeconomic groups, the is reached significance only among the least poor This picture persisted when households living within 5 km of a primary care facility were compared by wealth quintiles but disappeared with increasing distance.

A comparison of the trial-enrolled and self-enrolled arms by wealth quintiles showed that the self-enrolled arm utilized primary care services significantly more across all wealth

quintiles except among the least poor where the difference was not statistically significant.

There was an association between socioeconomic status and parasitaemia on one hand and wasting on the other both at baseline and at the end of the trial. No association between socioeconomic status and anaemia.was found.

CHAPTER 8 CONTEXTUAL AND EXPLANATORY FACTORS RELEVANT TO THE TRIAL

8.1 Overview

The first three of the following five sections cover sub studies that were carried out in the study area during and after the main trial whilst the last two sections report on-going malaria-control efforts in the study area during the period of the main trial. The aim of these reports is to document and assess the possible effect these contextual and explanatory factors might have had on the overall outcome of the study in order to provide assistance in the interpretation of the results of the trial.

The studies included the perception of members of the communities in the two sub districts of the quality of care they were receiving from the health facilities in the district. The perception of the quality of care in a health facility is known to be a major determinant of the level of its utilization. Additionally, an assessment of the level of use of chloroquine among study subjects in the study area where the first line anti-malarial prescribed in health facilities for the treatment of malaria had been changed locally from chloroquine to a combination of amodiaquine and artesunate was carried out. The effectiveness of this new drug combination for the treatment of uncomplicated malaria was also assessed. Finally, the perceptions of two groups of people in the district on various issues were elicited. The two groups were made up of those who had a card (green card) allowing them to access care without paying at the point of use and those who did not. This last study was carried out at the end of the trial.

8.2 Quality of care in health facilities in the study area

Client perception of the quality of care in a health facility may affect their willingness to utilize that health facility. The following section documents the quality of care in the two main health centres in the sub districts where the trial was carried out, both from the perspective of members of the communities and from an objective assessment based on an adapted Ghana Health Service Quality of Care Assessment Tool. To provide a complete picture, and avoid bias, both people who had used the health facility and those who were in their own communities away from the vicinity of the health facility were

interviewed. The aim of the study was to provide information on the willingness of the people to utilize the health facility. It was important to document the quality of care in the health facilities from the perspective of the community since a perception of poor quality would result in non-utilization of the facility by study subjects, even with free enrolment in the pre-payment scheme. Such a situation would affect the outcome of the trial.

8.2.1 Methods

Both quantitative and qualitative methods were used. The quantitative methods consisted of client exit interviews and involved people who had used the facility and were exiting as well as reviews of patient records. The interviews were carried out by means of an administered questionnaire. Focus group discussions were also conducted with groups of mothers with children under five who were enrolled in the pre-payment scheme and others who were not, using a focus group discussion guide.

Exit Interviews

Data collection was carried out by trained fieldworkers who were not health staff and had nothing to do with the health facilities, with supervision by a combination of research staff and one community health worker. A fieldworker sought consent from the client as he entered the clinic and when this was given, noted the name of the client, their age, time the client entered the clinic and the clinic-assigned outpatient department (OPD) registration number on a client recruitment slip. He then handed over the slip to the client with instructions to hand this over to the any of the fieldworkers based in a specific location outside the clinic on his/her way out. The fieldworker who saw the client as he/she exited the health facility carried out the actual interview. The interview took place under some trees a short distance away from the health facility. At the end of the day, the OPD registration numbers were used to trace the client treatment cards and details of complaints, diagnoses, examination findings and treatment were recorded.

Focus group discussions

Mothers were recruited in the communities with the help of contact persons from the 7 communities. In each community, the contact persons were asked to identify two groups of 8-12 women with children less than five years; one group comprising women who had a green card and another comprising those who did not, for the discussion on an agreed date. On arrival of the study team on the appointed date, the contact person in the community gathered the groups for the discussion.

8.2.2 Main findings

Findings from exit interviews

Background of respondents

Overall, 161 clients were interviewed as they exited the two health centres in the two sub-districts where the study was being carried out. Thirty-eight (23.6%) of the respondents were male. A total of 108 (67.1%) of them were enrolled in the pre-payment scheme whilst 53 (32.9%) of them were not. They comprised 57 (35.4%) traders, 31 (19.3%) artisans, and 17 (10.6%) civil servants; 23 (14.3%) respondents were unemployed. The rest included farmers, fishermen, and fishmongers among others.

Thirty-two (20%) of them had received no formal education. A total of 104 (64.6%) had primary level education whilst 14 (8.7%) and 11 (6.8%) had had secondary and tertiary level education respectively. The majority, 144 (89.4%) were of the Christian faith. One hundred (62.1%) out of the 161 clients belonged the Dangme ethnic group which is the major one in the area. The second largest ethnic group were Ewes and they formed about 25 (15.5%) of respondents. A total of 88 (54.7%) respondents said they were self-users of the facility whilst the rest were accompanying their wards.

One hundred and five (65.2%) clients had used the health facility three or more times whilst 34 (21.1%) were first time users. One hundred and fifteen (71.4%) had selected the health facility themselves whilst the rest took the decision to use it based on recommendation from other people such as family members, or other patients.

One hundred and forty-six (90.7%) out of the 161 clients had their temperatures taken on arrival at the health facility and 143 (88.8%) had their weights recorded. Blood pressures were recorded for all adults. The 74 clients (46%) who did not have their blood pressure recorded were children 7 years of age or lower. In general there were no significant differences between the enrolled and non enrolled in their assessment of the quality of care in the health facility except with regards to respect and courtesy shown by staff where none of the enrolled rated courtesy shown by staff as poor or very poor as compared to about 10% of the non enrolled who did so. In the same vein, the enrolled rated the sanitation at the health facility significantly better than the non enrolled.

Perception of the quality health care in the health facilities

The following table summarizes the responses given by clients when their perception of quality of health care provided in the health facilities was elicited.

Table 8.1: Quality of care in two health facilities

Indicator of Quality of Care	*Proportion(N=161)*
Examined by the health care provider	150 (93.2%)
Was told what was wrong with him/her	93 (57.8%)
Was given instructions concerning illness	90 (55.9%)
Nurses/other staff provided explanation about tests, treatments, and what to expect	121 (75.2%)
Had privacy during visit	149 (92.6%)
Staff willing to answer questions from client on things he/she did not understand	147 (91.3%)
Behaviour of staff friendly/helpful/polite/courteous	151 (93.8%)
Length of time spent at facility just enough or shorter than expected	77 (47.8%)
Length of time spent at facility too long	25 (15.5%)
Understood instructions from the dispensing technician	159 (98.8%)
Would recommend this health facility to family and friends	154 (95.7%)
Likely to return to this health facility	153 (95.0%)

Clients thought staff were friendly/courteous because they seemed to have time to respond to their concerns and spoke kindly to them. Some commented that they had heard that staff were sometimes impolite but had been surprised at how courteous they were when they actually utilized the health facility.

Most of those who said they had waited too long, said they had spent the time either waiting to be seen in the consulting room or to collect their prescribed medication at the dispensary. Most of those who thought they had waited for too long thought the long wait was due to either inadequate staff or the large number of patients. Others thought the delay was due to lateness of staff. A few also talked about other patients being allowed to jump the queue. Thirty-six (38%) of those who felt they had waited for too long thought the delay was unnecessary and could have been avoided. The suggestions they made towards solving the problem of delay reflected the causes they had pointed out. Out of the 12 clients who said they had reported to some of the primary care facilities with emergencies before, only one said she was not seen to promptly.

When the clients were asked to rate the staff and services received at the health facility using indicators of quality of care from the patient's perspective, (Table 8.2), they rated them as follows:

Table 8.2: Client rating of the quality of care received in the health facility

Indicators of Quality of Care (N=161)	Good/excellent		Poor	
	n	%	n	%
Amount of information given about client's illness, its treatment, and what to do after leaving the health centre	121	75.2	24	14.9
Respect and courtesy of staff at the health facility	150	93.2	3	1.9
Skills of staff in treating illness of client	149	92.6	4	2.5
Quality of drugs given at health facility	147	91.3	6	3.7
Physical structure of health facility	104	64.6	20	12.4
Sanitation at health facility	125	77.6	2	1.2
Overall quality of care received	147	91.3	5	3.1

When asked about what more they would like to see done to improve the quality of the drugs being dispensed, 112 (69.6%) of the 161 clients talked about an improvement in the packaging of drugs. They would like more of the drugs to be dispensed in boxes/packets and sealed or blister packed instead of being dispensed in envelopes. However, they seemed to be largely satisfied with the quality of drugs being currently dispensed to them at the health facility. When asked about how availability or non availability of drugs would affect their perception of the quality of service, they thought that availability of drugs was very important in determining the quality of care offered in health facilities and since, in this case, drugs were available in both health centres, most of them expressed satisfaction.

Findings from focus group discussions

The group discussions were held with women with children less than five years of age who either had or had not been enrolled in the scheme over the previous six months. Their perceptions on the various issues explored were generally the same except for a few that related to payment for health services. This was not surprising in view of the fact that when the scheme was set up, the health staff in the district were asked to provide equal services for equal need making a difference only in the mode of payment for the services provided between those enrolled and those who were not. The following section, therefore, sets out the perceptions in general for both groups only differentiating between the two groups in the issues where perceptions were different.

Background of focus group discussants

One hundred and sixteen women from seven (7) randomly selected communities in the Dangme West district were interviewed. The ages of the women interviewed ranged from 15 to 52 years; 86 (74.1%) were married, 29 (25%) unmarried and 1 divorced. Their educational levels ranged from no formal education to the Senior Secondary School (SSS) level with the majority ending their education at the Junior Secondary School (JSS) or Middle School Leaving Certificate (MSLC) level. Their occupations were

predominantly farming and trading. The average number of children each woman had was 3, with an average of 2 children less than five years of age.

Perception of what constitutes good quality health services

The community members' perception of what constituted health services that were of good quality hinged mainly on the kind of staff-client interpersonal relationships that existed at the health facility. They rated the quality of the services in the health facility mainly according to how they were received by staff on reporting at the facility and how they were treated whilst they were there, unprompted.

> *"It depends on how the nurses receive and welcome you. That gives you joy."* **(Asutuare Junction women enrolled)**

> *"It depends on how one would be treated and the friendliness expressed. This is what would encourage one to visit again."* **(Mobole women not enrolled)**

> *"You will get to know it is a good health centre from its reception and the kind of treatment you will be given by the nurses and doctors of the place. What we mostly need is someone to calm us down, comfort us and even assure us that things will be okay."* **(Hiowe Gblaka women not enrolled)**

A few mentioned facilities like a laboratory, an ambulance and the availability of drugs and equipment in the health facility unprompted. One group talked about the infrastructure.

On probing further into the role various indicators such as the general appearance of the health facility, the time spent at the health facility, privacy, the kind of drugs prescribed, the number of drugs, staff interaction with clients, whether they received adequate counselling on their illness and what to do, played in their assessment of quality of care at the health facilities, the two groups in each community came up with very similar responses.

<u>General appearance</u>

Community members were particular about neatness at the health facility. A health facility offering good quality health services should be painted and the buildings should be in a good state of repair. The place should be weeded and flowers planted to give the place a beautiful appearance. Sign posts indicating that this was a health facility as well as directional signs within the facility were thought to be important. Sanitation of the place should be good with well-kept disposal areas for rubbish. Good seating for patients was also thought to be a plus.

> *"There should be veranda and shade as in Dodowa Clinic."* **(Asebi women enrolled)**

> *"There should be a signboard at the roadside so that immediately you see it you will know that this is a clinic."* **(Prampram women not enrolled)**

> *"The place must be decorated and painted."* **(Fiankonya women enrolled)**

<u>Waiting time</u>

All the community members preferred a health facility where they spent very little time at the clinic. However, they conceded that the possibility of this happening in reality depended on several factors. These included the time of one's arrival at the health facility, the number of patients to be seen on a particular day, the type of illness and the number of health staff available to attend to patients.

> *"It depends on the attendance of the day. At times when you go, you meet a lot of people and when you get there in the morning, you may leave around four in the evening. But if you are lucky, by twelve noon they have finished with you."* **(Asutuare Junction women enrolled)**

> *"It depends on the type of illness you will take there. When your child's illness is serious, you will spend some time there, but when the illness is not serious, then you will come home early."* **(Mobole women enrolled)**

They mentioned that sometimes longer periods were spent at some clinics because staff preferred to wait for several patients to arrive before they started the day's work. This, they had noticed, occurred particularly in maternity units. Sometimes health staff arrived

late for work or gave preference to their friends, thereby disrupting the queue. Some others simply did not carry out their work fast enough in their opinion. The latter situations were unacceptable to them as causes of the prolonged waiting times.

"Sometimes too the patients are there but it depends on how fast the nurses will be. Sometimes they will be passive and you will all be at where you are in the queue and that makes us delay." **(Prampram women not enrolled)**

Privacy

The community members were unanimous in their preference for a private place for consultation with the clinician where no one else could listen to their discussion relating to their illness.

"As for sickness, everybody has his own so I would not like someone to hear about mine." **(Asutuare Junction woman not enrolled)**

Drugs

Most of the community members agreed that the effectiveness of drugs could only be attested to after use. In effect, one could not just tell by looking at the drug whether it would be effective or not. However, in the case of syrups, when it seemed dilute, they were unsure about its quality. A few seemed to equate the quantity of drugs given with being given good treatment.

"They only give two or three different drugs. We become happy when we are given many drugs. We consider ourselves well treated." **(Agomeda women not enrolled)**

Most disagreed with this view and felt that the effectiveness of the drugs did not really depend on the quantity of drugs given.

"Some of the drugs are small in number yet they are very effective. Some are plenty yet ineffective." **(Asebi women not enrolled)**

"The drug being many or few does not matter. What matters is the recovery from illness." **(Fiankonya women not enrolled)**

"As for me, if I send my child and I am given one type of drug, I don't care provided my child is healed. So either it is plenty different types of drugs or one type the most important thing is to see my child well." **(Asutuare Junction woman enrolled)**

Overall impression of quality of care

When asked to give their overall impression of the quality of care in the health facilities based on the discussions held earlier and any other indicators they might want to use, they thought the quality of care in the health facilities was adequate.

"They give us good drugs and treat us well and also the children recover when we give them the drugs." **(Fiankonya women enrolled)**

"Once I bought some drugs from the drug store for my sick child. He emptied two bottles of the drug but did not recover. When I sent the child to Dodowa, the Doctor gave me some tablets and some other drugs. The child recovered within 4 days. There, one is told to come for review if the given drugs are finished and the child does not recover and if necessary, the drugs would be changed." **(Asebi Women enrolled)**

"At Agomeda when one visits the clinic with a sick child, they come home to visit after two to three days." **(Agomeda women not enrolled)**

Some of the FGD discussants had concerns about how they were treated on some occasions by some nurses. Most discussants seemed to be happy with the main clinician, however.

"Some of the nurses do well when on duty but others are not friendly to patients." **(Hiowe Gblaka women not enrolled)**

"Doctor is friendly. She takes her time to ask questions and examine. With the doctor, one can have her privacy." **(Agomeda Women not enrolled)**

Others in the group were quick to point out that the quality of care in the health facilities had improved considerably over the years and that the treatment one received at the health facility was sometimes a result of how one also related to the health staff.

"………it is like we've been to a big hospital." **(Hiowe Gblaka Women)**

"Just as the elders say 'efie bia Mensah wom' you can go to a place and whether you will be treated well or not will depend on your own deeds." **(Asutuare Junction women not enrolled)**

8.2.3 Summary

Overall, the clients appeared to have a perception of good quality of care in the health facilities. They rated the facilities and the staff highly, although they pointed out a few areas like behaviour of some staff, privacy and the waiting time that were not so acceptable to them. Even though they appreciated the fact that these were probably due to clinic infrastructure and patient load respectively, they still thought something should be done to improve the situation. The perception of the quality of care in this study area is, therefore, unlikely to affect the utilization of health care adversely.

8.3 Assessment of the use of chloroquine among a randomly selected sub-set of study subjects

To assess whether the study subjects had been taking chloroquine over the previous three to four months, an assessment of the presence of chloroquine in the urine was carried out among a random selection of study subjects during the final cross-sectional survey. This was to ensure that the results of the trial would not be confounded by the intake of an ineffective anti-malarial by any group of study subjects. The dipsticks and accompanying re-agents together with a protocol for their use were obtained directly from the manufacturer, Dr. Teunis Eggelte of the Academic Medical Center in the Netherlands.

The test is based on the dip-stick technology in which an immobilized antibody is first reacted with the test sample and then with a drug/enzyme-conjugate (Eggelte 1990; Eggelte *et al.* 1992). It uses monoclonal antibodies raised against pyrimethamine and chloroquine. The antibodies against chloroquine are raised against a protein-hapten conjugate in which hydroxychloroquine is coupled to the protein. The monoclonal antibody, F 73-8 used in this test recognizes the 4 aminoquinoline-7-quinoline moiety of chloroquine. It may also recognize other 4-aminoquinolines such as amodiaquine but the sensitivity to this drug is 10 times lower than that of chloroquine. The test is very sensitive for chloroquine and will detect choloroquine a long time (3-4 months) after intake of a therapeutic dose (personal communication, T. Eggelte).

8.3.1 Methods

Urine samples were collected in the field and transported to the nearest health centre for testing. The dipstick was immersed in urine for 1 minute and, after rinsing with distilled water, placed into a vial containing 1 ml of drug-HRP-conjugate (Horse Radish Peroxidase) for 5 minutes. After rinsing again the dipstick was incubated in a vial containing DAB-solution (Diaminobenzidine) for another minute. After washing in water and drying, the lower line (F 73-8) was compared with the upper control line (F 172-2). If the sample does not contain CQ, both lines have the same colour (negative); if the sample contains significant amounts of CQ, the lower line is visible but less pronounced

than the control line (positive). The lower limit of the semi- quantitative detection of CQ for the ELISA dipstick is approximately 120 nmol/l (Eggelte *et al.* 1992). It was reported to detect chloroquine in the urine taken as far back as 3-6months prior to the test (Schwick *et al.* 1998). Overall, urine samples were taken from 925 randomly selected subjects during the final cross-sectional survey. These comprised 429 subjects in the control arm, 395 in the intervention arm and 101 subjects in the self-enrolled arm.

8.3.2 Main findings

Overall, only 1.4% (n=4) out of the 925 study subjects had a positive reaction suggesting that they had taken chloroquine within the past four months; two from the control group and the other two from the self-enrolled group. None of the intervention group tested positive.

8.3.3 Summary

The results showed that over the period of the study, very few of the study subjects had taken any chloroquine over the previous 3-6 months. Although this does not exclude the fact that they may have taken other effective anti-malarials, the results of this sub study show that the new anti-malarial (a co-packaged amodiaquine-artesunate combination) in use at health facilities all over the district was probably seen as effective by community members. They probably, therefore, they did not need to resort to the use of ineffective anti-malarials such as chloroquine. The reason for the change in anti-malarial prior to the study was therefore largely achieved.

8.4 Assessment of the effectiveness of amodiaquine-artesunate among RDT positive children during cross-sectional survey

An assessment of the effectiveness of the amodiaquine-artesunate combination anti-malarial was carried out during the final cross-sectional survey. This opportunity was taken to find out how effective the drug was for use in the study area.

8.4.1 Methods

During the final cross-sectional survey, each mother or carer was asked whether the study child had had fever during the week. If she answered in the affirmative, a malaria antigen assay was carried out using an Optimal IT® (*Flow Incorporated, USA*) Rapid Diagnostic Test (RDT). Additionally the body temperatures of all the 2689 children were taken during the survey. Any child found with a temperature above 37.5°C also had the antigen assay carried out. This was in addition to the collection of thick and thin films that was carried out for each of the children as part of the final cross-sectional survey.

Whenever a child tested positive, the study nurse was informed immediately. The child was then visited within the hour, and given a pack of pre-packaged amodiaquine-artesunate depending on his/her age. The mother/caretaker was given detailed instructions on how to administer the medication. They were also advised to take the child to hospital if the health of the child did not improve within 48 hours. On the 14th day after the treatment, the child was visited by the study nurse and a field worker. The mother was asked about the child's health and a thick and thin film slide for malaria parasites was taken. Any child who had not recovered was to be promptly transported to hospital. The day 14 slides were double read by experienced microscopists.

8.4.2 Main findings

Out of the 2482 children visited, 339 (13.7%) had either a history of fever during the week or a temperature > 37.5°C on the day of the visit (day 0). One hundred and six (31.3%) children tested positive for the RDT and received amodiaquine-artesunate packs.

Their mothers/principal carers were given instructions on how to administer the medications. All the children were followed up at home on day 14. Eighteen (17 %) were not found at home on the day of follow-up but were reported to have recovered completely. Eighty-eight children (83%) completed follow-up; all their day 14 slides were negative for malaria parasites on microscopy.

8.4.3 Summary

These results show that the artemisinin combination, amodiaquine-artesunate, is effective for use in the treatment of uncomplicated malaria in the study area. Its use for treatment is, therefore, unlikely to have resulted in treatment failures during the trial which would have had an effect on the main outcome.

8.5 Community perceptions at the end of study period

This study, which used qualitative methods similar to those described earlier, aimed at documenting community knowledge, attitude and practice with regard to quality of care at the health facilities, treatment seeking behaviour of mothers with children less than five years of age, the newly introduced ACTs, the existing pre-payment scheme and ITNs. It had the following objectives:

1. To document the perceptions of mothers on the quality of care in the public health facilities in the district.

2. To explore the treatment seeking behaviour of mothers with children less than five with or without improved financial access to health care.

3. To find out perceptions of the pre-packaged amodiaquine-artesunate combination being dispensed at the health facilities among mothers with children less than five, with or without improved financial access to health care.

4. To explore perceptions on Dangme West pre-payment scheme among mothers with children less than five with or without improved financial access to health care.

5. To explore perceptions and practices related to the use of ITNs among mothers with children less than five with or without improved financial access to health care.

8.5.1 Methods

Data collection involved mainly FGD in 7 communities with mothers of children less than five years of age, using an FGD guide. The FGD was conducted to elicit responses or information from mothers of children less than five years of age with or without improved financial access to health care. Earlier contacts were made with the elders and opinion leaders of the randomly selected communities and permission sought. They were asked to identify 8-12 women with children less than five years with a "green card" and the same number without one for a discussion on an agreed date. On the arrival of the study team on the appointed date, a contact person in the community gathered the groups, for the discussion.

8.5.2 Main findings

Background of discussants

A total of 116 women from seven (7) different communities in the Dangme West district were interviewed. The communities were in the following categories:

Distance of Residence from Health Facility	Community
< 5km	Hiowe Gblaka , Agomeda, Prampram
5-10km	Asebi
> 10 km	Mobole, Fiankonya and Asutuare Junction

The ages of the women interviewed from the above-mentioned communities ranged from 15 to 52 years; 86 were married, 29 unmarried and 1 divorced. Their educational levels ranged from no education to the senior secondary level with the majority ending their education at the Junior Secondary School (JSS) or Middle School Leaving Certificate (MSCL) level. Their occupations were predominantly farming and trading. The average number of children the women had was 3 with an average of 2 children less than five years old.

Table 8.3 Study communities and number of women interviewed.

Community	Females with card FGD	Females without card FGD
Agomeda	8	10
Asebi	9	10
Fiankonya	8	8
Mobole	6	7
Prampram	10	6
Hiowe Gblaka	7	10
Asutuare Junction	11	6
Total	**59**	**57**

Perception of the quality of health care in the district health facilities

The findings with regards to this were discussed earlier in this chapter in section 8.2.2 together with those obtained from client exit interviews.

Illnesses commonly affecting children

At the end of the malaria transmission season, both groups still identified malaria, diarrhoeal diseases, measles and convulsions as the commonest illnesses affecting their children.

Health seeking behaviour

When asked at what stage they usually sought care for their children, surprisingly there were very little differences between the responses given by the two groups. Most said they would first give some medication at home, either herbal or orthodox medicine (usually paracetamol), to see if child would recover. They would do this for two to three days and then go to the health facility in the event of there being no improvement in the condition. Three days of observation appeared to be a firm belief and practice in the community and whether they had the means to pay for services or not they observed and tried remedies at home for the first two or three days.

"What I know is, mothers with small children must always be having some paracetamol and other syrup on them. So when you administer the drug for three days and there is no improvement, you then have to rush the child to the health facility." **(Prampram Women, enrolled)**

"When you give home treatment for about two to three days before you would visit the health centre based on the condition of the illness." **(Agomeda women not enrolled)**

"It is not all children whose condition become critical, so after waiting for about three days and no sign of relief is seen one can send the child to the health centre." **(Mobole women not enrolled)**

"I also try to treat the illness for three days, when it is not okay then I will send the child to the health centre." **(Mobole Woman, enrolled)**

These comments were surprising since it was assumed that if people did not have to pay for health care, they would automatically go to the clinic as soon as the child was ill. It appears that it is generally after the second or third day of illness that the difference came in. Those who could pay or who did not have to pay went to the health facility whilst the others looked for money to go, sought alternative sources of care or stayed at home and continued trying home remedies while they hoped for the best.

Some illnesses were said not to be meant for orthodox treatment. With such illnesses, seeking care at the health facility might result in death of the person who was ill

> *"There are some illnesses that are not meant for the doctors but must be taken to the fetish. Sending them to the doctors may lead to death."* **(Asebi Women enrolled)**

Causes of delay in seeking care

The most commonly mentioned cause of delay in seeking care from the health facility was money to pay for medical bills.

> *"Sometimes the money to pay for medical bills is the problem."* **(Asutuare Junction woman non enrolled)**

> *"It may be that one does not have money at the point of the ailment."* **(Hiowe Gblaka Women not enrolled)**

> *"Sometimes it is due to money problem. So when it happens like that people decide to try at home. Or they will go to the drug store and describe it to the chemical seller who is there what is happening to the child. He will then give some medicine for the child."* **(Asutuare Junction women enrolled)**

A few also mentioned money for transport. Only one person mentioned the fact that the father may not be at home being the cause of delay in sending the child to the health facility when ill. Some also said that if one has leftover drugs at home, one may consider trying those first to see if the child will improve.

> *"I send my child to the health centre after I have given her some leftover drugs to no avail."* **(Mobole woman not enrolled)**

Perceptions of new anti-malarial drugs introduced

All discussants confirmed that they had noticed a change in the anti-malarial drugs that were being given in the health facilities over the past few months.

> *"Yes, at first we were being given chloroquine syrup but now, some broken tablets are being given."* **(Asebi woman, enrolled)**

> *"I also visited there recently and I was given some drugs in a sachet and they've sealed it. One is yellow and white and they have been broken into two equal parts and they mixed some there for my child and gave me the rest to bring home and they also gave me paracetamol in addition."* **(Prampram woman non-enrolled)**

When asked to give their opinion on which of the drugs they preferred, nearly all indicated a preference for the new drugs because they thought they were more effective and did not cause one to itch as chloroquine did.

> *"One experiences itching after administering the chloroquine but this does not itch."* **(Mobole Woman not enrolled)**

> *"With the broken tablets, when you administer as prescribed, the hotness stops getting to dusk or the next day. As she said, the child is relieved the next day."* **(Asebi woman enrolled)**

A few women from the same group, however, said the children became weak after taking the drug and slept for a long time after taking the medication after which they recovered.

> *"If you give it to the child, he sleeps and becomes weak."* **(Hiowe Gblaka woman enrolled)**

> *"Yes, they sleep for a long time and recover when they wake up."* **(Hiowe Gblaka woman enrolled)**

Perceptions of the pre-payment scheme

The women were asked how they settled their medical bills. Those who were enrolled in the scheme did not have to pay at the point of use of health services. They only presented their cards and received services. A few of those who had the green card said they had not used it over the past months because the child had not been ill all that time.

"You don't pay anything so it's just for you to pick up your card and go to the place and report." **(Hiowe Gblaka woman enrolled)**

"You will be given free medication if you visit the health facility with your green card." **(Agomeda woman enrolled)**

"When I was not enrolled, I paid the medical bills of my child but now that I am enrolled, I only take the green card when my child is ill and he is treated and given medicine." **(Agomeda woman enrolled)**

They differed from those who were not enrolled who said they had to find a way of paying for health services themselves.

"We don't have the green card so we pay ourselves." **(Agomeda woman not enrolled)**

"After being seen by the doctor and given drugs, I am given the bills and I have to then pay." **(Hiowe Gblaka woman not enrolled)**

They had all heard about the pre-payment scheme and several had good experiences with the use of the card. Some had heard about it for the first time when this study began and they were recruited. Among those who were not enrolled for the year, some also had friends and relatives who had benefited a lot from the use of the card and most had therefore decided to enrol in the coming year. Three or four women still held a negative view of the pre-payment scheme, based on stories they had heard from others and in the case of one woman, because of a bad experience she had had.

"I decided not to get enrolled but an Auntie of mine visited the clinic with her child and the drugs given to the two of them could cost hundreds of thousands of cedis. The drugs were given to them for free. This encouraged me to get enrolled but mine is still being processed." **(Hiowe Gblaka Woman enrolled)**

"At the time of your illness it may happen that you don't have money so if you have the green card, the moment you pick it up, you are gone." **(Prampram Woman not enrolled)**

Most said they would like to enrol in the scheme the following year because they found the scheme beneficial and that included even some of those who had narrated their

negative perceptions. The rest said they needed more explanation as to how the scheme works.

8.5.3 Summary

At the end of the peak malaria transmission season in the study area, the illnesses affecting children in the area had not changed as far as the women with children were concerned. The promptness with which health care was sought for children who are ill appeared not to be influenced significantly by the fact that one did not have to pay for services at the point of use even though it influenced greatly the mother or carer's choice of health care after the apparently usual two to three days of observation. Those with improved financial access to health care, at this point, to sought formal sources of health care whilst the others sought traditional sources or stayed at home and "hoped for the best". In cases where there was no improved financial access, it took a further two to three days or more to go round and look for money to meet the cost of illness.

Many had very positive views about the new anti-malarial that had been introduced and thought that it was more effective than the chloroquine that was previously being prescribed. The packaging of the combination drug was appreciated and may have had a positive effect on the perception of quality of care.

The pre-payment scheme in the area appeared to be well known. Those who had enrolled seemed to be enjoying the benefits whilst those who had not done so mostly had not joined because of rumours they had heard about the scheme not being effective. Some had subsequently found these not to be true and had taken a decision to enrol in the subsequent year. The perceptions of the pre-payment scheme did not therefore seem to have had a negative effect on utilization of services.

These perceptions were not different between the enrolled and the non enrolled groups and are therefore unlikely to have had any impact on the main trial.

8.6 Global Fund for malaria control activities in the district

Ghana received funding from the Global Fund to fight malaria in the year 2003. Subsequently, 20 pilot districts were selected to implement coordinated malaria control activities aimed at reducing infections, illness and death due to malaria. The study site was one such selected district and submitted proposals on a quarterly basis for approval by the National Malaria Control Programme (NMCP) of the Ghana Health Service (GHS). Funds were released based on these proposals for implementation of the said activities after which reports were submitted and funds accounted for. To achieve the aims and objectives set, the District Health Directorate partnered with some local Non Governmental Organizations (NGOs) and Community Development Workers from the Local Government Office. These activities were therefore on-going during the study period all over the district. The main areas covered by the activities included the following:

- Intermittent Preventive Treatment (IPT) for prevention of malaria in pregnant women.
- Promotion and sale of ITNs.
- Information, education and communication (IE&C) activities.
- Promotion of home based care for malaria.

Intermittent Preventive Treatment (IPT) for pregnant women

All pregnant women visiting public health facilities and private maternity centres for antenatal care services were given a maximum of three doses of two tablets of sulphadoxine-pyrimethamine, after quickening, beginning from the month of July 2004. The doses were given at monthly intervals and were taken under the direct supervision of the midwife. Several campaign strategies, including community durbars and floats through all the towns in the district, were carried out to create awareness all over the district. In 2004, 1229 pregnant women received the first dose of IPT, 630 women received two doses and 310 received a total of three doses. In the study area, most pregnant women begin attending antenatal care clinics in the second or third trimester of pregnancy so it is possible for most to deliver after just completing just one or two doses.

The total number of expected pregnancies for the district in 2004 was approximately 4600 with a recorded antenatal care coverage of 83% (n=3816) for the whole year.

Promotion and sale of ITNs

The district received a 1000 treated bed nets for sale at heavily subsidized prices to pregnant women and children less than five years in the district. The target groups paid 25% of the actual retail price. The nets were available in the public health facilities and at outreach clinics. In addition 500 treated nets were received from Mobil Ghana (a petroleum company) for sale to pregnant women using a voucher system. The company was working in partnership with the Ghana Health Service. Pregnant women attending public health facilities for antenatal care services received vouchers worth 40,000 Ghanaian cedis (£2.50) which they could redeem at any public health facility for a net worth C70,000. They had to pay an additional 30,000 Ghanaian cedis (£2.00)

Over the period of the trial there were increases in the use of treated nets in all three arms but the differences were not significant. The increase in prevalence of treated bed-net use among the control, intervention and self-enrolled arms were 5.2%, 4.2% and 7.4% respectively. A Greater Accra review of performance of the health sector identified the district as the best performing with regards to the use of ITN by children less than five years of age. The district had increased coverage of ITN use by children less than five from a low of 1% in 2002 to a little over 30% by the year 2005. Overall use of treated and untreated nets in the district was reported to be 32.7% and 55.7% respectively (GHS-GAR 2006).

Training of health staff and community based volunteers

A total of 80 Community Based Agents (CBAs) were trained to carry out IEC activities on home based care, ITNs, and IPT. They were also trained to retreat bed nets at community level.

All health staff in the district including private facility staff were re-trained in various aspects of malaria control. They were also trained to carry out IE&C activities both at the health facility and community level.

Information, Education & Communication (IE&C) activities

Various IE&C activities on malaria control were carried out by a combination of health staff, community development workers, staff of NGOs and trained CBAs. These utilized various strategies including discussions at small group community meetings, church and mosque meetings. In addition there were community durbars and floats.

All these activities were carried out all over the district and each of the study arms were likely to benefit equally from the activities.

8.6.1 Summary

The Global Fund activities which took place during the period of the trial concurrently all over the district, may have led to an improvement in overall malaria control during the period.

CHAPTER 9 DISCUSSION AND CONCLUSION

9.1 Overview

This randomized, controlled trial was conducted in a rural malaria endemic district in the southern part of Ghana, to examine whether a reduction in the direct cost of health care for households would lead to an increased utilization of health care services and an improvement in health outcomes among children 6 to 59 months. In this final chapter, the main findings of the study are discussed.

The initial sections discuss the context within which the trial was carried out. The relationships between household socio-economic status and various aspects of health in the study area are discussed. Also discussed are strategies adopted by households in the study area to cope with the costs of health care.

Households randomized to intervention and control arms are compared with regards to the main trial outcomes. The discussion will concentrate in particular on possible reasons why removing financial barriers to healthcare did not, in this setting, lead to improved malariometric outcomes. Households which enrolled themselves in the pre-payment scheme operating in the area are also compared to households in the trial arms. The differences in socio-economic status between the trial-enrolled and self-enrolled households are also discussed in relation to the main trial end-points.

The effectiveness of the existing pre-payment scheme in reducing inequalities in health is assessed. A few lessons learnt during the trial on translating research findings into policy in the context of a district health setting are shared. Finally, the strengths and weaknesses of the study as well as the implication of the findings for research, policy and practice are discussed.

9.2 Relationships between household socio-economic status and health in the study area

9.2.1 Health-seeking behaviour

Filmer suggests that the risk of malarial fever appears to vary across socio-economic quintiles but this relationship is not a steep one (Filmer 2005), although an important gradient between the least poor and the poorest with regards to the risk of adverse outcomes has been recognized (Nathan *et al.* 2004), possibly due to differences in health seeking behaviour.

In this study, the poorest intervention households used primary care services and the hospital significantly less than the least poor intervention households, and resorted to informal sources of health care such as the traditional healer, the chemical seller and home treatment significantly more than the least poor intervention households. The quality of health care service used by the poor tended to be worse than the better off (Table 7.4).

Household socio-economic status is known to influence care-seeking for childhood illness. Several studies have reported that members of the poorest households are less likely to seek care than people from more affluent households (Gotsadze *et al.* 2005; Taffa and Chepngeno 2005) even within a rural society that might easily be assumed to be uniformly poor (Schellenberg *et al.* 2003). Schellenberg and others found in Tanzania that although the likelihood of falling ill was not different between the poorest and the better off, there was a difference in the probability of obtaining suitable treatment once ill. Carers of children from wealthier families were found to have better knowledge about danger signs and were more likely to bring their children to a health facility when ill. They were also more likely to have had a shorter journey to the health facility than poorer families (Schellenberg *et al.* 2003).

Available evidence suggests that health service use is affected by the individual's socio-economic status when user fees are charged (Ensor and San 1996; Falkingham 2004; Gilson 1996; Russell and Gilson 1997). In Nairobi, it was reported that sick children

belonging to households of the lowest socio-economic status (assessed by monthly expenditure) were 20-30% less likely to be taken to health facilities depending on the degree of perceived illness severity (Taffa and Chepngeno 2005). Data from Sierra Leone showed that the poor are much more disadvantaged by user charges for health care because they end up paying a greater proportion of their income for health care than do wealthier households (Fabricant *et al.* 1999).

In this study, therefore, as has been found elsewhere, household socio-economic status had a big influence on health seeking behaviour, and this was so even among those who had improved access to health care (Table 7.4).

9.2.2 Illness prevention

Baseline data from this study showed that ownership of any bed net was highest among the poorest and that 78.3% of children from the poorest households used untreated bed nets as compared to 29.8% belonging to the least poor households. In contrast, treated bed nets were used more by the least poor and 81.8% of the least poor households had screening on their doors and windows as compared to 19.6% of the poorest; these differences were statistically significant (Section 7.2). Nathan and others found a statistically significant association between net ownership and wealth score. The lower use of treated nets, they suggested, was probably due to lower purchasing power of the poor (Nathan *et al.* 2004).

Tugwell and others postulated that the poorest are more likely to adhere to the use of nets than the least poor because of the higher exposure to nuisance biting and the availability of other mosquito avoidance technologies to the least poor such as screened windows (Tugwell *et al.* 2006).

In this area bed nets have been used traditionally for years, for the avoidance of the nuisance of mosquitoes. Most of the poorest households live mainly in mud houses with no ceiling. The rooms are therefore accessible to mosquitoes. The least poor usually live in houses built of cement with ceilings and screening on windows and doors.

9.2.3 Health outcomes

Data from this study showed that in this setting household socio-economic status had an influence on the risk of the child having a fever episode. Children from the poorest households had significantly more fever episodes than children from least poor households (Table 7.4). One of the possible reasons for this finding is the kind of houses the poorest often live in, which may have importance both for malarial and non-malarial causes of fever. Their houses often have no screening and ceilings and the eaves are exposed. This would expose the poorest households to more mosquito bites than the least poor households who live in screened houses. The poorest also tended to use untreated nets as compared to the least poor who relied more on the screening of their doors and windows and used insecticide treated nets more. Water sources, and crowding, may also have an impact on faeco-oral and respiratory diseases.

The living conditions of the poorest, therefore, may explain why in this study, the number of fever episodes per person-year was much higher among the poorest. Children belonging to the least poor households in this study were also less likely to be parasitaemic than the poorest at the end of the peak malaria transmission season.

The effect of the intervention on anaemia was, however, greatest among the poorest; especially those of them who lived within 5km of a health facility (Table 7.10). In the latter group, there was no distance barrier and the barrier due to direct cost of care had been removed. It appears that both barriers needed to be removed to see an impact. Indirect costs were also likely to be much less in this group since less time would be spent travelling to and from the health facility which then translates into less time off normal duties for the carer who accompanies the child to the health facility.

9.2.4 Household coping strategies in the face of ill health

Households mentioned several ways in which they tried to cope with ill health, initially to avoid or reduce the direct and indirect cost of illness, and finally to deal with the costs when it could not be avoided. Some of the coping strategies they mentioned have been documented in previous studies.

Households reported that they initially tried to mobilize whatever savings they had to settle the costs of illness, although as has been found elsewhere, relatively few households had the ability to do this (Kabir *et al.* 2000; Russell 1996; Sauerborn *et al.* 1996b; Wilkes *et al.* 1997). Another frequently mentioned strategy by households in this area when they had no ready access to physical cash was the sale of household assets such as livestock. This strategy has been reported in other places. Sauerborn describes the perception of animals in some parts of Africa as 'ambulatory savings-banks' (Kabir *et al.* 2000; Sauerborn *et al.* 1996b; Wilkes *et al.* 1997).

Borrowing from family and friends was also a strategy that was used by households as has been found by other studies (McPake *et al.* 1993; Nahar and Costello 1998). Households were, however, as much as possible reluctant to borrow from commercial money lenders as they had to pay exorbitant interests and had no resources to do so and also because then they remained in debt for a long period of time even after the illness had subsided. However, sometimes, they had no option but to do so, especially when they did not have a strong and supportive social network -such as church or family.

Many in this study also mentioned selling labour for cash, sometimes with the assistance of other family members or friends as found by Sauerborn and others (Sauerborn *et al.* 1996b). In contrast to what has been found in other areas, community members did not know of any formal structures in the community to provide support for the poor in the case of such an eventuality (Lucas and Nuwagaba 1999; Ranson 2002; Schneider *et al.* 2001). Households in this study area did not mention deliberately reducing consumption of food as a coping strategy. However, when there was no money, they often went without some meals, were forced to eat less nutritious meals *("only one piece of fish dancing round all alone in the soup")* or smaller quantities of food.

Using some of the coping strategies resulted in delay in seeking health care. However, when households could not obtain any support to enable them pay for their health care, they just stayed home prayed and hoped for a good outcome to the illness.

There were no known formal structures in the community to assist them when they had to cope with illnesses considered "ordinary" such as malaria. Other authors have found in

some West African areas, that contrary to the perception of 'tightly knit' African community, support from village groups and non-kin households was rare (Sauerborn *et al.* 1996b).

The findings of this study largely support such a view. There were only two exceptional cases found in this study involving support from outside the household. One was the case of a particular clan which seemed to be well organized and met to contribute as support to any household in crisis. The members of this clan all belonged to an extended family system and as such were related to each other in one way or another. However, the amount contributed to assist the family in crisis had to be paid back once the household was out of the difficulty. Another exceptional case was the support of close friends and relatives in providing labour for cash to meet health care bills. Apart from these two cases, outside help would mostly come when the illness was catastrophic; otherwise resources for coping were from within the household itself (Section 4.1.3).

9.3 Reduced direct cost of care and utilization of health care services

There was a significant impact of the intervention on the utilization of primary care services as well as on overall use of non-formal sources of care.

Since the aim of the intervention was to remove the barrier due to the direct cost of health care in order to improve access, it was expected that if the direct cost of care is the critical barrier in health-seeking behaviour, the intervention group would have a marked increase in utilization of formal health care services as compared to the control group who had to pay out of pocket. The study demonstrated that households in the control arm, who did not have an improved access to formal health care, tended to use non-formal sources of health care, like the chemical seller and home treatment, more than the intervention arm who tended to use the services of the primary care clinic significantly more. Thus in this regard, the intervention was effective.

These results are similar to those found in South Africa and Uganda where removal of user fees led to increased health care utilization (Deininger and Mpuga 2004; Nabyonga

et al. 2005) In Rwanda and Zaire, health facility data showed higher utilization rates for the insured compared to the uninsured (Criel *et al.* 1999; Schneider and Hanson 2006). The negative effects of user fees is well documented (De Bethune X 1989; Fabricant *et al.* 1999; McPake *et al.* 1993; Russell and Gilson 1997). It is believed that since user fees restrict utilization of health services and create a large pool of unmet need, their removal is likely to result in substantial and sustained increases in utilization of services and this study has demonstrated this clearly.

Households in the control arm used the hospital slightly more than those in the intervention, although not significantly so. This may have been due to the fact that the control households often tried other treatments around the home, like left-over drugs and the chemical seller, and had to rush directly to the hospital when the illness subsequently became severe. Data from focus group discussions showed that carers often took a decision on where to seek care based on their perception of the severity of the illness.

Overall, although there was a significant difference between the control and intervention households with regards to utilization of formal health care services. The increase in utilization was not as marked as might have been expected and did not reach the level seen among the self-enrolled group. Some of the possible reasons discussed in section 9.5.5 below may have accounted for this.

9.4. Distance or travel costs and utilization of health care services

Utilization of primary care services among the intervention households decreased with increasing distance of residence from the nearest health facility (Tables 7.6 and 7.7). Overall, those who had no distance barrier and had their financial barrier reduced as well, utilized the health facility much more than those who lived further away. It was interesting to find that among the control households as well, those who lived closest to the health facility used the primary care services more and non formal services less than those who lived further away. However, the removal of the financial barrier led to an increase in utilization among the intervention over and above that seen among the control households.

A comparison of the poorest and least poor intervention households showed that the least poor as a group used primary care services more than the poorest probably because a much greater proportion of the former lived within 5km of a health facility as compared to the latter (Table 7.1). Some studies have found that following reduction of direct cost of health care, as occurs with enrolment in a pre-payment scheme, utilization of health care increases more among enrolled households located close to the health care facility. Bennett and others suggest that since, under most such schemes, people pay the same premium wherever they live, those distant from the health facility (who might be poorer) in effect cross-subsidize those who live close to the facility and may with time drop out of the scheme when they look at the high cost of premiums and the additional cost of reaching the health facility (Bennett *et al.* 1998). Some studies reported that even though there was an overall increase in utilization for insured members of the schemes they evaluated, members living further away had lower hospitalization rates for non-critical illnesses (Bennett *et al.* 1998; Criel *et al.* 1999).

This is similar to the findings of this study and was perhaps demonstrated by baseline results which showed that none of the household belonging to the self-enrolled group lived more than 10 kilometres away from a health facility. Such a situation may lead to a reduction of the overall effect in terms of health outcomes if it is the study subjects who live closest to the health facilities who account for most of the utilization whilst the rest contribute little.

In Sierra Leone, one third of the decrease of about 30% in utilization of Primary Health Care (PHC) units observed during the rainy season, when malaria transmission is known to be highest, was due to poor physical access (Fabricant *et al.* 1999). Sinha and others found when they evaluated a community-based health insurance scheme, that the barriers to hospitalization mentioned by subscribers included distance from the health facility (Sinha *et al.* 2006). It has been found that transport costs, which are often related to the distance of the residence of the household from the health facility, or geographic access can be substantial and may exceed 20% of the direct costs of health care (Attanayake *et al.* 2000; Nahar and Costello 1998).

9.5 Reduced direct cost of care and health outcomes

In their review of 82 health insurance schemes worldwide for people outside the formal sector, Bennett and others found that none of them had been evaluated with regards to their impact on health status. They suggest that this is to be expected because it is commonly very difficult to judge the health impact of such interventions (Bennett *et al.* 1998).

9.5.1 Impact on anaemia

The intervention did not have any impact at the end of the peak malaria transmission season on the prevalence of anaemia (Hb<8 g/dl) or severe anaemia (Hb<6g/dl). The prevalence of anaemia in the intervention and control arms was similar- 3.2% and 3.1% respectively. The possible reasons for this lack of effect are discussed in detail in section 9.5.5.

Surprisingly, at the end of the peak malaria transmission season, there was an increase in the mean haemoglobin concentration in both trial arms (Tables 6.4 and 6.11). Most studies in West Africa have found an increase in the prevalence of anaemia and a reduction in mean haemoglobin concentration at the end of the peak malaria transmission season. With an effective intervention, an increase in mean Hb concentration or a reduced prevalence of anaemia has been shown as compared to non intervention levels (Greenwood *et al.* 1989; Korenromp *et al.* 2004; Massaga *et al.* 2003; Schellenberg *et al.* 2001). It is obvious, however, that the increase which occurred in all the three study arms including those who did not have a reduction in their direct cost of health care, may not have been due to the intervention of interest in this trial.

Another intervention which took place in the study area prior to the trial was a change of anti-malarial from chloroquine with a 39% efficacy to a very effective artemisinin-combination drug with a reported efficacy of 100% from other areas in Ghana and a similar proven efficacy in study children (Koram *et al.* 2005). This change affected all study arms.

Study subjects in each trial arm made an average of 2.5 visits each, over the 6-month period, to one of the primary care clinics where they were likely to be prescribed the new and more effective anti-malarial if they reported with fever. Thus, each child is likely to have received at least one therapeutic dose of an artesiminin-combination drug over a six-month period and this could have resulted in the overall increase in mean haemoglobin seen in all three study arms, even though not all treated children would have had malaria (Dunyo *et al.* 2000). Recent intervention studies which involved the administration of a full dose of anti-malarial at intervals to infants or children have found that it has resulted in a marked increase in haemoglobin concentration (Dicko *et al.* 2004; Massaga *et al.* 2003; Schellenberg *et al.* 2001).

Treatment with an artemisinin, which kills gametocytes as well as asexual parasites, may interrupt transmission and produce a good overall haematological outcome. On the Thai-Burmese border, replacement of the first-line treatment of mefloquine with mefloquine-artesunate was reported to have resulted in a substantial reduction in the incidence of *P. falciparum* infection. The same results were obtained when ineffective sulphadoxine-pyrimethamine was replaced with an artemisinin-combination therapy in South Africa, although the latter involved the introduction of other malaria control measures concurrently (Barnes *et al.* 2003; Greenwood 2004; Nosten *et al.* 2000).

No mass de-worming programme was undertaken in the district during the period of the trial. The relative contribution of malaria to anaemia in the study area is, however, not known. There was a slight increase of 5.2%, 4.2% and 7.2% in ITN use among the control, intervention and self-enrolled arms respectively over the period but these increases were not significantly different. There was not much difference in the rainfall pattern between the year of the trial and the previous year's based on data from the Meteorological Services of Ghana. The average rainfall for the period May to November 2004 was just about 11 mm less than that of the previous year. The number of cases of malaria reported by health facilities in the district, increased in 2004 in accordance with increasing population, as had been the pattern over the previous four years (DHMT/Dangme-West 2004).

The on-going intensive malaria control activities supported by the Global Fund during the period may also have contributed to the overall increase in haemoglobin concentration since this involved community IE & C as well as staff training programmes on the prevention and management of malaria, as described earlier. These district wide community based activities may have stimulated greater parental awareness and practice.

Anaemia as a marker of malaria in the study area

There is no ideal method of assessing the effects of an intervention on malaria at a community level, but of the possible methods available (parasiataemia, spleen size, treatment incidence density etc) anaemia has become the most widely used proxy. It is objective, and whilst anaemia is subject to a number of different factors, including diet and worm infestation, it has a number of clear advantages. Several studies in Africa have shown that in areas of high and stable transmission, malaria is the major contributor to anaemia (Kahigwa *et al.* 2002; Koram *et al.* 2000; Menendez *et al.* 1997; Murphy and Breman 2001; Newton *et al.* 1997; Slutsker *et al.* 1994a; Snow *et al.* 1994; Stoltzfus *et al.* 2000) and parasitaemia is reported to be the primary cause of anaemia in Africa, especially among very young children (Kahigwa *et al.* 2002; Kitua *et al.* 1997; Koram *et al.* 2000; Menendez *et al.* 1997; Stoltzfus *et al.* 2000). The study area is an area of high and stable transmission, however, though the reduction in the prevalence of parasitaemia was consistent with the magnitude of increase in haemoglobin concentration in each trial arm, the association between the prevalence of parasitaemia and anaemia was not statistically significant. Blood samples from 57 (80.3%) of the 71 study children examined also showed signs of microcytic and not normocytic anaemia as one would generally expect with anaemia caused by malaria.

It is possible that the picture that would have been seen has been in terms of the contribution of malaria to anaemia in this study area may have been affected by the introduction of a very effective artimisinin combination therapy for malaria in the area prior to the onset of this trial. This may have resulted in an apparent increase in the contribution of other causes of anaemia in this area which would dilute an effect, but should not eliminate it. Against this possibility is the fact that even in the children found

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to be anaemic the prevalence of alternative causes of anaemia (eg hookworm) was low, although there was indirect evidence of iron deficiency anaemia in the finding of microcytic anaemia.

9.5.2 Impact on parasitaemia

Consistent with the observation of an increase in mean haemoglobin concentration in each study arm, was an overall reduction in the prevalence of parasitaemia observed among children belonging to each trial arm. Again there was no evidence of any impact of the intervention on parasitaemia.

Existing data suggests that the prevalence of parasitaemia is associated with the levels of anaemia (Abdalla et al. 1980; Weatherall and Abdalla 1982). Although an earlier study among children 0-5 years old in the Kassena-Nankana district in the northern part of Ghana reported a significant negative correlation between the geometric mean parasite density and Hb concentrations (Binka et al. 1996), subsequent studies in the same area looking at children 6-24 months obtained no evidence of positive or negative correlation between the two malariometric indicators (Koram et al. 2000; Owusu-Agyei et al. 2002). The two studies, however, identified statistically significant associations between severe anaemia and parasite rates. Though the reduction in the prevalence of parasitaemia was consistent with the magnitude of increase in haemoglobin concentration in each trial arm, the data did not show evidence of a statistically significant association between the prevalence of parasitaemia and anaemia in this study.

In the current study, P. falciparum accounted for 93% of patent infections in the dry season and 84% at the end of the wet season. In the same area, 12 years ago, Afari and others found prevalences of 78-85% and 93-99% respectively in different parts of the district, however, with no intervention in the intervening months between the end of the dry and wet seasons as happened in the current study.

Parasite rates at the end of the rainy season were 8%, 16% and 19% in the self-enrolled, control and intervention arms respectively. In the same location, without any intervention, a previous study reported parasite rates during the rainy season 26.6 and

51.3% (Afari *et al.* 1995). Agyepong reported crude parasite rates among adolescent girls 10-19 years of 47% and 49% at the end of the dry and wet seasons respectively, in the Dangme West District, 14 years ago (Agyepong 1992).

9.5.3 Impact on anthropometric measurements

There was no evidence of an impact of the intervention on anthropometric measurements in children in this trial. Changes observed in the basic anthropometric indicators such as the weight, height and MUAC over the period of the study were consistent with that of overall primary outcome. Although there was a general improvement in these indicators over the period, and the increases were slightly higher amongst children from households belonging to the intervention as compared to those from households in the control group (Table 6.18), none of the differences between groups were statistically significant.

There were general increases in the mean weights, heights and MUAC of the children in both study arms. However, this was not seen when the composite indicators such as the z-scores of the weight-for-height (WHZ), weight-for-age (WAZ) and height-for-age (HAZ) were computed. The increase in weight over the period was much lower than the corresponding increases in the heights of the children, especially against the background of natural increases in age. This resulted in lower mean z-scores for all the indicators at the end of the peak transmission season as compared to the baseline. The prevalence of wasting increased slightly among all the groups with that of underweight remaining generally the same whilst the prevalence of stunting reduced slightly.

There is conflicting evidence on the relationship between nutrition and severe malaria. Whist some older studies indicate that well-nourished children are more likely to develop severe disease than those who are malnourished (Edington 1967; McGregor 1982; Murray *et al.* 1975), others have not found any evidence that a child's anthropometric status at the beginning of the malaria transmission season affected his or her subsequent malaria experience (Snow *et al.* 1991). Koram and others did not find any seasonal variation in nutritional status among the children aged 6-24 months as measured by anthropometric indices at the end of the low and high malaria transmission seasons in

Northern Ghana even though the prevalence of severe anaemia increased (Koram *et al.* 2000).

9.5.4 Impact on mortality

Although this study was not powered to assess the impact of the intervention on mortality, data on mortality were collected on the study subjects in the three study arms, intervention, control and the self-enrolled arms. Since there were no deaths at all among subjects in the self-enrolled arm, the intervention and control arms are compared. The results did not demonstrate any significant difference between the two arms in terms of all-cause child mortality or household mortality.

Few studies are powered to assess the impact of malaria control efforts on mortality as this often requires huge sample sizes or long follow-up periods with attendant increase in required resources. Some studies using chloroquine chemoprophylaxis did not observe any impact on mortality among children (Bradley-Moore *et al.* 1985a; McGregor *et al.* 1956). Geerligs and others, in their review, believe that this may have been due to small numbers and loss-to follow-up (Geerligs *et al.* 2003). A more recent study in Tanzania using pyrimethamine-dapsone as chemoprophylaxis reported no difference in mortality between infants who received chemoprophylaxis or placebo (Menendez *et al.* 1997) but this was also a small trial. One trial of chemoprophylaxis in the Gambia in the early 1980s reported a significant reduction in mortality of 35% among children given Maloprim® (*GlaxoSmithkline, Brentford, UK*) throughout the rainy season. This study had a long follow-up period of five years (Greenwood *et al.* 1988).

Several studies on bed nets have reported a reduction in all cause mortality among children who used treated nets (Lengeler 2006). In Northern Ghana, the use of permethrin impregnated bed nets was associated with 17% reduction in all-cause mortality in children aged 6 months to 4 years (RR = 0.83; 95% CI 0.69-1.00; P = 0.05) (Binka *et al.* 1996) whilst in the Gambia, a reduction of 23% of all cause mortality was reported (D'Alessandro *et al.* 1995a).

To my knowledge no studies have looked at the impact of improved financial access to health care on child mortality.

9.5.5 Possible reasons for a lack of an effect of the intervention on health outcomes

The most striking finding, and in many ways a counterintuitive one, is that the intervention provided free healthcare leading to almost no direct financial barrier to healthcare, but had no impact on health outcomes, despite a significant effect on healthcare utilisation.

There may have been several possible reasons for the finding; these are discussed below.

- **The indirect cost of care may be more important**

The financial costs of health care may not be the major financial barrier to care in this area, so removing it may have had relatively limited impact. Other direct costs, including travel costs and indirect costs such as time costs and opportunity costs, both of which are greater the further households live away from the health centres, may well be more important.

McIntyre and others reported in their framework on the economic consequences of illness, that the direct cost of care is only one part of the financial barrier (McIntyre *et al.* 2006). The other part is the indirect cost of seeking health care for the ill person and this barrier is known to be less modifiable; it may in some cases be much higher than the direct cost (Koopmanschap and Rutten 1994). Although no previous study has documented the relative contribution of direct and indirect cost to the total cost of health care in this study area, it is possible that the indirect cost of care is much higher than the direct cost. Some studies in other parts of Ghana and elsewhere estimated that indirect costs were 2 to 3.6 times higher than the direct costs (Asenso-Okyere and Dzator 1997; Attanayake *et al.* 2000; Ettling and Shepard 1991; Sauerborn *et al.* 1996a). Asenso-Okyere and Dzator reported that a substantial amount of time was spent in seeking malaria care and taking care of the sick, which made the indirect cost per case of fever

represent 79% of the total cost of seeking treatment in the two areas where their study was carried out (Asenso-Okyere and Dzator 1997).

Nutritious food for the sick family member, accommodation whilst seeking health care far from home, and food for the accompanying household member has also been estimated to account for approximately 20% of direct health care costs (Attanayake *et al.* 2000; Babu *et al.* 2002; Nahar and Costello 1998).

It is also known that in an effort to lower the direct and indirect cost of treating an episode of illness, people first wait to see whether it is serious then try medications at home; these may be biomedical medications, herbal medications or both. The biomedical medications may be drugs left over from a previous health facility visit or purchased from a nearby chemical shop. They finally seek care from other sources which may include formal biomedical sources if these options do not work and the illness progresses (Agyepong and Manderson 1994; D'Souza 1999; Foster 1991; Mugisha *et al.* 2002).

If the indirect cost is much higher than the direct cost, and other financial costs form a much higher proportion of the direct costs, this will effectively reduce the expected improved access to health care from the reduction of the barrier due to direct cost, and subsequently, the expected difference in health outcome.

- **Non-cost barriers may be important**

Non-cost barriers to healthcare such as distance, lack of knowledge, or incorrect perception of healthcare services and when to utilise them may be important in determining health-seeking behaviour; this will not be affected by reducing the direct cost of care (Ahorlu *et al.* 2006).

Social norms and practices have also been found to have an influence on treatment seeking behaviour. In Western Kenya, although mothers could recognize mild malaria, they did not link the symptoms of severe malaria to the disease (Mwenesi *et al.* 1995). In many communities, convulsions are thought to be "not a hospital disease" and therefore ought to be treated at home. Some also argue that access to health care is responsible for

only a relatively small part of health, with more important determinants being genetics, environment and health behaviour (IFTF 2000). In this study, although financial access to health care was improved, social norms and practices of households involved in the study were not directly influenced.

Previous interaction with the health system is also known to encourage its use for an illness episode (Csete 1993). In the Danfa project, it was found that previous interaction with the health system was more likely to result in use of the system for an illness episode (Belcher *et al.* 1975).

The majority of study households may not have been familiar with the use of the health system and that may have contributed to their decision not to enrol in the scheme. For such people, the utilization of the health system may take some getting used to and this may take some time. As such their health seeking behaviour, although it may change significantly, may not reach the level of those who use the system regularly. It is also known that anticipation of relatively high utilization of medical services might lead an individual or household to enrol in an insurance or pre-payment scheme and this would tend to impart an upward bias in their utilization as compared to those who do not enrol and are enrolled as part of a trial (Meer and Rosen 2004). The utilization rate among households who belonged to the intervention arm in this study, was about half that of the self-enrolled households.

This particular intervention, unlike interventions in other randomized controlled trials, was not directly administered, but was left to the discretion of the study subjects; it is very different from directly observed efficacy trials. This probably made room for the socio-cultural milieu in which the trial was taking place to play a role, producing real life results. In this trial, there was no direct elimination of the parasite or vector. The study provided access to good quality drugs but could not guarantee the taking of those drugs during clinical illness.

It is similar in some respects to studies on bed-nets which do not carry out daily checks on the use of the nets but provide them to the study subjects and expect that they will be used. In a Ghanaian study by Browne and others, only 70% of pregnant women who had

access to treated bed-nets actually used them (Browne *et al.* 2001). The latter situation is what pertains in real life and provides information on the actual outcomes to be expected. Tugwell et al, argue that community effectiveness is often substantially lower than efficacy because of what they described as 'staircase effect'. This staircase effect they suggest, is a result of lower awareness, compliance of providers and adherence of consumers among others (Tugwell *et al.* 2006).

The haematological improvement observed was in proportion, therefore, to the extent to which households accessed good quality services. And although a significant difference was observed between the two study arms with respect to utilization of services, this did not translate into a significant difference in any of the health outcomes. A similar situation was observed when the self-enrolled group was compared to the trial arms. Again, although the difference in utilization was statistically significant, even the much higher utilization rate of the self-enrolled group did not also translate into a significant difference in health outcome between the two groups.

- **Quality of health care in the study area may have been generally poor**

It may be argued that the quality of health care in the study area may have been no better in the formal than the informal sector, either because the formal sector is less good than hoped, or because the informal sector in this area is better than expected. If this is so, increasing access may lead to increased utilisation in the formal sector without any impact on health.

However, the data on quality of care in the formal sector is reassuring that it is unlikely that the health care is poor in the formal sector, but does not exclude better-than-expected care in the non-formal sector. It, however, is very unlikely from prior knowledge of the study area, that health care in the non-formal sector will be better than that of the informal sector in this district.

- **Introduction of a new and more effective anti-malarial**

The introduction of a new and more effective anti-malarial in the study area just prior to the trial and available to all study subjects may have reduced transmission. This may have resulted in a good health outcome for all study subjects, thus reducing the magnitude of the effect expected. It is possible that the improvement was so marked it swamped a smaller effect of lowering the direct cost of care.

This is a credible possibility. It is possible that the introduction of a new, attractively packaged and more effective anti-malarial into the primary care clinics in the study area just prior to the onset of the trial, may have resulted in the control households utilizing the primary care facilities more than they normally would have done, leading to a reduction in the magnitude of the differential effect between groups in terms of health outcomes. Data from FGDs in the community showed that there was recognition of the fact that a new and more effective anti-malarial which was nicely packaged and dispensed for the treatment of malaria in the clinics, had been introduced. Community members agreed that it was more effective by far than chloroquine.

In a recent RCT in Senegal involving IPT as an intervention among children 2 to 59 months, both arms were given adequate treatment for malaria whenever they presented at any of the health centres in the study area. Cisse and others reported that even though there was a significantly lower prevalence of parasitaemia among the children who had received active drugs as compared to the placebo group and the prevalence of anaemia was higher in the latter group, the difference in prevalence of anaemia was not significant (Cisse *et al*. 2006) .

Overall, the introduction of an ACT in the area may have been beneficial to all study arms in terms of health outcomes.

9.6 A comparison of trial outcomes among self-enrolled and trial enrolled participants

A marked difference was observed between the households who chose to enrol themselves in the pre-payment scheme when the registration window was open and those who were enrolled later as part of the randomized controlled trial.

Significant differences were observed at baseline with regards to their socio-economic status and malaria prevention practices. Although, at the end of the peak malaria transmission season, this group was still significantly different in terms of their utilization of health care services, this did not also translate into a significant difference in health outcome between them and the households who were enrolled as part of the trial. They were also not significantly different from the control arm with regards to health outcomes.

The difference in the prevalence of anaemia between the self-enrolled and trial-enrolled arms, was not statistically significant. Only one of the children in the self-enrolled arm had anaemia and none had severe anaemia. An increase in the mean haemoglobin was observed among children belonging to this group as in the intervention and the control arms. The mean change in Hb concentration was highest among them, followed by the intervention and the control group in that order and this was consistent with the level of utilization in the three arms. The reduction in the prevalence of parasitaemia was also highest among children who belonged to the self-enrolled group. There were also slightly greater increases in the mean weights, heights and MUAC of the children in this arm and a reduction in the composite indicators such as the z-scores of the weight-for-height (WHZ), weight-for-age (WAZ) and height-for-age (HAZ). There was no death among children belonging to this arm as compared to the intervention and control arms which had 5 and 4 deaths among children respectively.

It was, however, interesting to note that, as was observed with the trial arms, although observed differences in health outcomes did not achieve statistical significance, they were consistent with differences in utilization.

Importance of inclusion of the self-enrolled group in this study

The self enrolled group which happens to be a self selected group provides a very useful and interesting insight into the dangers of carrying out observational studies using groups such as this for comparison. Had this trial only been an observational study of those who were enrolled (by their choice) compared to those who are not it would have given a wholly misleading impression of the impact of enrolling people into an insurance scheme both on healthcare utilisation and on health outcomes. Their inclusion in this trial demonstrates the utility of randomized approaches when examining interventions of this type. It has provided the chance to measure the bias which results when an observational study design is used especially where enrolment rates are low as pertains in most of Africa where enrolment is voluntary.

This group is clearly very different from the rest of the population who did not choose to enrol. They are significantly better off, better educated and have a better geographical access to health and other services. They generally live closer to the health facility. Comparison of such a group to others who have to overcome distance, socio-cultural and other factors in order to access services will suffer terribly from severe bias and will not provide reliable answers to the study questions. It is possible that those who self-enrolled were also those who predicted they needed health services more, and that the increased utilisation in this group reflects this as much as an intrinsic difference in healthcare seeking behaviour.

Levy and Meltzer point out in their discussion paper that the production of health is a complex process and factors such as income and beliefs about Western medicine will affect whether or not an individual has insurance coverage (Levy and Meltzer 2001).

9.7 Effectiveness of reducing inequalities by means of the existing pre-payment scheme

One of the aims of financial protection schemes, apart from improving overall access to health care, is to reduce inequalities and improve equity.

Equity is an ethical concept that relates to some theory of social justice or fairness. It is different from equality. Equity in health has been defined in the literature as "the absence of potentially remediable, systematic differences in one or more aspects of health across populations or population groups defined socially, economically, demographically, or geographically" (ISEqH 2006). The World Health organization defines this operationally as "minimizing avoidable disparities in health and its determinants –included but not limited to health care-between groups of people who have different levels of underlying social attributes (WHO 2000d). (In)equity is different from (in)equality in that the former requires standardization for need (Dror *et al.* 2006).

Many pre-payment schemes do not appear to actually cover those who really do need them: the poorest. The results of this study showed that those who choose to enrol in pre-payment schemes such as operates in the Dangme West District are significantly different from those who do not. The heads and mothers of households who self-enrol are more educated and socio-economically better off than those who do not. Maternal education is widely held to be a key determinant of child health and survival (Bender and McCann 2000; Rajna *et al.* 1998).

In this study, the difference was also seen in the lower unemployment rates among the self-enrolled (8.5%) as compared to the non-enrolled (9.7%). Most of the self-enrolled lived not very far away from the health facilities compared to the non-enrolled. None of those who enrolled themselves lived more than 10km away from the health facility, which also meant that they also tended to use the health facility more. This is not surprising since distance is one of the well documented barriers to seeking healthcare. All these factors resulted in a better health status at baseline, which was to be expected. The children from the self-enrolled households had mean haemoglobin at baseline which was significantly higher than that of the other group by 0.4g/dl.

A little over 44% of households who had enrolled themselves had more than one child aged less than 5 years of age as compared to approximately 37% of households enrolled as part of the trial. It appeared the self-enrolled households had some incentive to enrol since children less than five years of age often carry the greatest burden of illness. Over 60% of households, who enrolled in the scheme themselves, belonged to the two least

poor quintiles and just 7% belonged to the poorest quintile in contrast to those who did not enrol. Data from a Philippines study by Dror and others demonstrated that the success of the micro-insurance units (MIUs) in including the poorest households was uneven (Dror *et al.* 2006).

However, among those who self-enrolled, the poorest appeared to benefit most in terms of improved access to primary care services. They utilized primary care services most whether they lived closer or far away from the health facility. Schneider and Hanson reported that the horizontal inequity in the utilization of care for user-fee paying individuals did not exist among members of micro-insurance schemes in Rwanda. They measured horizontal inequity (HI) in utilization by using concentration indices for actual use and need-adjusted use. They also measured household socio-economic status by assessing household income, and need for health care as self-assessed severity. The results of the Rwandan study suggest that the insured use care according to need and independent of their socio-economic background (Schneider and Hanson 2006).

Dror and others also looked at micro-health insurance units (MIUs) in the Philippines. They also used concentration curves and indices to examine income-related (in) equality and measured health service use from household survey data relying on a 2-year recall period. Their data showed an equal distribution of increased access to health care among the insured, and a clear advantage for richer households in access to healthcare among the uninsured households (Dror *et al.* 2006).

The methods used in these two studies were different from the ones that were applied in the current study. In this study, measurement of household socio-economic status was carried out by means of a household asset-ownership index and actual utilization was assessed by documented household pictorial diaries supplied and collected by fieldworkers on a monthly basis during a six-month period of follow-up. The data were used to assess the person-years of follow-up.

Data from this study suggest that in the study area, there is horizontal inequality in the utilisation of healthcare both among those who themselves enrolled in the pre-payment scheme and those who were enrolled as part of the trial. Whilst among those who

enrolled of their own volition, there was a steady decrease in actual utilization of primary care services from the poorest towards the least poor; the reverse was the case among those who were enrolled as part of the trial, among whom the least poor had the highest utilization. For the trial-enrolled group, however, marked differences in the distribution of households by distance of residence from a health facility may have influenced the observed utilization among the wealth quintiles. Since, however, actual need for health services was not measured; it is difficult to draw any conclusions with regards to equity, although inequalities in primary health care service utilization were demonstrated among the wealth quintiles.

The pre-payment scheme in this area, therefore, did not seem to be reaching the poorest, less educated and those of lower socio-economic status in the community in its current mode of operation which relies on voluntary enrolment by households. However, although among those who self-enrolled, the poorest benefited most in terms of improved access to health care. The scheme is actually being used by those who are better off. New strategies are required to ensure that the scheme reaches the group that most need financial protection.

9.8 Lessons on translating research findings into policy in the context of a district health setting

Translating research findings into policy and practice is not always easy. As part of this study, it was possible to do this in the study area where the first-line anti-malarial was changed from chloroquine to an amodiaquine-atesunate combination ahead of the national change. A few lessons were learnt during this process which took place in a district setting and these are discussed in this section.

With regards to health matters at the district level, the District Health Management Team (DHMT) is a very useful ally to court. Its members can provide much needed support to health related programmes aimed at improving the health of the people they serve if they are brought on board at the very onset of the project. With their invaluable knowledge of the district they can provide immense help particularly in relation to locally and

culturally acceptable norms of doing things. These grey areas are not readily obvious to the outsider.

Key members representing the DHMT must be made aware of the various stages of the project and be involved in some level of decision-making. This prepares the stage for a feeling of ownership by the DHMT of whatever results are obtained from the study and willingness to implement or advocate for implementation of the findings. In addition, this makes for integration and sustainability of whatever good interventions are put in place. The DHMT can then make sure health staff who are sometimes very critical to the running of particular projects do not see the work involved as extraneous and a bother. They move from the level of "their project" to "our work".

Secondly, projects must aim at "putting something back" into the areas where data are collected so that the whole exercise is seen as beneficial. "Putting something back" may be in the form of capacity building in areas where there is an identified need such as laboratory skills. It can also be in the form of much needed equipment used on the project being left behind at the end for the improvement of health service delivery in the area.

The current study was explained to the DHMT as a team and some key members were involved in the assessment of the therapeutic efficacy of chloroquine. Prior to the onset of the study, they discussed the issue at length and as such were very interested in the results. They were initially divided on what the efficacy of chloroquine in the area might be based on their individual observations and suspicions. Due to their sense of ownership of the study and its results, they re-assigned certain staff to assist with various aspects of the study. The drug study was integrated into the day to day running of the health centres as the clinician on the project saw other patients apart from the study children and provided clinical support to other clinicians in the health facility. The laboratory was upgraded, improving the quality of care being offered in the health facilities and this made the staff very happy.

Finally, the results of the study were disseminated to all staff on sub district basis with the assistance of the DHMT. Meetings were then held to plan the way forward in the

light of the finding that chloroquine was no longer efficacious in the area. This brought on board all private providers in the district with whom the DHMT already had a close working relationship. The District Medical Store then became involved in the purchase and unit dose packaging of the new anti-malarial drugs to ensure adherence by patients to dosage schedule. This was done through the regular drug revolving fund system already existing in the district through which health facilities purchased and paid for drugs.

The reverse of this situation can be very frustrating, almost unmanageable and can derail the very success of any project.

9.9 Strengths and weaknesses of the study

Design and methods

This study utilized a randomized, controlled trial to assess the effect of improving financial access to health care through a pre-payment scheme on health service utilization as well as health outcomes among children less than five years of age. To my knowledge this is the first study using such a methodology.

In cases in which randomized trials of similar interventions have been carried out, they have looked at utilization of services as the main outcome. This study in addition, looked at health outcomes, using as an indicator, the most commonly reported illness at outpatient departments and the disease imposing the greatest burden on children less than five years of age in sub-Saharan Africa.

Randomized controlled trials are designed to eliminate bias, making comparison of two groups much easier in terms of the issue being assessed. Randomization, when applied to a sufficiently large number of individuals, will ensure that the groups are similar at baseline. Thus, any difference observed between groups is very unlikely to be due to measurement error or confounding, increasing the credibility of the inference that any difference observed is due to the intervention (Kirkwood *et al.* 1997).

Such a design avoids the biases associated with differences in socio-economic status between those who choose to enrol voluntarily in pre-payment schemes and those who do not. The significant differences between the self-enrolled and randomized groups show the dangers pf observational studies in this area. Observational studies will suffer terribly from selection bias (Levy and Meltzer 2001). It also ensures that the intervention and control arms are very similar at baseline so that the effect of the intervention is clear. Although it cannot completely unravel all the complex associations that contribute to the outcomes, it can at least answer the core question and help to define the importance of the contribution of the intervention to the outcomes.

The use of a variety of different methods for collecting data, including, household cross-sectional surveys, focus group discussions, individual in-depth interviews, observation, client exit interviews, anthropometric measurements as well as laboratory assessments as done in this current trial, is likely to produce findings that are more comprehensive than using one method.

The relatively large number of interviews conducted as part of the qualitative studies made it possible to confirm the various findings. Whilst not random, the consistency of views across a fairly large number of people increased confidence in the results. Interviewing a variety of groups and individuals also ensured triangulation of the data collected. The qualitative data were very useful in fine-tuning the household survey questionnaire, enabling the insertion of relevant questions and options for responses. Although data from FGDs cannot be analyzed using statistical methods, it plays its role in providing a clearer picture and direction. A well known limitation of this method, in spite of the rich and meaningful data it provides, is the danger of discussants blowing out of proportion what may be an everyday reality (Schneider and Palmer 2002).

The cross-sectional survey provided a snapshot of households across the district especially since households were scattered in 150 communities out of the total of over 380 communities in the district. In view of the large sample size of the randomly selected households with low rates of loss to follow-up, the results are likely to be representative of households in the district. Responses were found to correspond to a large extent with the results obtained from focus group discussions. However, in hindsight, it is clear that

the income and expenditure data collected may not be very reliable and a reliance on assets as a proxy for household wealth was a good idea.

Schneider and Palmer reported from their South African study that responses from exit interviews held in the clinic (separate room) showed very low response variability and very little dissatisfaction in contrast to responses from FGDs on the same subject held in the residential areas, which brought up some issues of quality as concerns. They therefore suggest caution in the use of these methods on their own. They agree, however, that these may be used for triangulation of data (Schneider and Palmer 2002). To minimize bias and low response variability in this study, the exit interviews were not held on the clinic site but away from the clinic when the client had exited and was on his/her way home. The results of the exit interviews were also triangulated with results from FGDs.

There is no reason to expect that the occurrence of measurement errors could be different between the arms, since in the field, the main method of identification of households and study children was by means of the household IDs and child IDs respectively, and this was not in any way related to the study arm they belonged to.

Measurement of socio-economic status

Filmer and Pritchett showed that principal components analysis provided an index that was as good as more conventional approaches based on income and expenditure (Filmer and Pritchett 1998; Filmer and Pritchett 2001). A well known problem with collecting detailed income or expenditure information is the fact people may be unwilling to disclose financial data and what they do disclose may be biased (Worrall et al. 2002). The advantage of using a wealth index is that there is likely to be much less recall bias or mis-measurement; a particularly important attribute for data collection in a typically rural area with a literacy rate of about 50% where most of the people are in informal employment. It is also not affected by seasonality and ability to compute. The time taken to collect the data was therefore much shorter and data could be easily collected together with other issues of interest (McKenzie 2003). Assets, however, may not be useful as a proxy for actual specific expenditure such as healthcare expenditure.

Onwujekwe and others in their Nigerian study found that many of the asset variables commonly used to generate indices of socio-economic status demonstrated low to moderate levels of inter-rater reliability (different interviewer using same questionnaire after a maximum of five days) and test-retest reliability (same interviewer using same questionnaire after a month). They therefore caution unquestioned reliance on asset-based indices and advise that studies using these should incorporate a test of their reliability in order to increase confidence in the results (Onwujekwe *et al.* 2006). There is really no gold-standard to compare with and this does limit the certainty with which conclusions can be drawn.

Mackenzie refers to two potential problems if the asset indicators used are not broad enough to distinguish clearly between households. Indices that are not very good, show clumping or truncation when the kernel density function is plotted. Truncation may occur either at the top with a lot of households having all or most of the assets or at the bottom where it becomes less useful for determining inequality amongst the poorest. The index may also show evidence of clumping, suggesting that the indicators making up the index, are not able to fully distinguish between households (McKenzie 2003).

Our indices constructed from a limited number of indicators showed similar characteristics when the kernel density function of the asset indices were each plotted using the Epanechnikov kernel with Stata's default band-width. The overall index which was reasonably smooth, with little evidence of clumping and truncation appeared to make for a better, more robust, and internally coherent index. This means that the index consistently produces sharp distinctions across socio-economic groups on almost all assets.

Possible overall limitations

The study had a number of limitations which were taken into consideration and minimized as much as possible. They need however to be considered carefully in the light of the finding that reducing the direct cost of care did not lead to improved health outcome. Some of these could be minimized by design, and some measured and adjusted for in analysis, but some are unavoidable.

- There is a lower limit of quality of care beyond which giving free care will not make any impact. Care was taken at all times to ensure that the quality of care in the health facilities was maintained in areas such as drug and staff availability. An objective assessment, as well as client perception of the quality of care in the health facilities, was carried out.

- There was a possibility that children in the study arm who had been enrolled might be discriminated against because they were not paying for health care up front. This was minimized by ensuring timely re-imbursements to health facilities by the scheme administrator as well as regular and timely payment of staff bonuses instituted by the scheme for taking care of its members.

- A potential limitation of this study could be what is known as the "Hawthorne Effect" where the households in the study may improve health-related behaviour with regards to the study child because their morbidity was being monitored (Gale 2004). However, the possibility of this happening is minimal for a number of reasons. There was such a variety of data being collected from the households at different times that they were not sure what the outcomes of the study were. The main outcome was haemoglobin concentration which they had no real control over, as was the case for several of the other outcomes such as parasitaemia and nutritional status. Utilization of heath services is the outcome that could have been influenced. However, the design of the pictorial diary did not give an indication of researcher bias towards any particular source of care. Respondents were asked to indicate all sources of health care including the home and were unaware of the interest in formal sources.

- The general increase in Hb after the peak transmission season, and the reduction measurement was automated using a robust system (Haemocue) and parasite counts done in a well-known research laboratory. It may be due to the introduction of ACTs leading to reduced transmission as discussed earlier. It is possible that the improvement was so marked it swamped a smaller effect of lowering the direct cost of care.

- Malaria may be a relatively small contributing factor to anemia in this setting. This intervention is, however, not malaria-specific, so this is less likely to be a problem for this study than it would be for, say, bednets. It would also need to apply also to other causes of anaemia which might be treated by visits to health centers (eg helminth infections) since the intervention was not malaria-specific but rather health-care system specific.

- The sample size is too small to detect a difference. Because the prevalence of anaemia was not as high as predicted this is always a theoretical possibility. Certainly the study was not powered to detect a very small difference in Hb concentration (less than 0.3g/dl Hb) between arms. The fact that the odds-ratios are so close to 1, however, with no good evidence of a trend in favour of the intervention, makes it fairly unlikely this is an effective intervention which simply failed to reach statistical significance.

9.10 Implications for research

The results of this study bring to the fore, gaps in knowledge that need to be addressed to provide a complete picture. It was expected that removal of the direct cost of care would lead to an improvement in utilization due to the fact that financial access had improved. This did happen. It was also expected that an improvement in utilization would translate into a measurable improvement in health outcome, especially during the peak malaria transmission season when malaria is thought to be the greatest contributor to anaemia in an endemic area such as this study site. The fact that this latter outcome was not clearly demonstrated raises some additional questions which have implications for research as follows:

- What are the relative contributions of different causes of anaemia to the prevalence of anaemia in the study area?
- What are the relative contributions of direct and indirect costs to the economic consequences of illness, especially malaria in the study area?

- What is the impact of improved financial access on health outcomes in an area where an effective anti-malarial has been in use for some time?

No previous study has quantified the relative contribution of *P. falciparum* related anaemia to the burden of anaemia in the study area or assessed the relative contribution of direct and indirect costs to overall heath care costs. A study such as the current one, has not yet been carried out in an area where an effective anti-malarial such as an ACT (Artemisinin combination therapy) has been in use over a period of time. In the current study, since an ACT was introduced just prior to the onset of the trial, this may have led to a reduction in the expected difference in utilization levels between the control and intervention arms.

The answers to these questions should provide some more information to improve knowledge on the subject of improved financial access and health outcomes among children.

9.11 Implications for policy and practice

The removal of direct cost of care in this study, did improve utilization of health services and should do so in many other areas similar to Ghana, where the reported OPD utilization per capita has remained almost constant at an extremely low level of between 0.3 and 0.4 visits per capita for several years, being worse in the rural areas (MOH 2001) Each enrolled person paid an average of 2.5 visits to a primary care facility over the 6-month period as compared to 1.5 in the non-enrolled. It did not, however, at least in this setting, over a 6-month period, lead to any measurable difference in health outcomes. The data raises the possibility that interventions which change healthcare utilization levels may not necessarily translate into improved healthcare outcomes; this clearly needs to be tested in other settings. It certainly lends support to having health outcomes rather than process indicators as the outcome of choice for studies of interventions if their results are to be most useful to policy makers.

A probable increase in utilization by the control households due to the introduction of new and effective drugs may have reduced the magnitude of the effect which might have been achieved. It is possible that given a longer period after the introduction of the ACT, a greater difference in the utilization of health services would have been seen between those enrolled and those who were not, and this may then have translated into a measurable difference in health outcome. It is doubtful that within the same period of time an impact on other health indicators would have been seen under the circumstances.

The intervention therefore, achieved its objective in terms of improvement in access to health services. It is possible that with time it might have done so in terms of improved health outcomes. Using an econometric model, Meer and others suggest that the wealth-health connection is not driven by short-run changes in wealth while not ruling out the possibility of a long-term impact (Meer *et al.* 2003). Benzeval and Judge, in their analysis of data from the British Household Panel Survey 1991-1997, suggest that persistent poverty is more harmful for health than occasional episodes and conclude that long-term income is more important for health than current income (Benzeval and Judge 2001).

Such an intervention should, however, go hand in hand with an improvement in geographic access to basic health services and continuous education aimed at changing health seeking behaviour and practices in the community for maximum effect. Removal of the barrier of direct cost of health care should, therefore, be given serious consideration especially for a vulnerable group such as children less than five years of age who bear the greatest burden of malaria.

Pre-payment schemes are a credible means for improving financial access to health care for vulnerable groups. This can be done by subsidizing the premiums of individuals belonging to the target group such as children less than five years of age. Such an intervention would be more effective as has been shown by the significant increase in utilization than exemption schemes which have been shown to be largely ineffective in increasing access. It ensures that the intervention reaches its intended target because it is not dependent on an administrative decision by a health worker every time health care is

sought and removes the attending uncertainty in the mind of the person who is seeking health care.

9.12 Conclusions

In conclusion, we have demonstrated by this study that improved financial access does lead to significant change in health care use; however, improved utilization over the period of the peak malaria transmission season did not translate into a reduction in the prevalence of anaemia, or any other important health outcome in this setting. There was a tendency to there being a greater effect in the poorest, but the study was not powered to explore this statistically. In theory this could mean that a targeted intervention for the poorest should be explored, but in practice identifying a 'poorest' group is not easy and interventions targeted at particular socioeconomic groups are difficult to apply.

The study makes it clear that we should be cautious about assuming that interventions which lead to a change in health-seeking behaviour do lead to improved health outcomes, an unstated assumption of a number of studies. It does not, however, exclude the possibility that a bigger difference in healthcare utilisation would lead to a significant difference in health outcomes. Although a measurable effect on malaria-associated healthcare outcomes was not demonstrated in this current study which covered a period of six months, it is possible that continued access to good quality health services over a period would lead to a measurable outcome.

Those who enrolled voluntarily in pre-payment schemes were significantly different from those who did not both socio-economically and in health seeking behaviour.

The introduction of ACTs seems to have coincided with a significant reduction in malaria in the study area, with both prevalence of anaemia and parasitaemia dropping despite the rainy season. This occurred at the same time as other malaria control interventions, and it is not possible to be sure how much, if any, the reduction is due to ACT introduction.

Removal of direct cost of care for a vulnerable group such as children less than five years of age should, therefore, be given serious consideration in malaria endemic areas such as this study site in Ghana; it is likely to lead to changes in healthcare utilisation, but we need to be careful in assuming this will lead to better health outcomes, and it may not be an effective or cost-effective intervention in the absence of other interventions.

APPENDICES

APPENDIX 1 RECRUITMENT FORM 1

INVITATION!   INVITATION!!   INVITATION!!!
HOUSEHOLD HEADS WITH CHILD/REN AGED 6 MONTHS - 59 MTHS

Your child/ren and your entire household have been selected to benefit from a subsidy for the health insurance scheme

The aim is to monitor the health of your child/ren under five years of age who benefit from it.

You are therefore invited to attend a very important meeting where issues relating to this will be discussed.

Please come along with the following
This Invitation Card
Weighing Card or Birth Certificate of Your Child/ren

DATE:
VENUE:
TIME:

HEAD OF HOUSEHOLD NAME:_____

COMMUNTY:_____

HOUSEHOLD ID:_____

INVITATION!   INVITATION!!   INVITATION!!!
HOUSEHOLD HEADS WITH CHILD/REN AGED 6 MONTHS - 59 MTHS

Your child/ren and your entire household have been selected to benefit from a subsidy for the health insurance scheme

The aim is to monitor the health of your child/ren under five years of age who benefit from it.

You are therefore invited to attend a very important meeting where issues relating to this will be discussed.

Please come along with the following
This Invitation Card
Weighing Card or Birth Certificate of Your Child/ren

DATE:
VENUE:
TIME:

HEAD OF HOUSEHOLD NAME:_____
COMMUNTY:_____
HOUSEHOLD ID:_____

APPENDIX 2 RECRUITMENT FORM 2

INVITATION!   INVITATION!!   INVITATION!!!
HOUSEHOLD HEADS WITH CHILD/REN AGED 6 MONTHS - 59 MTHS

Your child/ren and your entire household have been selected to benefit from a subsidy for the health insurance scheme

The aim is to monitor the health of your chil/ren under five years of age who benefit from it..

You are therefore invited to attend a very important meeting where issues relating to this will be discussed.

Please come along with the following
This Invitation Card
Weighing Card or Birth Certificate of Your Child/ren

DATE:
VENUE:
TIME:

HEAD OF HOUSEHOLD NAME:_____

COMMUNTY:_____

HOUSEHOLD ID:_____

INVITATION!   INVITATION!!   INVITATION!!!
HOUSEHOLD HEADS WITH CHILD/REN AGED 6 MONTHS - 59 MTHS

Your child/ren and your entire household have been selected to benefit from a subsidy for the health insurance scheme

The aim is to monitor the health of your chil/ren under five years of age who benefit from it..

You are therefore invited to attend a very important meeting where issues relating to this will be discussed.

Please come along with the following
This Invitation Card
Weighing Card or Birth Certificate of Your Child/ren

DATE:
VENUE:
TIME:

HEAD OF HOUSEHOLD NAME:_____

COMMUNTY:_____

HOUSEHOLD ID:_____

APPENDIX 3 RECRUITMENT FORM 3

INVITATION!   INVITATION!!   INVITATION!!!
HOUSEHOLD HEADS WITH CHILD/REN AGED 6 MONTHS - 59 MTHS

Your child/ren and your entire household have been selected to benefit from a subsidy for the health insurance scheme

The aim is to monitor the health of your child/ren under five years of age who benefit from it.

You are therefore invited to attend a very important meeting where issues relating to this will be discussed.

Please come along with the following
The Invitation Card
Weighing Card or Birth Certificate of Your Child/ren

DATE:
VENUE:
TIME:

HEAD OF HOUSEHOLD NAME:_____
COMMUNTY:_____
HOUSEHOLD ID:_____

INVITATION!   INVITATION!!   INVITATION!!!
HOUSEHOLD HEADS WITH CHILD/REN AGED 6 MONTHS - 59 MTHS

Your child/ren and your entire household have been selected to benefit from a subsidy for the health insurance scheme

The aim is to monitor the health of your child/ren under five years of age who benefit from it.

You are therefore invited to attend a very important meeting where issues relating to this will be discussed.

Please come along with the following
The Invitation Card
Weighing Card or Birth Certificate of Your Child/ren

DATE:
VENUE:
TIME:

HEAD OF HOUSEHOLD NAME:_____
COMMUNTY:_____
HOUSEHOLD ID:_____

APPENDIX 4 INFORMATION SHEET AND CONSENT FORM 1

FORM 1A INFORMATION AND CONSENT (IC) FORM FOR RANDOMLY ALLOCATED GROUP

A randomized controlled trial of the impact of improved financial access to health care on morbidity due to malaria and health care utilization among children 6 to 59 months of age in a malaria endemic area in Ghana

Field Worker's code ☐☐   Date   ☐☐/☐☐/☐☐

1. Randomization Group *(Indicate A, B or C as appropriate)*   ☐

2 Community ☐   3.Community ID ☐☐/☐☐

4. House ID   ☐☐/☐☐/☐☐☐

5. Mother's Name

6. Name of Household Head

7. Eligible Children

Name	Date of Birth	Sex
1	☐/☐☐☐☐	☐
2	☐/☐☐☐☐	☐
3	☐/☐☐☐☐	☐
4	☐/☐☐☐☐	☐
5	☐/☐☐☐☐	☐

Information for Parents and Guardians

Every year about one million children around the world including this district die from severe disease. One of the reasons for these deaths is because their parents are unable to seek care promptly for them since they cannot afford it at the time of illness.

We plan to carry out a study to find out the impact of ensuring that every child under five years has access to health care at the time they are ill without thinking of payment for services. To do this, we have to screen and select about 2500 children, half of whom will

be given a card that ensures free care for them under the *Dangme Hewami-nami kpee* scheme this year. The other half will also receive the same benefit next year though they will have to pay for health services as usual this year. This means that if the premium increases next year they will only have to pay the difference. Allocation is random and your child may fall into either group. We hope that you will be able to take part in the study.

During the study, tiny drops of blood will be taken on two occasions at home daytime from a finger-prick. This is to assess your child's haemoglobin level and to check for the presence of malaria parasites. Other measurements that include your child's weight, height and the thickness of his/her arm will be taken to enable us know how well your child is growing. In the process of collecting the blood sample from the finger tip your child may experience mild discomfort. This does not represent a health risk to your child. None of these tests will cost you any money and in the process, you will find out about the health status of your child. We will explain to you the outcome of the test result.

All the information collected about you and your child will be kept confidential and only the general findings will be made available to relevant authorities for the purpose of making important decisions and conclusions for this study.
You are at liberty to refuse or withdraw your child from the study at any time and this will not prejudice the standard of medical care your child is supposed to receive at the health facility. Any time after this child has been enrolled you are at liberty also to contact Dr. Evelyn Ansah / her assistant if you feel that you have not been adequately informed about the procedure, potential risks, benefits, rights as parents of this child, and indeed any other aspects of this study.

Do you have any questions about the study?

The contact address for Dr. Evelyn Ansah is as follows:

District Health Administration/Research Center
Dodowa

Consent Form

I have been adequately informed of the purpose of this study, procedures, potential risks, benefits and consequences.

I also understand that half of the children will receive the benefit of being enrolled in a scheme that will give them free care this year. I understand that I am at liberty to withdraw consent for my child's participation any time in the course of the study. I understand that the information obtained as a result of my child's participation will be treated as confidential and only the general findings will be made available to relevant authorities for the purpose of making important decisions and conclusions for this study.

The investigators have answered all my concerns.

Parent/Guardian Name: Date [ ][ ]/[ ][ ]/[ ][ ]

Signature/Thumb-print

I have adequately informed the parents or legal guardians of the child/ren the purpose of this study, its procedures, risks, benefits and consequences. I have answered the parents' questions regarding the study conduct and explained their concerns about the child's participation in the study. I will be available to continue doing so in the course of the study if the need arise.

Signature of Dr. Evelyn Ansah: Date [ ][ ]/[ ][ ]/[ ][ ]

APPENDIX 5 INFORMATION SHEET AND CONSENT FORM 2

FORM 1B INFORMATION AND CONSENT (IC) FORM FOR SELF ENROLLED GROUP

A randomized controlled trial of the impact of improved financial access to health care on morbidity due to severe malaria and health care utilization among children 6 months to 5 years of age in a malaria endemic area in Ghana

Field Worker's code ☐☐   Date   ☐☐/☐☐/☐☐

1. Randomization Group *(Indicate A, B or C as appropriate)*   ☐

2 Community ☐   3.Community ID ☐☐/☐☐

4. House ID   ☐☐/☐☐/☐☐☐

5. Mother's Name ☐

6. Name of Household Head ☐

7. Eligible Children

Name	Date of Birth	Sex
1	☐/☐☐/☐☐☐☐	☐
2	☐/☐☐/☐☐☐☐	☐
3	☐/☐☐/☐☐☐☐	☐
4	☐/☐☐/☐☐☐☐	☐
5	☐/☐☐/☐☐☐☐	☐

Information for Parents and Guardians

Every year about one million children around the world including this district die from severe disease. One of the reasons for these deaths is because their parents are unable to seek care promptly for them since they cannot afford it at the time of illness.

We plan to carry out a study to find out the impact of ensuring that every child under five years has access to health care at the time they are ill without thinking of payment. To do

this, we have to screen and select about 2500 children, half of whom will be randomly allocated to receive a card that ensures free care for them under the *Dangme Hewami-nami kpee* scheme this year. The other half will also receive the same benefit next year though they will have to pay for health services as usual this year. Since you have already enrolled your household for this year, the members of your household will receive an equal amount per person towards your premium next year. If the premium increases you only pay the difference next year. We hope that you will be able to take part in the study.

During the study, tiny drops of blood will be taken on two occasions at home daytime from a finger-prick. This is to assess your child's haemoglobin level and check for the presence of malaria parasites. Other measurements that include your child's weight, height and the thickness of his/her arm will be taken to enable us know how well your child is growing. In the process of collecting the blood sample, from the finger tip your child may experience mild discomfort. This does not represent a health risk to your child. None of these tests will cost you any money and in the process, you will find out about the health status of your child. We will explain to you the outcome of the test result.

All the information collected about you and your child will be kept confidential and only the general findings will be made available to relevant authorities for the purpose of making important decisions and conclusions for this study.
You are at liberty to refuse or withdraw your child from the study at any time and this will not prejudice the standard of medical care your child is supposed to receive at the health facility. Any time after this child has been enrolled you are at liberty also to contact Dr. Evelyn Ansah / her assistant if you feel that you have not been adequately informed about the procedure, potential risks, benefits, rights as parents of this child, and indeed any other aspects of this study.

Do you have any questions about the study?

The contact address for Dr. Evelyn Ansah is as follows:

District Health Administration/Research Center
Dodowa

Consent Form

I have been adequately informed of the purpose of this study, procedures, potential risks, benefits and consequences.

I also understand that since I have already enrolled this year, I will have the benefit of receiving the same amount towards enrollment of my household for next year. I am at liberty to withdraw consent for my child's participation any time in the course of the study. I understand that the information obtained as a result of my child's participation will be treated as confidential and only the general findings will be made available to relevant authorities for the purpose of making important decisions and conclusions for this study.

The investigators have answered all my concerns.

Parent/Guardian Name   Date ☐☐/☐☐/☐☐

Signature/ Thumb-print:

I have adequately informed the parents or legal guardians of the child/ren the purpose of this study, its procedures, risks, benefits and consequences. I have answered the parents questions regarding the study conduct and explained their concerns about the child's participation in the study. I will be available to continue doing so in the course of the study if the need arise

Dr. Evelyn Ansah: Date ☐☐/☐☐/☐☐

APPENDIX 6 SCREENING AND ENROLMENT FORM 1

FORM 2 SCREENING AND ENROLMENT (SE) FORM FOR CHILD

RANDOMIZATION GROUP　　　YES ☐　　OR　　NO ☐

1. Date of enrolment　　　　　　　☐☐/☐☐/☐☐

2. Randomization Stratum ☐　　　**3. No. of other siblings 6-59 mths** ☐

4. Community ☐　　　　　　　　**5.Community ID** ☐☐/☐☐

6. House ID　　　　　　　☐☐/☐☐/☐☐☐

7. Household head Name ☐

8. Name of Child ☐

9. Sex　　　　Male　(1)　☐　　Female　　(2)　　☐

10. Date of Birth (dd/mm/yy)　　☐☐/☐☐/☐☐☐☐

11. Cross-checked from	Road to Health Chart	(1)	
	Birth certificate	(2)	☐
	Baptismal certificate	(3)	
	Other (specify)...................................(5)		
12. Age(*in completed months*)	☐☐ Months		

13. Address and detailed direction to child's home
Briefly describe and include any landmark that will make it easy to locate home e.g bar, church, school etc

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14. Inclusion Criteria (*all must be answered yes for child to be eligible*)

Yes.(1) No (2)

- Age documented to be between 6 months and 59 months? ☐

- Household not already enrolled in pre-payment scheme? ☐

- Parents/Guardians intend to remain in study area for next 2 yrs? ☐

- Parents willing to participate ☐

15. Exclusion Criteria (*all must be answered no for child to be eligible*)
- No verifiable record of age ☐

- Parents/Guardians not permanently resident ☐

- Parents unwilling to participate ☐

16. Is child eligible? ☐

17. If Yes (to Q.16), child's study number is ☐/☐☐☐☐

Open community ballot among households living less than 5km from a health facility at a randomization meeting.

Screening and enrolment at a randomization meeting

APPENDIX 7 BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 1

INTRODUCTION OF FIELDWORKERS TO HEADS OF HOUSEHOLDS

We are _____ and _____. We are from the Ghana Health Service at Dodowa. We are taking a look at the impact of having access to health care on children between the ages of 6 to 59 months. To do this we are visiting some households in the district to examine the children and also have a discussion with their caretakers/parents. You may have already been notified of this.

As part of the study, we will take tiny drops of blood. This is to assess your child's haemoglobin level and check for the presence of malaria parasites. Other measurements that include your child's weight, height and the thickness of his/her arm will be taken to enable us know how well your child is growing. This does not represent a health risk to your child. None of these tests will cost you any money and in the process, you will find out about the health status of your child. We will explain to you the outcome of the test result.

All the information collected about you and your child will be kept confidential and only the general findings will be made available to relevant authorities for the purpose of making important decisions and conclusions for this study.

APPENDIX 8 BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 2

FORM 4A BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY (XS) QUESTIONNAIRE- HOUSEHOLD DATA

Every year several in this district die from severe disease. As discussed with you earlier, we are carrying out a study to look at factors contributing to the development of severe disease and death among children less five years of age. We would therefore like to ask you a few questions concerning your household and your child/ren. We assure you that any information collected will be kept confidential. General findings will be made available to relevant authorities for the purpose of making important decisions and conclusions from this study.

(Interview to be conducted with household head and mother/principal female caretaker of child)

Field Worker code ☐☐   **Date of Interview** ☐☐/☐☐/☐☐
DD/MM/YY

Community..

Time Interview begun ☐☐.☐☐ am/pm

House ID ☐☐/☐☐/☐☐☐

Household ID ☐/☐☐☐

Name of Household Head _____

Name of Mother _____

Child/ren Study IDs
☐/☐☐☐/☐
☐/☐☐☐/☐
☐/☐☐☐/☐
☐/☐☐☐/☐

A .Household background Information

1. How many people are there in this household? *(Those who share economic resources or eat from the same pot. We will define these as your household members)*	☐☐
2. How many of your household members are less than five years of age?	☐

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3. What is your main occupation Farming (1) Fishing (2) Civil servant (3) Artisan (4) Other. Specify....................... (5) Trader (6) Unemployed (7)	☐
4. What is your religion? Christian (1) Muslim (2) African Traditional (3) Agnostic (4) Other (specify)..........................(5)	☐
5. What is your ethnic group? Dangme (1) Ga (2) Akan (3) Ewe (4) Other (specify)........................ (5) Krobo(6) Northern/Upper (7)	☐
6. Marital status of main respondent Married (1) Single (2) Separated (3) Divorced (4) Widowed (5)	☐
7. Number of years of formal education completed by mother/principal caretaker	☐☐
8. Number of years of formal education completed by household head (if different from mother/principal caretaker. *(Indicate '99' if same person is mother/principal caretaker)*	☐☐

B. Perception of Malaria

9. What is the commonest illness that affects children in this area? Malaria/ 'asra'/fever (1) Convulsion (2) Worms (3) Diarrhoeal diseases (4) Other (specify)..............................(5) Measles (6) Stomach pain (7)	☐
10. What causes malaria ("asra")? Mosquito bite (1) Too much sun (2) Worms (3) Poor nutrition (4) Other (specify)..............................(5) Eating unripe fruit (6) Eating oily foods (7) Don't know (88)	☐

11. Does malaria ("asra") ever become severe in children and kill them? Commonly (1) Sometimes (2) Infrequently (3) Never (4)	☐

C Health facility utilization

12. Can you tell me which the closest health facility to your home is? Dodowa health centre (1) Prampram health centre (2) Agomeda community clinic (3) Doryumu community clinic (4) Other specify.. (5) Kordiabe community clinic (6) Dawhenya community clinic (7) Ebenezer clinic (8) Grace Maternity Home (9)	☐
13. From which health facility do you usually seek care for \<child/ren\>? Same as above (1) A hospital (2) Traditional healer/TBA (3) Other (specify).. (5) Chemical Seller (6) Drug peddler (7) Treat all illnesses at home myself (8) Child has never been ill (9)	☐
14. How do you usually get there? By private car (1) By taxi (2) By tro-tro (3) By Motor-bike (4) Other. Specify...(5) By bicycle (6) By walking (7) Not Applicable. (99)	☐☐
15. How long does it take you and how much does it cost you to get there? Time (in minutes) ....mins Cost ....cedis	

D. Mortality

16. In this past year, that is from Easter of last year to now, how many children under five years in this household has died from a febrile illness? None (1) One (2) Two (3) Three (4) Other specify...................(5)	☐

F. Pre-payment scheme

17. Have you ever heard about the Dangme Hewaminami Kpee (health insurance scheme)?(If NO go directly to Q23 and indicate "99" forQ17 to Q22) Yes (1) No (2)	☐
18. How did you hear about it? Through friends (1) Through Radio (2) Leaflets/brochures (3) Through health staff (4) Others (Specify)...(5) Information van (6) Gongong beating (7) Assembly men (8) Not applicable 99)	☐☐
`19. Have you ever enrolled in the scheme? Yes (1) No (2) Not Applicable (99)	☐☐
20. Have you enrolled this year? Yes (1) No (2) Not Applicable (99)	☐☐
21. Why did you not enroll this year? No Money (1) Poor quality drugs (2) Poor quality of health care offered at the clinic (3) Staff reception poor (4) Other (specify).......................................(5) I live too far away from the nearest clinic (6) I did not hear when the registration was going on (7) Don't understand it (8) I think premiums are too high (9) Prefer to take the risk of falling ill (10) Had traveled during registration period (11) Not Applicable (99)	☐☐
22. Why have you never enrolled? No Money (1) Poor quality drugs (2) Poor quality of health care offered at the clinic (3)	

Staff reception poor (4)	☐☐
Other (specify)..(5)	
I live too far away from the nearest clinic (6)	
I never hear when the registration is going on (7)	
Don't understand it (8)	
I think premiums are too high (9)	
Prefer to take the risk of falling ill (10)	
Not Applicable (99)	

G. Exemptions

23. Does the government provide free health services for any category of people? Yes (1) No (2) Don't Know (88)	☐☐
24. Which category of people are entitled to these free services? (Do not prompt. Allow respondent to list as many as possible) Children under five mentioned (1) Children under five not mentioned (2) Don't know (88) Not Applicable (99)	☐☐
25. Do you know anybody who has benefited from this before? Yes (1) No (2) Not Applicable (99)	☐☐

H. Poverty

26. What indicates that a household in this area is poor? *(Multiple answers allowed. Prompt client with "Is that all?" Tick all responses given)* The kind of clothing they wear (1) The number and quality of meals they have in a day (2) The kind of house they live in (3) The assets they own (4) Other. Specify..(5)	
27. How do poor households survive in this area? *(Multiple answers allowed. Prompt client with "Is that all?" Tick all responses given)* Borrow from family members (1) Borrow from neighbours and friends (2) Helped by family members (3) Helped by neighbours and friends (4) Other. Specify..(5) Provide labour for money (6)	

H. Household wealth

28. Who owns this house?

Household owns it	(1)
Family house(jointly owned)	(2)
Belongs to a relative. Not paying rent	(3)
Renting it from someone	(4)
Other. Specify………………………………	(5)
Provided by govt/employer	(6)

☐

29. What is the main lighting fuel of this household?

Electricity	(1)
Gas	(2)
Kerosene	(3)
Candles	(4)
Other. Specify…………………………………..(5)	

☐

30. What type of fuel does your household mainly use for cooking?

Electricity	(1)
LPG/ natural gas	(2)
Kerosene	(3)
Charcoal	(4)
Other (specify)……………………………..(5)	
Firewood	(6)
Dung	(7)

☐

31. What is the source of drinking water for this household?

Piped water (into residence)	(1)
Piped water (public tap/neighbour's house)	(2)
Well/Borehole	(3)
River/stream/pond/lake	(4)
Combination.specify…………………………..(5)	
Rain water	(6)
Tanker truck	(7)
Pure water	(8)

☐

32. Time to water source (to the nearest 10 minutes)

Less than 10 minutes	(1)
10 minutes	(2)
20 minutes	(3)
30 minutes	(4)
40 minutes	(6)
50 minutes	(7)
1 hour or more	(8)

☐

33. What sort of sanitation facility does this household use?

Flush toilet (used by household only)	(1)
Flush toilet shared	(2)
Own KVIP/ bucket/pan/ traditional pit latrine (Household)	(3)
Shared KVIP/ bucket/pan/ traditional pit latrine	(4)

☐

Other specify..(5)		
Public Toilet	(6)	
No facility/bush	(8)	

34. What is the main floor material of the house (*Record observation*)

Ceramic tiles/terrazzo	(1)	
Cement	(2)	
Brick/cement blocks	(3)	
Mud/sand/earth	(4)	☐
Other...5)		
Zinc/Asbestos/Aluminum sheets	(6)	
Tarpaulin, plastic sheets	(7)	
Asbestos	(8)	

35. What is the main material of the walls?(*Use options for Q34*) ☐

36. What is the main material of the roof? (*Use options for Q34*) ☐

37. How many households share this compound?

One	(1)	
Two	(2)	
Three	(3)	☐
Four	(4)	
Five	(6)	
Six	(7)	
More than six	(8)	

38. How many rooms in this compound belong to this household?

One	(1)	
Two	(2)	
Three	(3)	☐
Four	(4)	
Five	(6)	
Six	(7)	
More than six	(8)	

39. Does this household own:

A radio	Yes	(1)	No	(2)	☐
A Television	Yes	(1)	No	(2)	☐
A Refrigerator	Yes	(1)	No	(2)	☐
A Telephone	Yes	(1)	No	(2)	☐

40. Does any member of this household own:

A bicycle?	Yes	(1)	No	(2)	☐
A motor-cycle?	Yes	(1)	No	(2)	☐
A tractor?	Yes	(1)	No	(2)	☐
A fishing vessel?	Yes	(1)	No	(2)	☐
A private car?	Yes	(1)	No	(2)	☐
A commercial vehicle?	Yes	(1)	No	(2)	☐

41. Does this household own:						☐
A subsistence farm?	Yes	(1)	No	(2)		☐
A commercial farm?	Yes	(1)	No	(2)		☐
Land	Yes	(1)	No	(2)		☐
Cattle?	Yes	(1)	No	(2)		☐
House/s for renting out?	Yes	(1)	No	(2)		☐

42. How much average income per month has this household been getting over the past six months from the work you do? *(FW to get the total for 6 months and divide by 6)*

....cedis

43. How much average monthly remittance have you received as remittance from relatives/friends over the period?

....cedis

44. Have you had to borrow any money over the same period (six months)?

Yes   (1)   No   (2)   ☐

45. How much in total have you had to borrow over the period?

......................cedis   Not Applicable   (99)   ☐☐

Thank you very much for your very useful answers and your time.

Time Interview ended   ☐☐☐☐am/pm

APPENDIX 9 BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 3

FORM 4B BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY (XS) QUESTIONNAIRE- CHILD DATA

(Interview to be conducted with household head and mother/principal female caretaker of child)

Field Worker code ☐☐   **Date of Interview** ☐☐/☐☐/☐☐

Community..

Time Interview begun ☐☐.☐☐ am/pm

A. *Child Background Information*

1. House ID ☐☐/☐☐/☐☐☐

2. Household ID ☐/☐☐☐☐

3. Name of Household head [   ]

4. Child's Study ID ☐/☐☐☐☐/☐

5. Child's Name [   ]

6. Sex   Male (1)   Female(2)   ☐

7. Date of Birth (*FW to check Birth Certificate/RTH Card*) ☐☐/☐☐/☐☐
DD/ MM / YY

8. Age (*in completed months*)   ☐☐ Months

9. Number of <u>other</u> siblings less than five years old   ☐

10. Relationship of main respondent to child

Mother (1)   Father (2)   Grandmother (3)   Grandfather (4)

Other specify ....(5)   Aunt (6)   Uncle (7)   ☐

265

B. <Child> morbidity

11. In this past year, that is from Easter of last year to now, has <child> been admitted to a hospital and slept overnight? Yes (1) No (2)	☐
12. How many times was <child> admitted for malaria within the last year?	☐ times
13. When was the most recent admission? Yesterday (1) Two to three days ago (2) A week ago (3) Two weeks ago (4) A month ago (6) More than a month ago (7) More than a year ago (8) Child has never been admitted before (9)	☐
14. Now we want to talk about your child's most recent illness. When was the last time your <child> fell ill? Yesterday (1) Two to three days ago (2) A week ago (3) Two weeks ago (4) A month ago (6) More than a month ago (7) More than a year ago (8) Child has never been ill before (9)	☐
15. When <child> was last ill, where did you seek care for <child>? *(if child was sent to health facility, go directly to Q18 and indicate "Not Applicable" for Q16 and Q17)* Home (1) Drug Peddlar (2) Chemical seller (3) Traditional Healer (4) Other. Specify...(5) Clinic (6) Hospital (7) Not Applicable (99)	☐☐

16. There are many reasons why children are not sent to a health facility when they are sick. In this instance what was the special reason *(tick all the spontaneous responses after listening carefully to the mother's report)*?	
Too expensive. Could not afford it (1) Transport costs too high (2) Difficult to obtain transport (3) Staff there are not technically competent (4) Other(specify)..(5) Staff there are not nice to patients (6) Know how to treat the illness at home (7) Prefer to use herbal drugs (8) Chemical seller closer (10) Traditional healer/TBA closer (11) Not applicable. Child taken to health facility (99)	☐☐
17. You have said that_____ and _____ and _____ are the reasons why <child> was not sent the health facility. Of all the reasons you have given me which is the most important *(Still use the options in Q16)*	☐☐

C. Household expenditure on health care for child

18. Now let's discuss expenditure for this last illness. How much did you spend on:

Place	Activity	Amount Spent
	Direct health care costs	.........................cedis
	Transportation to and fro	.........................cedis
	Other costs(gifts, food)	.........................cedis
	Direct health care costs	.........................cedis
	Transportation to and fro	.........................cedis
	Other costs(gifts, food)	.........................cedis
	Direct health care costs	.........................cedis
	Transportation to and fro	.........................cedis
	Other costs(gifts, food)	.........................cedis

Total costs ....cedis Not Applicable. (99)		☐☐

19. Was enough money available in the house to pay? Yes　(1)　　　No　(2)　Not Applicable　(99)	☐☐
20. If enough money was not available, how was money obtained to pay? 　　Sold agricultural produce (crops, animals etc) to pay(1) 　　Provided paid labour to pay　　　　　　　　(2) 　　Sold personal effects to pay　　　　　　　　(3) 　　Money contributed by relatives/friends　　　(4) 　　Other specify...(5) 　　Pawned personal effects to pay　　　　　　(6) 　　Went for a loan　　　　　　　　　　　　(7) 　　Not applicable. Money was available at home　(99)	☐☐
21. Who in the family decides that a mother should take her child for consultation when child is ill? 　　Mother (1)　　　　Father (2)　　　　Both parents (3) 　　Grandmother (4)　　Other (Specify)........................... (5)	☐

D. Malaria and preventive measures

22. Does this household use any preventive measures for malaria ("asra" / "atridii")? 　　Yes　(1)　　　　No　(2)	☐
23. How do you usually protect <child> against malaria? (*Interviewer to prompt if a preventive method is not mentioned unprompted*) i)Treated bed nets/curtains　　　　Yes　(1)　　No　(2) ii)Untreated bed nets　　　　　　　Yes　(1)　　No　(2) iii)Mosquito netting on windows/doors　Yes　(1)　　No　(2) iv)Mosquito spray/coils　　　　　　Yes　(1)　　No　(2) v)Burning of local herbs/orange peels　Yes　(1)　　No　(2) vi) Other (specify)..	☐ ☐ ☐ ☐
24. Does this household own a bed net ("mudo") ? 　　Yes　(1)　　　　No　(2)　Not Applicable　(99)	☐☐
25. How many nets does the household own? (*indicate 99 if household does not own a net*)	☐☐

26. How many nights has <child> slept under net during the past one week? *(indicate "99" if household does not own a net and "00" if the child did not sleep under net))*	☐☐
27. Has the net <child> slept in ever been treated with a chemical to kill insects and mosquitoes? *(indicate 99 if household does not own a net and"77" if they own one but child did not sleep in it)* 　　Yes　(1)　　　　No　(2)　　Not Applicable　(99)	☐☐

Thank you very much for your very useful answers and your time

Time Interview ended　　☐☐.☐☐ **am/pm**

APPENDIX 10 BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 4

FORM 5 BASELINE ANTHROPOMETRIC AND HAEMATOLOGICAL FIELD ASSESSMENT (AH) FORM

Field Worker's code ☐☐   Date of examination ☐☐/☐☐/☐☐

Community...

Time Examination begun ☐☐☐ am/pm

1. House ID ☐☐ / ☐☐ / ☐☐☐☐

2. Household ID ☐/☐☐☐☐

3. Name of Household head ☐

4. Mother's Name ☐

5. Child's Study ID ☐/☐☐☐/☐

6. Name of Child ☐

7. Sex of child   Male   (1)   Female   (2)   ☐

8. Age (*in completed months. FW to check study ID*)	☐☐ Months
9. Mid Upper Arm Circumference	☐☐.☐ cm
10. Height/length	☐☐☐.☐
11. Weight	☐☐.☐ kg
12. History of fever in the past week? Yes (1) No (2)	☐
13. Temperature today(*FW to measure temperature and record)*	☐☐.☐ °C
14. Smear taken? Yes (1) No (*state why in space for comments*) (2)	☐
15. Haemoglobin count	☐☐.☐ g/dl
16. Dipstick Results Positive (1) Negative (2)	☐☐

Not Applicable(no history of fever & child's temp below 37.5°C (99)	
17. Body Mass Index (BMI = Wght/Height$^{2.}$ *(FW to leave this blank)*	☐☐kg/m^2
Time Examination ended ☐☐ ☐☐am/pm	

18. Comments

*The **difference** between the two results for **height/length should not exceed 5mm.** If it does two fieldworkers should retake measurements

Checked: Supervisor Code   ☐☐   **Date**____/____/04

APPENDIX 11 BASELINE HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 5

<u>**REFERRAL – DANGME WEST DHA/RESEARCH CENTER**</u>

CHILD NAME:...

COMMUNITY OF RESIDENCE......................................

Please take care of this child under five with the following lab results under the **Exemptions Policy**:

    Hb.................................g/dl

    Temperature.......................°C

    Dipstick for Malaria Parasites: Positive/Negative

....

APPENDIX 12 BASELINE QUALITATIVE STUDY FORM 1

BASELINE FOCUS GROUP DISCUSSION GUIDE FOR MOTHERS/CARERS WITH CHILDREN LESS THAN FIVE YEARS OF AGE

1. BACKGROUND INFORMATION

Name	Marital Status
Age	Educational Status
Sex	Number of children
Occupation	Number Under 5

2. GENERAL INFORMATION ON HEALTH AND TREATMENT SEEKING BEHAVIOUR

1. What disease conditions in this community lead to severe illness in children?
2. What disease conditions in this community lead to death in children?
3. What are the available sources of health care for mothers with sick children in this community?
4. At what stage of the illness do mothers take their children for consultation?
5. Who in the family decides that a mother should take her sick child for consultation?
6. Who gives advice to the mother/caretaker when a child is sick?
7. Does a woman need permission to send her child for health care?
8. Under what circumstance does this happen?
9. How long does it take to get to the nearest health facility?
10. What factors delay seeking health care and treatment promptly?

3. INFORMATION ON MALARIA AND ITS COMPLICATIONS

What types of febrile illnesses are there in this community? (If not mentioned, ask about malaria. Go on to ask specifically about the following complications of malaria

- Anaemia
- Recurrent Convulsion
- Inability to sit or stand
- Unrousable coma/unconsciousness
- Failure to eat or drink
- Repeated vomiting
- Deep breathing
- Change in mental status

For each of the conditions above, ask for the following
- Local name
- Types
- Perception on cause
- Signs and symptoms
- Prevention and treatment.

4. PERCEPTIONS ON PAYING FOR HEALTH CARE

1. How do you pay for bills when a child is sick
2. Big bills   Small Bills
3. Ask for what the group means by either big or small bills
4. If you did not use the money for health care, what would you have used it for?
5. Have you heard of the DHK
   a. What have you heard about it
   b. From whom
   c. Are you members
   d. What are some of the benefits
6. Perceptions and experience with the scheme
7. Knowledge about government exemption policy
   a. Source of knowledge
   b. Who benefits
   c. Perceptions and experience with exemptions for children under 5

5. PERCEPTIONS ON POVERTY

1. How would you describe a poor person or household in this area
2. How would you describe a rich person in this area
3. How do poor people survive in this area
4. What are the existing community structures for helping poor people in this community

Thank you very much for your time and for giving us insight into these important issues affecting health in this area.

APPENDIX 13 BASELINE QUALITATIVE STUDY FORM 2
INTERVIEW SCHEDULE: COMMUNITY KEY INFORMANTS

1. PERSONAL INFORMATION

Name	Address
Sex	Age
Occupation	Education
Number of children	Number under five

2. INFORMATION ABOUT THE KEY INFORMANT'S ROLE

What is your field of responsibility?

3. INFORMATION ABOUT HEALTH AND MALARIA

What is the most important disease leading to death in adults and in children in this community?
What signs and symptoms does the person associate with severe malaria? (*Note all signs and symptoms mentioned*)

4. INFORMATION ABOUT HEALTH CARE

Where do mothers go for advice and treatment when their children are very sick?
Who in the family decides that the mother should take a sick child to hospital?

5. INFORMATION ABOUT SEVERE MALARIA

a) What types of febrile illnesses are there in this community? (If not mentioned, ask about malaria. Go on to ask specifically about the following complications of malaria
- Anaemia
- Recurrent Convulsion
- Inability to sit or stand
- Unrousable coma/unconsciousness
- Failure to eat or drink
- Repeated vomiting
- Deep breathing
- Change in mental status

b) For each of the conditions above, ask for the following
- Local name
- Types
- Perception on cause
- Signs and symptoms
- Prevention and treatment.
- Sources of care
- Constraints to seeking help
  - ➤ How long does it take to get to the nearest health center or hospital, during the rainy season and at other times?
  - ➤ What factors delay seeking care and treatment promptly?

6. PERCEPTIONS ON PAYING FOR HEALTH CARE

- How do you pay for bills when a child is sick
- Big bills   Small Bills
- Ask for what the group means by either big or small bills
- If you did not use the money for health care, what would you have used it for?
- Have you heard of the DHK
  - d. What have you heard about it
  - e. From whom
  - f. Are you members
  - g. What are some of the benefits
- Perceptions and experience with the scheme
- Knowledge about government exemption policy
  - h. Source of knowledge
  - i. Who benefits
  - j. Perceptions and experience with exemptions for children under 5

7 PERCEPTIONS ON POVERTY

1. How would you describe a poor person or household in this area
2. How would you describe a rich person in this area
3. How do poor people survive in this area
4. What are the existing community structures for helping poor people in this community

Thank you very much for your time and for giving us insight into these important issues affecting health in this area.

APPENDIX 14 BASELINE CASE STUDY FORM 1

INTERVIEW SCHEDULE FOR HOSPITAL CASE STUDIES
MALARIA AND ACCESS STUDY

Information to be gathered from mother/caretaker

1. PERSONAL INFORMATION

Name

Age	**Number of children**	**Occupation**
Sex	**Age of children**	**Education**

Home Address

What condition do you think the child has?
What have the people here told you your child has?
Where did the patient fall ill?(*name of the community*)

2. MOTHER'S RECOGNITION OF SIGNS, SYMPTOMS AND CLINICAL COURSE

What signs and symptoms did the mother notice when the child became ill?

(*Let her mention symptoms spontaneously first tick off and then prompt for those unmentioned. After symptoms have been mentioned, go back one after the other and ask about when it started, time of day and treatment given.*)

Symptom	Date and time of day	Treatment
Fever		
Vomiting		
Recurrent Convulsions		
Rash		
Sweat/Chills		
Paleness of hands eyes or mouth		
Lethargy and increased sleepiness		
Fast/difficulty in breathing		
Coma		

Of all the symptoms mentioned above which of them disturbed you most and why?

3 MOTHER'S HEALTH SEEKING BEHAVIOUR

What did the mother do when she first realised that her child was ill? *(Ask for all places she went to before arriving at the hospital)*

Place	Date and time	What was done	Referral to hospital	How long it took to bring the patient to the hospital	Anti malarial given and when	Which anti-malarial	Was course completed?	Changes in symptom (improvement or worsen)
Home Remedies								
Chemical shop/pharmacy								
Health Centre								
Traditional healer								
Private practitioner								
Healing rituals								
Prayers								
Other Specify								

Of the various treatments you received, which were you most satisfied with?

. Of the treatments received, which were you most dissatisfied with?

DECISION MAKING AND OBSTACLES TO SEEKING CARE

- Who made the decision to first seek care?
  Did the mother of the child decide? Did the father decide?

- Was there any discussion about when and where to take the child? Who actually took the child for care?

- Did anyone give them advice about what to do for the child (*for example, about care seeking or home care*)?
  Who?
  What advice did they give?

- Did the mother go to any other place for advice or information?

- Were there any obstacles to seeking care as quickly as the mother would have liked (*for example, lack of money, or transport*)?

- Who decides about expenditure on health care?

****

INFORMATION TO BE GATHERED FROM CLINICAL RECORDS

1. Hospital and admission information

- Name of hospital   Date and time of admission (*use 24 hour time, e.g. 13.30 rather than 1.30*)
- Referred from
- Referred by
- Self referred

2. Clinical diagnosis

- Patient name   Age   Sex   (F)   (M)
- What state was the patient in at the time of admission?
- Confirmed blood film?   (Yes)   (No)

3. Check for and record the following:

- Symptoms recorded
- Preliminary diagnosis
- Final Diagnosis made
- Treatment

Focus group discussion with a group of mothers with children less than 5 years of age at Fiankonya

Group discussion with a group of mothers with children less than five years of age using the problem tree method at Luom

APPENDIX 15 PASSIVE MORBIDITY MONITORING FORMS 1 AND 2

This is a two-page Pictorial diary for monitoring morbidity of the study child/ren during the month. Each individual study child had a separate form for the month. The first page of the diary was adapted from the Ghana Health Service Road to Health Chart. This had already been extensively pre-tested in the country by the Health Education Unit before publication. It was however pre-tested again locally to ensure that mothers could recognize and identify with the pictures indicating common signs and symptoms of childhood illness.

The second page was developed by an Artist-Pharmacist, Mr. Jones Abban, who worked closely with the Principal Investigator to put down the concepts. The pictures were pre-tested extensively in the district with further modifications until they were easy for community members to recognize and identify with.

Form 1

First page of Pictorial Diary for mothers to thumb print using any locally available marker such as soot or ash from the kitchen fire. To thumbprint each time child develops any of the symptoms in the picture during the month.

- Picture 1   Child has diarrheoa and bloody stools
- Picture 2   Child is lethargic or unconscious
- Picture 3   Child is convulsing
- Picture 4   Child has difficulty in/fast breathing
- Picture 5   Child is vomiting everything
- Picture 6   Child has fever

Form 2

Second page of Pictorial Diary for mothers to thumbprint the sources of health care for the illnesses indicated on the first page.

- Picture 1   Chemical seller
- Picture 2   Hospital
- Picture 3   Treatment at Home
- Picture 4   Traditional Healer
- Picture 5   Primary Care Clinic

SIGNS & SYMPTOMS OF CHILDHOOD ILLNESS

Child has diarrhoea and bloody stools

Child has difficulty fast breathing

Child is lethargic or unconscious

Child is vomiting everything

Child is convulsing

Child has fever
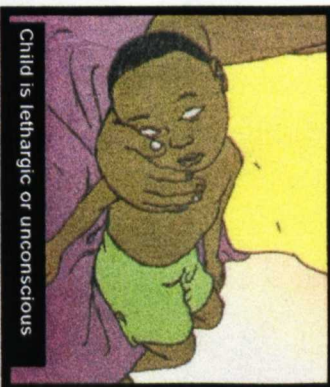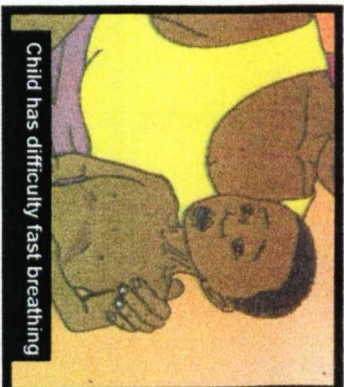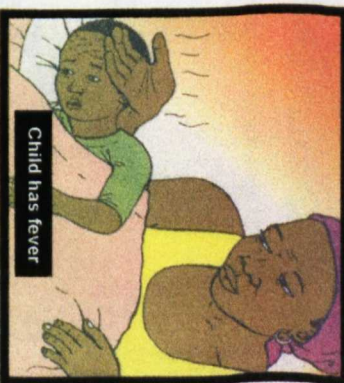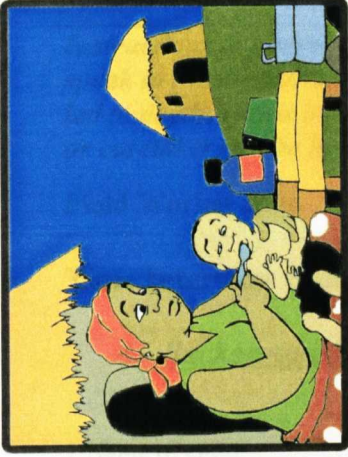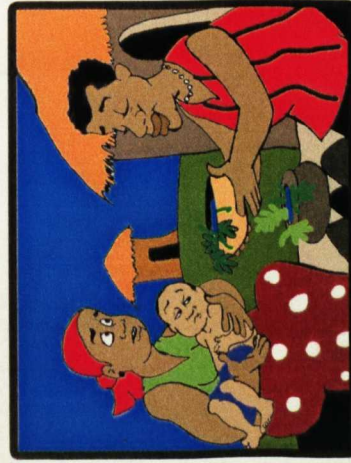
APPENDIX 16 PASSIVE MORBIDITY MONITORING FORM 3

FORM 6 VERBAL AUTOPSY QUESTIONNAIRE (ADAPTED FROM IN-DEPTH NETWORK)

Instructions to interviewer: Introduce yourself and explain the purpose of your visit. Ask to speak to the mother or to another adult caretaker who was present during the illness that led to death. If this is not possible, arrange a time to revisit the household when the mother or caretaker will be home.

Field Worker code ☐☐ **Date of Interview** ☐☐/☐☐/☐☐

Time Interview begun ☐☐.☐☐ am/pm

A. *Background Information on the Deceased*

1 Name of child:................................... ID: ☐

2 Community name .... ID: ☐

3 House ID ☐☐☐☐☐☐☐

4. Household Head name...

5. Household ID ☐☐☐☐☐

6. Date of Birth of child:...(dd/mm/yy) ☐☐☐☐☐☐

7. Sex of child:

1. Male	2. Female

8. Number of other siblings less than five years old ☐☐

9. Date of death of child: (dd/mm/yy) ☐☐☐☐☐

10. Age at death (Completed months) ☐☐☐☐ MTH

11. Where did (name of child) die?	1. Hospital	2. Other health facility	3.On route to hospital or health facility
	4: Home	5. Other (specify):.....................................	

12. For deaths at hospital or health facility, record facility name and address:

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B. INFORMATION ABOUT CARETAKER/RESPONDENT

13. What is the name of the main respondent: ....

14. What is the relationship of the main respondent to the deceased child?

1. Mother	2. Father	3. Grandmother	4. Grandfather	5.Aunt
6. Uncle		7. Other (specify):		

15. What is the age of the main respondent?   YRS

16. How many years of school has the main respondent completed?*

17. Highest level of education of respondent*:

1. Primary	2. Secondary	3. Tertiary	4. None

18. Of those present at the interview, which of the following were present at the time of the illness that led to death (YES, NO)?

	Present during illness	
1. Mother	1. Yes	2 . No
2. Father	1. Yes	2 . No
3. Grandmother	1. Yes	2 . No
4. Grand father	1. Yes	2 . No
5. Aunt	1. Yes	2 . No
6. Uncle	1. Yes	2 . No
7. Other (specify):	1. Yes	2 . No

19. Were other people present at the interview?

1.Yes	2.No

20. How is the mother's health now?

1.Not alive	2. Not healthy	3. Healthy

21. How is the father's health now? Is the father of the dead child healthy?

1.Not alive	2. Not healthy	3. Healthy

C. OPEN HISTORY QUESTION

22. Could you tell me about the illness that led to the childs's death?

Instructions to interviewer - Allow the respondent to tell you about the illness in his or her own words. Do not prompt except for asking whether there was anything else after the respondent finishes. Keep prompting until the respondent says there was nothing else. While recording, underline any unfamiliar terms.

Take a moment to tick all the signs and symptoms mentioned spontaneously in the open history questionnaire. Use this to guide you through the rest of the questionnaire.

Signs and symptoms	How many days after the illness started did the signs begin	Duration of signs (days)	Severity: (Mild-moderate or Severe)
22.1			
22.2			
22.3			
22.4			
22.5			
22.6			
22.7			
22.8			
22.9			
22.10			

Note: When possible, use local term for the symptom.

23 When did the problem/illness start?

1. Immediately after birth	2. After a period of well being
	999. NK

24 What was the length of time of the illness immediately preceding the child's death?

	999.NK

25. Was care sought outside the home while he/she had this illness?

1.Yes	2. No	999. NK

If 2 or 999 go directly to section D

26. How many days after illness started was care sought?

	999. NK

27. Where or from whom did you seek care? *(Record all responses)*

Traditional healer	1. Yes	2. No	999. NK
Religious leader	1. Yes	2. No	999. NK
Government hospital	1. Yes	2. No	999. NK
Government health centre/clinic	1. Yes	2. No	999. NK
Community-based practitioner	1. Yes	2. No	999. NK
Private physician or nurse	1. Yes	2. No	999. NK
Pharmacy	1. Yes	2. No	999. NK
Drug seller, store or market	1. Yes	2. No	999. NK
Relatives or friends	1. Yes	2. No	999. NK
Other (specify)	1. Yes	2. No	999. NK

After respondent finishes prompt: Did you seek care anywhere else?.....................................

28. Where or from whom was care sought first?

	888. NA	999.N K

29. Where or from whom was care sought second?

	888. NA	999.N K

30. Where or from whom was care sought third?

	888. NA	999.N K

D. ACCIDENTS AND INJURIES

31. Did s/he die from an injury or accident?

1.Yes	2. No	999. NK

If 2 or 999, go to section E

32. If yes ask: **What kind of injury or accident?** *Allow respondent to answer spontaneously.*

1. Transport accident (pedestrian)		2. Transport accident (passenger/driver)		3.Fall	4. Drowning	5. Poisoning (specify) ....
6. Animal bite	7. Other bites or sting	8. Burn	9. Firearm	10. Sharp object- e.g. knife		11. Circumcision
12. Assault/abuse (specify):			13. Other (specify):			

33. If answer to 32 is 6, please specify

1. Dog	2. Snake	3. Other (specify)	999.NK

34. Did s/he die at the site where accident or injury occurred?

1.Yes	2.No	999.NK

35. For how long after the accident or injury did s/he survive?

1.Died at the site	2. <24 hours	3.>=24 hours	999. NK

36. Did the child receive medical care before death?

1.Yes	2. No	999. NK

37. Did the child have an ongoing chronic illness or was he/she sick in the month before the accident or injury?

1.Yes	2. No	999. NK

38. If yes to 37, What was the illness? ....

Illness code | | |

Please check: If the child died from injury or accident skip to section F

E OTHER CHILDHOOD CONDITIONS
Reference period is within 1MONTH of the event of death.

39. Was the child growing normally for his/her age?

1.Yes	2. No	999. NK

40. Did the child get more sicknesses or illnesses than other children in the family or in the community?

1.Yes	2. No	999. NK

41. During the illness that led to death, did s/he have a fever?

1.Yes	2. No	999. NK

42. How many days did the fever last?

	999. NK

43. During the illness that led to death, did s/he have diarrhoea (more frequent or more liquid stools than usual)?

If no, go DIRECTLY to Q 49

1.Yes	2. No	999. NK

44. For how many days were the stools more frequent or liquid?

	999. NK

45. On the day when the diarrhoea was most severe, how many times did he/she pass stools?

	99. NK

46. Was there visible blood in the stools?

1.Yes	2. No	999. NK

47. Did the child have sunken eyes when he/she was ill with diarrhoea?

1.Yes	2. No	999. NK

48. During the diarrhoeal episode, was the child given any fluids such as or ORS? *(when preparing the country-specific questionnaire, insert a list of home made fluids recommended by the National CDD program)*

1.Yes	2. No	9. NK

49. During the illness that led to death, did the child have a cough?

If no, go DIRECTLY to Q 52

1.Yes	2. No	999. NK

50. For how many days did the cough last?

	999.NK

51. Was the cough severe?

1.Yes	2. No	999. NK

52. During the illness that led to death, did s/he have difficulty with breathing?
If no, go DIRECTLY to Q 54

1.Yes	2. No	999. NK

53. For how many days did the difficulty with breathing last?

	999. NK

54. During the illness that led to death, did the child have fast breathing?

If no, go DIRECTLY to Q 56

1.Yes	2. No	999. NK

55. For how many days did the fast breathing last?

	999. NK

56. During the illness that led to death, did s/he have in drawing of chest?

1.Yes	2. No	999. NK

57. During the illness that led to death, did he/she have wheezing? *(Demonstrate sound)*

1.Yes	2. No	999. NK

58. Did the child experience any generalised convulsions/fits during the illness that led to death?

1.Yes	2. No	999. NK

59. Was the child unconscious during the illness that led to death?

1.Yes	2. No	999. NK

60. At any time during the illness that led to death, did the child stop being able to grasp?

1.Yes	2. No	999. NK

If no, go DIRECTLY to Q 62

61. *If yes, ask:* How long before he/she died did the child stop being able to grasp?

1. Less than 12 hours	2. 12 hours or more	999. NK

62. At any time during the illness that led to death, did the child stop being able to respond to a voice?

1.Yes	2. No	999. NK

If no, go DIRECTLY to Q 64

63. *If yes, ask:* How long before he/she died did the child stop being able to respond to a voice?

1. Less than 12 hours	2. 12 hours or more	999. NK

64. At any time during the illness that led to death, did the child stop being able to follow movements with his/her eyes?

1.Yes	2. No	999. NK

If no, go DIRECTLY to Q 66

65. *If yes, ask:* How long before he/she died did the child stop being able to follow movements with their eyes?

1. Less than 12 hours	2. 12 hours or more	999. NK

66. Did the child have a stiff neck during the illness that led to death? (*Demonstrate*)

1.Yes	2. No	999. NK

67. Did the child have a bulging fontanel during the illness that led to death?

1.Yes	2. No	999. NK

68. During the illness that led to death, did s/he have a skin rash?

1.Yes	2. No	999. NK

If no, go DIRECTLY to Q 75

69. *If yes, ask:* Was the rash all over the child's body?

1.Yes	2. No	999. NK

70. Was the rash on the child's face?

1.Yes	2. No	999. NK

71. For how many days did the rash last?

	999. NK

72. Did the rash have blisters containing clear fluid?

1.Yes	2. No	999. NK

73. Did the skin crack/split or peel after the rash started?

1.Yes	2. No	999. NK

74. Was this illness measles (LOCAL TERM)?

1.Yes	2. No	999. NK

75. During the illness that led to death, did the child become very thin?

1.Yes	2. No	999. NK

76. During the illness that led to death, did the child have swollen legs or feet?

1.Yes	2. No	999. NK

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77. How long (days) did the swelling last?

	999. NK

78. During the illness that led to death, did the child's skin flake off in patches?

1.Yes	2. No	999. NK

79. Did the child's hair change in colour to a reddish (or yellowish) colour?

1.Yes	2. No	999. NK

80. Did the child have generalised body swelling during the month before he/she died (kwashiorkor)?

1.Yes	2. No	999. NK

81. Was the child miserable in the month prior to the death?

1.Yes	2. No	999. NK

82. Did the child have wasting and appear like an old man (marasmus) during the month before he/she died?

1.Yes	2. No	999. NK

83. During the illness that led to death, did the child suffer from lack of blood or appear pale?

1.Yes	2. No	999. NK

84. During the illness that led to death, did the child have pale palms?

1.Yes	2. No	999. NK

85. During the illness that led to death, did the child have white nails?

1.Yes	2. No	999. NK

86. During the illness that led to death, did the child have swellings in the armpits?

1.Yes	2. No	999. NK

87. During the illness that led to death, did the child have swellings in the groin?

1.Yes	2. No	999. NK

88. During the illness that led to death, did s/he have swellings in the neck?

1.Yes	2. No	999. NK

89. During the illness that led to death, did the child have a whitish rash inside the mouth or on the tongue?

1.Yes	2. No	999. NK

F TREATMENT AND RECORDS

Treatment

90. Did s/he receive any drug during the illness?

1. Yes	2.No	999. NK

91. Did s/he receive any antibiotics during the illness?

1. Yes	2.No	999. NK

92. Did s/he receive any anti-malarial drug during the illness?

1. Yes	2.No	999. NK

93. *If yes ask*: Which anti-malarial drug did s/he receive?

1.Choroquine	2.Fansidar	3.Quinine
4.Other	888. NA	999. NK

Health records

Source	Summary of details
Death Certificate	Cause of death:
Burial permit	Cause of death:
Post-mortem results	Cause of death:
MCH Card	
Hospital prescription forms	
Treatment cards	
Hospital discharge forms	Diagnosis:
Other hospital documents	
Laboratory/cytology results	
None	Tick here if there are no treatment records

G. INTERVIEWER COMMENTS AND OBSERVATIONS

_____

_____

_____

_____

_____

Certify correct on: | | | | | | | **By:** | | |

APPENDIX 17 FINAL HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 1

FORM 4C FINAL HOUSEHOLD CROSS-SECTIONAL SURVEY (XS) QUESTIONNAIRE- HOUSEHOLD DATA

About six months ago, we visited your home to discuss with you the health of your child/ren under five years of age. During our visit, we examined your child/ren. Today we have brought you the results of the first examination. In addition we will ask you a few questions and examine the children again to see if there is any change in their growth and development. We assure you once more that any information collected will be kept confidential. General findings will be made available to relevant authorities for the purpose of making important decisions and conclusions from this study.

(Interview to be conducted with household head and mother/principal female caretaker of child)

Field Worker code ☐☐   **Date of Interview** ☐☐/☐☐/☐☐
DD/MM/YY

Community..

Time Interview begun ☐☐.☐☐ am/pm

House ID ☐☐/☐☐/☐☐☐

Household ID ☐/☐☐☐

Name of Household Head [   ]

Name of Mother [   ]

Child/ren Study IDs ☐/☐☐☐☐/☐
☐/☐☐☐☐/☐
☐/☐☐☐☐/☐
☐/☐☐☐☐/☐

A. Health facility utilization

1. Can you tell me which the closest health facility to your home is?	
Dodowa health centre (1)	
Prampram health centre (2)	
Agomeda community clinic (3)	
Doryumu community clinic (4)	
Other specify.. (5)	
Kordiabe community clinic (6)	
Dawhenya community clinic (7)	☐☐
Ebenezer clinic (8)	

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Grace Maternity Home (9)	
Afienya Youth Leadership Clinic(Gliding school) (10)	
Afienya Community Clinic (Roger) (11)	
Military Camp Clinic, Doryumu (12)	
Military Camp Clinic, Congo (13)	

2. From which health facility do you usually seek care for <child/ren>?

Same as above (1)	
A hospital (2)	
Traditional healer/TBA (3)	
Prayer camp (4)	
Other (specify)... (5)	☐
Chemical Seller/Pharmacy (6)	
Drug peddler (7)	
Treat all illnesses at home myself (8)	
Child has never been ill (9)	

C. Mortality

3. In this past year, that is from Easter of last year to now, how many people in this household have died? ☐

None	(1)	One	(2)	Two	(3)
Three	(4)	Other specify................. (5)			

4. How old was he/she (were they)?

Not Applicable (99)

_____ yrs

_____ yrs

☐☐

5. What was/were the relationship/s of those who died to the <child>

Mother	(1)	Father (2)	Grandmother (3)
Grandfather	(4)	Other (specify) ....(5)	
Aunt	(6)	Uncle (7)	
Study child/ren died	(8)		
Not Applicable	(99)		

☐☐

6. How many of the child/ren under five years who died during the period died from a febrile illness?

None	(1)	One	(2)	Two	(3)
Three	(4)	Other specify..............			(5)
Not Applicable. No child died					(99)

☐☐

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D. Pre-payment Scheme

7. Have you ever heard about the Dangme Hewaminami Kpee (health insurance scheme)? Yes (1) No (2)	☐
8. How did you hear about it? Through friends (1) Through Radio (2) Leaflets/brochures (3) Through health staff (4) Others (Specify)...(5) Information van (6) Gong-gong beating (7) Assembly men (8) Through research staff (9) Not applicable (99)	☐☐
`9. Have you ever enrolled in the scheme? Yes (1) No (2) Not Applicable (99)	☐☐
10. Have you enrolled this past year? Yes (1) No (2) Not Applicable (99)	☐☐
11. Who paid the premium for you for this past year? Paid the total amount ourselves (1) Received support from friends/family (2) Total amount paid for household by current study (3) Received support from ILO (4) Not Applicable. Not enrolled this past year (99)	☐☐
12. Why did you not enroll this past year? No Money (1) Poor quality drugs (2) Poor quality of health care offered at the clinic (3) Staff reception poor (4) Other (specify)... (5) I live too far away from the nearest clinic (6) I did not hear when the registration was going on (7) Don't understand it (8) I think the premium is too high (9) Prefer to take the risk of falling ill (10) Had traveled during registration period (11) Wanted to wait and see what will happen (12) Not Applicable (99)	☐☐

13. Why have you never enrolled?

No Money	(1)
Poor quality drugs	(2)
Poor quality of health care offered at the clinic	(3)
Staff reception poor	(4)
Other (specify)...	(5)
I live too far away from the nearest clinic	(6)
I never hear when the registration is going on	(7)
Don't understand it	(8)
I think premiums are too high	(9)
Prefer to take the risk of falling ill	(10)
Usually traveled during registration period	(11)
Not Applicable	(99)

15. Do you plan to enroll your household this year?

Yes	(1)	No	(2)
Not sure	(3)	If someone pays for me	(4)
Other (specify)..(5)			
Study promised to pay for us this year	(6)		

Thank you very much for your very useful answers and your time.

Time Interview ended ☐☐☐☐ am/pm

APPENDIX 18 FINAL HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 2

FORM 4D HOUSEHOLD CROSS-SECTIONAL SURVEY (XS) QUESTIONNAIRE- CHILD DATA

(Interview to be conducted with household head and mother/principal female caretaker of child)

Field Worker code ☐☐   Date of Interview ☐☐/☐☐/☐☐

Community...

Time Interview begun ☐☐.☐☐ am/pm

A. *Child Background Information*

1. House ID   ☐☐/☐☐/☐☐☐

2. Household ID   ☐/☐☐☐

3. Name of Household head   ☐

4a. Child's Study ID   ☐/☐☐☐/☐

4b. Does <Child> have a Green Card?   Yes (1)   No (2)   ☐

4c. Child's Green Card ID Number   ☐☐/☐☐/☐☐☐/☐☐

5. Child's Name   ☐

6. Sex   Male (1)   Female(2)   ☐

7. Child's Date of Birth (*Check Birth Certificate/RTH Card*) ☐☐/☐☐/☐☐
    DD/ MM / YY

8. Age (*in completed months*)   ☐☐ Months

9. Number of <u>other</u> siblings less than five years old   ☐

10. Relationship of main respondent to child

Mother	(1)	Father	(2)	Grandmother	(3)
Grandfather	(4)	Other specify ....(5)			
Aunt	(6)	Uncle		(7)	☐

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B. <Child> morbidity

10b. In this past year, that is from Easter of 2004 to now, how many times has <child> been ill?	☐ times
11. In this past year, that is from Easter of 2004 to now, has <child> been admitted to a hospital and slept overnight? Yes (1) No (2) Not Applicable (99)	☐☐
12. How many times was <child> admitted for malaria (asra) within the same period? Not Applicable (99)	☐☐ times
13. When was the most recent admission? Yesterday (1) Two to three days ago (2) A week ago (3) Two weeks ago (4) Two weeks to a month ago (6) A month ago (7) More than a month ago (8) More than a year ago (9) Child has never been admitted before (10)	☐
14. Now we want to talk about your child's most recent illness. When was the last time your <child> fell ill? Yesterday (1) Two to three days ago (2) A week ago (3) Two weeks ago (4) Two weeks to a month ago (6) A month ago (7) More than a month ago (8) More than a year ago (9) Child has never been ill before (10)	☐
15. When <child> was last ill, where did you seek care for <child>? *(if child was sent to health facility, go directly to Q18 and indicate "Not Applicable" for Q16 and Q17)* Home (1) Drug Peddler (2) Chemical seller (3) Traditional Healer (4) Other. Specify...(5) Clinic (6) Hospital (7) Not Applicable (99)	☐☐

16. There are many reasons why children are not sent to a health facility when they are sick. In this instance what was the special reason *(tick all the spontaneous responses after listening carefully to the mother's report)*?

Too expensive. Could not afford it	(1)
Transport costs too high	(2)
Difficult to obtain transport	(3)
Staff there are not technically competent	(4)
Other(specify)...(5)	
Staff there are not nice to patients	(6)
Know how to treat the illness at home	(7)
Prefer to use herbal drugs	(8)
Chemical seller closer	(10)
Traditional healer/TBA closer	(11)
Not applicable. Child taken to health facility	(99)

☐☐

17. You have said that_____ and _____ and _____ are the reasons why <child> was not sent the health facility. Of all the reasons you have given me which is the most important *(Still use the options in Q16)*

☐☐

C. Household expenditure on health care for child

18. Now let's discuss expenditure for this last illness. How much did you spend on:

Place	Activity	Amount Spent
	Direct health care costs	........................cedis
	Transportation to and fro	........................cedis
	Other costs(gifts, food)	........................cedis
	Direct health care costs	........................cedis
	Transportation to and fro	........................cedis
	Other costs(gifts, food)	........................cedis
	Direct health care costs	........................cedis
	Transportation to and fro	........................cedis
	Other costs(gifts, food)	........................cedis

Total costs ....cedis Not Applicable. (99)		☐☐

19. Was enough money available in the house to pay? Yes (1) No (2) Not Applicable (99)	☐☐

20. If enough money was not available, how was money obtained to pay?
 	
    Sold agricultural produce (crops, animals etc) to pay(1)
 	
    Provided paid labour to pay   (2)
 	
    Sold personal effects to pay   (3)
 	
    Money contributed by relatives/friends   (4)
 	
    Other specify...(5)
 	
    Pawned personal effects to pay   (6)
 	
    Went for a loan   (7)
 	
    Not applicable. Money was available at home   (99)
	☐☐

21. Who in the family decides that a mother should take her child for consultation when child is ill?
 	
    Mother   (1)   Father (2)   Both parents (3)
 	
    Grandmother (4)   Other (Specify)....................(5)
	☐

D. Malaria and preventive measures

22. Does this household use any preventive measures for malaria ("asra" / "atridii")? Yes (1) No (2)	☐
23. How do you usually protect <child> against malaria? *(Interviewer to prompt if a preventive method is not mentioned unprompted)* i)Treated bed nets/curtains Yes (1) No (2) ii)Untreated bed nets Yes (1) No (2) iii)Mosquito netting on windows/doors Yes (1) No (2) iv)Mosquito spray/coils Yes (1) No (2) v)Burning of local herbs/orange peels Yes (1) No (2) vi) Other (specify)..	☐ ☐ ☐ ☐ ☐
24. Does this household own a bed net ("mudo") ? Yes (1) No (2)	☐☐
25. How many nets does the household own? *(indicate 99 if household does not own a net)*	☐☐

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APPENDIX 19 FINAL HOUSEHOLD CROSS-SECTIONAL SURVEY FORM 3

FORM 5A FINAL ANTHROPOMETRIC AND HAEMATOLOGICAL FIELD ASSESSMENT (AH) FORM

Field Worker's code ☐☐   Date of examination ☐☐/☐☐/☐☐

Community...

Time Examination begun ☐☐☐ am/pm

1. House ID ☐☐/☐☐/☐☐☐

2. Household ID ☐/☐☐☐

3. Name of Household head

4. Mother's Name

5. Child's Study ID ☐/☐☐☐/☐

6. Name of Child

7. Sex of child   Male   (1)   Female   (2)   ☐

8. Age (*in completed months. FW to check study ID*)	☐☐ Months
9. Mid Upper Arm Circumference	☐☐.☐ cm
10. Height/length	☐☐☐.☐
11. Weight	☐☐.☐ kg
12. History of fever in the past week? Yes (1) No (2)	☐
13. Temperature today(*FW to measure temperature and record*)	☐☐.☐ °C
14. Smear taken? Yes (1) No (*state why in space for comments*) (2)	☐
15. Haemoglobin count	☐☐.☐ g/dl
16.Malaria Dipstick Results Positive (1) Negative (2) Not Applicable(no history of fever & child's temp below 37.5°C (99)	☐☐

17. Body Mass Index (BMI = Wght/Height^2 *FW to leave this blank*)	☐☐ kg/m^2
Time Examination ended ☐☐☐☐ am/pm	

18. Comments

19a. Urine sample taken:	Yes (1)	No(2)	☐
19b.Filter Paper blood sample taken?	Yes(1)	No(2)	☐

*The **difference** between the two results for **height/length should not exceed 5mm.** If it does two fieldworkers should retake measurements

Checked: Supervisor Code ☐☐   **Date_____/____/05**

Explaining to a mother how to administer the pre-packaged amodiaquine-artesunate tablets to her child who was found to have malaria during field-work

Anti-malarials, mostly of herbal origin, available in a chemical seller's shop in one of the communities

APPENDIX 20 FINAL QUALITATIVE STUDY FORM 1

FOCUS GROUP DISCUSSION GUIDE FOR MOTHERS AND FATHERS OF CHILDREN UNDER FIVE WITH OR WITHOUT IMPROVED FINANCIAL ACCESS TO HEALTH CARE

1.BACKGROUND INFORMATION

Name   Marital Status
Age   Educational Status
Sex   Number of children
Occupation   Number Under 5

2. GENERAL INFORMATION ON HEALTH AND TREATMENT SEEKING BEHAVIOUR

1. What disease conditions in this community lead to severe illness in children?
2. What disease conditions in this community lead to death in children?
3. What are the available sources of health care for mothers with sick children in this community?
4. At what stage of the illness do mothers take their children for consultation?
5. Who in the family decides that a mother should take her sick child for consultation?
6. How long does it take to get to the nearest health facility?
7. What factors delay seeking health care and treatment promptly?
8. Which source of care do you prefer?
9. What makes you prefer that source of care?

3. FACTORS INFLUENCING ADHERANCE TO DRUGS PRESCRIBED

What influences your decision to complete taking drugs you have been given at whichever source of care you prefer?

4. PERCEPTIONS OF THE PRE-PACKAGED AMODIAQUINE – ARTESUNATE COMBINATION

1. What drugs are you given when your children have malaria fever and you send them to the clinic?
2. Any change in the drugs being given over the past year?
3. Experience with packaged drugs? Compare to chloroquine syrup? Ability to cure the illness? Cost? Preference?

5. PERCEPTIONS ON QUALITY OF CARE IN THE PUBLIC HEALTH FACILITIES IN THE DISTRICT

1. What are some of the things you would you like to see in a health facility delivering quality health care?
2. How important are these to you in your perception of Quality?
   a. General appearance/surroundings of the clinic? What would you like to see?
   b. Length of time spent at clinic
   c. Content of Interaction with provider
   d. Privacy during consultation?
   e. Kind of drugs given at the dispensary?
   f. Number of different types of drugs prescribed?
   g. Interaction at the dispensary? Counselling on how to take drugs?

3. What do you think of the quality of care in the health facilities around here?

6. PERCEPTIONS AND PRACTICE ON Insecticide Treated Nets (ITNS)

1. What do you know about bed nets?
   a. Are there different kinds?
   b. Benefits of sleeping under them?
   c. What would prevent people from sleeping under them?
2. Sources of ITNs
3. Cost of ITNs
4. Re-treatment Issues: How often, who can do it, where can it be done, where can tablets/ chemical be obtained?
5. Who should have priority in sleeping under ITNs in the home if limited number available? Why?
6. Any promotional programmes for ITNs seen, heard, participated in since Easter till now?

7. PERCEPTIONS ON DANGME WEST HEALTH INSURANCE SCHEME

1. How do you pay for health care when your child is sick
2. Have you heard of the Dangme Hewaminami Kpee?
   k. What have you heard about it
   l. From whom
   m. Are you enrolled
   n. How did you get enrolled? Paid yourself? Someone paid for you?
3. Perceptions and experience with the scheme
4. What do you know about the National Health Insurance Scheme? **Probe for any difference between it and the DHK**
5. Do you plan to enrol in the Dangme West Health Insurance scheme next year? Why?

Thank you very much for your time and for giving us insight into these important issues affecting health in this area.

APPENDIX 21 QUALITY OF CARE STUDY FORM 1

QUALITY OF CARE STUDY-CLIENT RECRUITMENT SLIP
DANGME WEST DISTRICT

Name of Health Facility_____Client Serial No____/___ ___ ___

Time client entered clinic: ☐☐.☐☐ am/pm

Name _____Age_____yrs ____mths

OPD No:_____

Temp_____°C   Weight_____kg BP_____mmHg

Presenting Complaints

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

Diagnosis/es

_____

_____

_____

Treatment

_____

_____

_____

_____

Time client left clinic: ☐☐.☐☐ am/pm

APPENDIX 22 QUALITY OF CARE STUDY FORM 2

CLIENT PERCEPTION OF QUALITY OF CARE
AT HEALTH FACILITIES IN THE DANGME WEST DISTRICT

Good Morning/Afternoon. my name is .... We are assessing the services given at this Health Facility in order to find ways of improving on them and we would like to ask you a few questions.

Field Worker Code: ☐☐   Time interview begun ☐☐.☐☐ am/pm

Health Facility .... Date of Attendance ___ ___ / ___ ___ / ___ ___
                                                                        DD/MM/YY

OPD Card Number.................... Green Card Number............................

Community client lives in...

Study Serial Number ____ / ___ ___ ___

A. PERSONAL VARIABLES

1.Date of Birth *(Day/ Month/ Year)*	☐☐/☐☐/☐☐ DD/MM /YY
2.Age of respondent *(in completed years and months)*	☐☐ yrs ☐☐ mths
3.Age of patient *(in completed years and months)*	☐☐ yrs ☐☐ mths

4.Sex
 	
    Male   (1)
    Female   (2)
	'☐

5.Main Occupation
 	
    Farmer   (1)   Fisherman (2)
    Civil Servant (3)   Artisan   (4)
    Other. Specify...........................(5)
    Trader   (6) Fishmonger   (7)
    Unemployed (8)
	☐

6.Educational Level Tertiary {Post Sec., University, Polytechnic} (1) Second Cycle {Secondary, Commercial, Vocational (2) First Cycle {Primary, JSS, MSLC (3) None.......................................(4)	☐

7.Number of years of formal education completed by respondent	☐☐
8. What is your religion? Christian (1) Muslim (2) African Traditional (3) Agnostic (4) Other (specify)............................ (5)	☐
9. What is your ethnic group? Dangme (1) Ga (2) Akan (3) Ewe (4) Other(specify).........(5) Krobo (6) Northern/Upper (7)	☐
10.Type of respondent Accompanied ward (1) Self user (2)	☐
11. How many times have you visited this Health Centre? First Time (1) Second Time (2) Three or More Times (3)	☐
12. There are several health facilities in this district. For this visit who chose this particular Health Centre for you? A Nurse (1) Another patient (2) A family member (3) A friend (4) Other specify...................................(5) Self (6)	☐

B. Communication :(Staff/Patient)

13. Did Doctor examine you? Yes (1) No (2)	☐
14. Did she tell you what is wrong with you? Yes (1) No (2)	☐
15. Did she give instructions about your illness? Yes (1) No (2)	☐

16. Did the nurses or other staff explain to you about tests, treatments and what to expect? Yes (1) No (2)	☐
17 Did you have privacy during your visit? Yes (1) No (2)	☐
18. How do you rate the amount of information you were given about your illness, its treatment and what to do after leaving the health centre? Excellent (1) Good (2) Fair (3) Poor (4) Poor (6)	☐
19. Were the staff willing to answer any questions from you on things you did not understand? Yes (1) No (2)	☐

C. Attitude of staff:

20. Generally how did you find the behaviour of the staff at the Health Centre towards you? Polite/courteous (1) Friendly/helpful (2) Unfriendly (3) Rude (4)	☐
21. Explain your answer to the above question.	
22. In general how would you rate respect and courtesy of the staff at the Health Centre here? Excellent (1) Good (2) Fair (3) Poor (4) Very Poor (5)	☐

D. Length of time spent

23. What do you think about the length of time you spent at this health centre? Shorter than expected　　　　　　(1) Just enough　　　　　　　　　　(2) Long　　　　　　　　　　　　　(3) Very long　　　　　　　　　　　(4)	▢
24. Where exactly did you spend too much time (the most)? OPD (Records)　　　　　　　　　　　(1) OPD (Nurses Station for vital signs)　　(2) Consulting room　　　　　　　　　　(3) Dispensary　　　　　　　　　　　　(4) Other. Specify.................................. (5) Laboratory　　　　　　　　　　　　(6) Treatment/Dressing Room　　　　　　(7) Family Planning Clinic　　　　　　　(8) Child Welfare Clinic　　　　　　　　(9) Not Applicable. Did not spend too much time(99)	▢▢
25. What do you think might have accounted for the long time spent?.. .... Not Applicable. Did not spend too much time　　(99)	▢▢
26. Do you think it was an unnecessary delay? Yes　　　　　　　(1)　　　　No　　(2) Not Applicable　　　　　　　　　　(99)	▢
27. What suggestions can you make towards reducing the time spent at this health facility?...	
28. Have you attended this health facility for emergency care in the last six months? Yes　　　　　(1)　　　　No　　　　(2)	▢
29. If yes were you seen promptly? Yes　　　　　(1)　　　　No　　　　(2)	▢

Not Applicable. Have not attended this HF for an emergency (99)	☐

30. How would you rate the skills of the staff at this health centre in treating your condition? Excellent (1) Good (2) Fair (3) Poor (4) Very Poor (5)	☐

F. Availability of drugs

31. Did you understand your instructions from the Dispensary Technician? Yes (1) No (2)	☐

32. What do you think of the quality of the drugs you have been given? Excellent (1) Good (2) Fair (3) Poor (4) Very Poor (5)	☐

33. What would you like to see in order to improve the quality of the drugs

....

....

....

34. How does the availability/unavailability of drugs affect your perception of quality of service at this health facility? Explain

....

....

....

....

G. Physical structure of this Health Facility

35. How would you rate the building of this health centre overall? Excellent (1) Good (2) Fair (3) Bad (4)	☐

H. Sanitation

36. What can you say about sanitation at this health centre? Very neat (1) Neat (2) Fairly neat (3) Dirty/Untidy (4)	☐
37. Which place(s) were not neat if any? (*Multiple answers allowed. Tick all and write down options on the right*) OPD (Records) (1) OPD (Nurses Station for vital signs) (2) Consulting room (3) Dispensary (4) Other. Specify.. (5) Laboratory (6) Treatment/Dressing Room (7) Family Planning Clinic (8) Child Welfare Clinic (9) Not Applicable. All places neat (99)	☐☐

38. What do you think should be done to maintain proper cleanliness?

....

....

I. Overall Quality/Satisfaction

39. How would you rate the overall quality of care you received at this health centre? Excellent (1) Good (2) Fair (3) Poor (4) Very Poor (5)	☐
40. Would you recommend this health centre to your family and friends, if they need medical care? Yes (1)　　No (2)	☐
41. Please explain your answer to question 40 above	

42. Are you likely to return to this health centre if ever you needed medical care?

Yes   (1)   No   (2)

Not sure   (3)

☐

43. Please explain your answer to question 42 above.

....

....

44. Can you please suggest what can be done to improve upon the quality of care being rendered at this health centre.

....

....

45. Have you been given receipts for all payments made at this health facility?

Yes   (1)

No   (2)

Not Applicable. I did not pay anything   (99)

☐☐

46. Where and how much was paid?

Records	_____	(1)
Maternity	_____	(2)
OPD (Vital Signs Station)	_____	(3)
Consulting Room	_____	(4)
Dispensary	_____	(5)
Laboratory	_____	(6)
Child Welfare Clinic	_____	(7)
Family Planning Clinic	_____	(8)
TOTAL	_____	
Not Applicable		(99)

☐☐

Thank you very much for your useful answers and your time

Time Interview ended   ☐☐.☐☐ am/pm

    Checked: Supervisor Code   ☐☐   **Date Checked**
          ____/____/ 04

APPENDIX 23 LABORATORY FORM 1

FORM 5C FINAL ANTHROPOMETRIC AND HAEMATOLOGICAL FIELD ASSESSMENT REPORT FORM- FOR DAY 14 SLIDE AND URINE DIPSTICK RESULTS

Field Worker Code ☐☐

Community...

1. Child's Study ID ☐/☐☐☐/☐

2. Name of Child [ ]

3. Sex of child   Male   (1)   Female   (2)   ☐

4. Urine Sample taken?   Yes   (1)   No   (2)   ☐

5. Day 14 slide taken?   Yes   (1)   No   (2)   ☐

6. Date Day 14 slide taken ☐☐/☐☐/☐☐
DD/ MM / YY

****

Laboratory Staff Code   ☐☐

Day 14 Slide Results

a)Species* (see below)	b)Asexual Parasites / µl	c) Gametocytes/ µl	Comment

*Species: P. falciparum = 1 P. malariae = 2 P. ovale = 3 Pf + Pm = 4 Pf + Po = 5 Pf +Pm + Po =6

Urine Dipstick results

    Positive for Chloroquine/Pyrimethamine   (1)   ☐
    Negative for Chloroquine/Pyrimethamine   (2)

Checked: Supervisor Code ☐☐   Date____/___/05

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APPENDIX 24 LABORATORY FORM 2

FORM 9   MICROSCOPY RESULTS FORM DANGME WEST MALARIA AND ACCESS STUDY

Microscopist Name..   Institution...

Date of Examination (dd/mm/yy) ☐☐/☐☐/☐☐

No	Child ID	Date of (dd/mm/yy)	Smear	Species *(see below)	Asexual Parasites / µl	Gametocytes/ µl	Comment
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					
	☐☐☐/☐☐	☐☐/☐☐/☐☐					

*Species: P. falciparum = 1 P. malariae = 2 P. ovale = 3 Pf + Pm = 4 Pf + Po = 5

APPENDIX 25 LABORATORY FORM 3

ANAEMIA INVESTIGATION STOOL R/E RESULTS FORM – MALARIA AND ACCESS STUDY

Microscopist Name...

Institution...

Date of Examination (dd/mm/yy) ☐☐☐/☐☐/☐☐

S/N	Child ID	Date of Sample Collection (dd/mm/yy)	Child Name	Comm. Code	Ascaris	Hookworm	T.T	Other	Remarks
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							
	☐☐☐/☐☐/☐☐	☐☐/☐☐/☐☐							

APPENDIX 26 LABORATORY FORM 4

ANAEMIA INVESTIGATION URINE R/E RESULTS FORM – MALARIA AND ACCESS STUDY

Microscopist Name...   Institution...........................

Date of Examination (dd/mm/yy) ☐☐ / ☐☐ / ☐☐

S/N	Child ID	Date of Sample Collection (dd/mm/yy)	Child Name	Community Code	S. haematobium	S. mansoni	Comment
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					
	☐☐ / ☐☐ / ☐☐	☐☐ / ☐☐ / ☐☐					

APPENDIX 27 LABORATORY FORM 5

ANAEMIA INVESTIGATION G6PD RESULTS FORM – MALARIA AND ACCESS STUDY

Microscopist Name.. Institution...

Date of Examination (dd/mm/yy) ☐☐ / ☐☐ / ☐☐

S/N	Child ID	Date of Sample Collection (dd/mm/yy)	Child Name	Community Code	G6PD Status	Comment
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐				

APPENDIX 28 TRAINING MATERIAL 1

FIELD LABORATORY TRAINING PROTOCOL
DANGME WEST MALARIA AND ACCESS STUDY

Purpose of Training:

Malaria microscopy is the key to the diagnoses of malaria.

This training is to teach you:

➢ How to take capillary blood samples from a patient and prepare thick and thin blood smears on a slide.

➢ How to read the haemoglobin concentration of a patient using the **Haemocue.**

➢ How to use the Optimal –IT (Instant malaria strip) for the diagnosis of malaria.

A. BLOOD SMEAR FOR MALARIA PARASITES

Equipment required.

➢ Clean glass slides

➢ Sterile lancets

➢ Alcohol swabs

➢ Slide boxes

➢ Lead pencil/marker

➢ Disposable container

➢ Gloves

➢ Cotton balls

Method.

Slide Preparation.

➢ Label the slides with the child ID, Community and Date.

➢ Clean the slides thoroughly with a clean tissue handling the slides by the edges only, as any grease of fingerprints on the slides will impair smear quality.

Getting a blood sample from a finger prick.

➢ Turn the patients palm upwards and hold the third finger between your left thumb and first finger

➢ Wipe patient's finger with alcohol swab and dry with clean cotton.

➢ Puncture the ball of the finger with a sterile lancet and allow blood to ooze.

➢ Wipe away the first drop of blood with clean cotton and gently squeeze the finger to express more blood.

➢ Holding a clean slide by the edges, collect a single drop on the middle of the slide (thin film)

➢ Collect about 2-3 drops 1cm away from the single drop (thick film)

➢ Wipe away any excess blood.

Preparation of a thick film.

➢ Place about 2-3 drops on the lower section of the slide

➢ Using the edges of another clean slide spread the blood over an area of about 10mm diameter.

➢ Air dry the slide for about 15-20 mins (protect from flies and dust)

Preparation of a thin film.

➢ Place a small drop of blood on the middle of the slide.

➢ Bring the second slide (spreader) down horizontally at an angle of 30°-45° and steadily run the spreader down the surface of the slide drawing the blood behind it until the smear is formed. (**Blood is dragged behind the spreader not in front of it!**)

➢ Allow to air dry.

Pack the slides individually into slide boxes.

Qualities of good thick and thin smear.

Thick smear

➢ It should be 10mm away from the edges of the slide

➢ It is round in shape

Thin smear

➤ It is tongue shaped

➤ Uniformly spread over the slide

➤ Thin enough so that newsprint can be read through the smear.

NB.

◆ Wear gloves any time you are dealing with a patient's blood, as they may be infectious.

◆ All used lancets, cotton balls, swabs and other equipments used on the patient's blood should be disposed off into the disposable container right after use.

◆ Always keep your work clean and not messy.

◆ Wash hands often.

B. HAEMOCUE FOR HAEMOGLOBIN COUNT (Hb)

Use of Haemocue Photometer

◆ The Haemocue is calibrated before every days use by a standard calibration in the bag provided by the manufactures.

◆ A blood sample is obtained from a patient using the above-explained method (making finger prick).

◆ Make sure that the drop of blood is big enough to fill the cuvette completely.

◆ Introduce the cuvette tip into the middle of the drop to fill

◆ Wipe off the excess blood on the outside of the cuvettte tip. Make sure no blood is drawn out of the cuvette in this procedure.

◆ Place the cuvette into the cuvette holder immediately and push into the measuring position. After 15-45 seconds the result is displaced.

◆ Record the results on the child's form.

◆ Discard the used microcuvette

C. OPTIMAL IT KIT FOR INSTANT TEST FOR MALARIA PARASITES

Use of the Optimal IT. (Individual Rapid Malaria Test)

Optimal-IT is a dipstick test for the detection of an infection by *Plasmodium spp.* in human blood samples diffentiating between *P.falciparum, P.vivax, P.ovale* and *P.malariae.*

The test is only positive when live parasites are present in the blood. The result is obtained in 20mins.

Contents of test kit.

Each single test package contains;

- ➢ 1 device with dipstick, conjugate well, wash well and well cover
- ➢ 1 dropper ampoule with buffer
- ➢ 1 lancet
- ➢ 1 disinfecting swab
- ➢ 1 pipette
- ➢ 1 schematic test procedure

Procedure

- ➢ Place the device on a horizontal surface, write the patients name or number on the label
- ➢ Tear open the ampoule of buffer, add 1 drop of the buffer to the first well (conjugate well) and 4 drops to the second well (wash well). Allow standing for 1 minute.
- ➢ Clean the $3r^d$ finger of the patient with the swab, let dry and prick the finger with the lancet. Take the pipette, squeeze it and place the open tip into the blood drop, release pressure and draw blood to the black line. *NB* Discard used swab and lancet into a suitable container.
- ➢ Add the blood to the 1st well by squeezing the pipette gently.
- ➢ Stir gently with the upper end of the pipette and allow to stand for a min. (discard pipette)

> Pull the IT device apart using the thumb and forefinger and insert the legs of the dipstick holder into the holes beside the conjugate well so that the dipstick reaches the bottom of the conjugate well. Allow standing for 10 mins. *The conjugate mixture should be completely soaked up.*

> Transfer the dipstick too the 2nd well and allow to stand for 10 mins. The reaction field should then be completely cleared off.

> Remove the dipstick from the wash well and place it back in the clear plastic piece. Close the well with the well cover.

> Read the reaction and interpret the results.

Positive results:

"P" and "C" bands present- Positive *for P. vivax or P. malariae or P. ovale.* But negative for *P. falciparum*

"Pf", "P' and 'C" bands present- Positive for *P. falciparum.*

NB.

The dipstick slide could be kept for future reference and for comparison in case of further tests and for monitoring the efficacy of treatment.

Valid Results.

The result is valid if the
> Reaction field is cleared of blood.

> Control and diagnostic bands are clearly visible (dense line).

Results is not valid if

> The dipstick is not sufficiently cleared of blood.

> The control band is not present

> The control band is not visible even if one or both of the diagnostic bands are present.

> The control band and the band "Pf" band are present whilst the "P" band is absent.

Note.

• Always handle blood specimens with care, as they may be infectious.

• Wear gloves any time you are dealing with a patient's blood.

- All used lancets, cotton balls, swabs and other equipments used on the patient's blood should be disposed off into the sharps bin and gloves into the polythene provided right after use.
- Always keep your work clean and not messy.
- Wash hands often.

D. TAKING OF A FILTER PAPER SAMPLE

- Make a finger prick to obtain a good blood sample

FILTER PAPER SAMPLE
- Fold the filter paper into two halves and tear
- Label Child's ID and date at the bottom of the paper
- Make a finger prick to obtain a good blood sample from the third finger
- Use the filter paper to absorb the blood ball formed
- Make two spots on the paper
- Allow it to dry
- Keep sample in a clean place
- Submit it to supervisor at the end of the day for storing in a cool place

APPENDIX 29 TRAINING MATERIAL 2

INSTRUCTIONS FOR ANTHROPOMETRIC MEASUREMENTS

1. TAKING BODY LENGTH MEASUREMENTS USING THE ROLLAMETRE

1. Remove from container and lay flat on any suitable surface (e.g. mat). It is essential that the Rollametre is fully unrolled and lies as flat as possible. The foot-rest, on which the measuring rule is located, should now be against the foot end of the Rollametre.

2. Place the infant on the black foam bed (with rubber covered to avoid soiling) with its' head resting against the headpiece, (on which the name Rollametre appears).

3. Following standard practice the child's head is held in position, with the legs straightened for total length.

4. The foot-rest on which the measuring tape is mounted is moved to touch the Infant by depressing the red button on the tape and the measurement read from the Cursor in the tape window.

5. Take another measurement and strike average.

This instrument will not work satisfactorily unless a child is placed on the mattress as the child's weight will stabilize the Rollametre.

To store the Rollametre, return the foot-rest to the end of the Rollametre so that the tape is fully retracted into its case. Beginning at this end, roll the instrument over and over until the mattress is fully wound and the foot end rests against the headboard. Replace in container.

N.B: ALWAYS DEPRESS THE BUTTON WHEN MOVING THE FOOT-REST

2. TAKING THE MID-UPPER ARM CIRCUMFERENCE (MUAC) USING THE SHAKIR'S STRIP

1. **Measurer:** Keep your work at eye level. Sit down when possible. Very young children can be held by the mother during this procedure. Ask the mother to remove clothing that can cover the child's left arm.

2. **Measurer:** Calculate the midpoint of the left upper arm by first locating the tip of the child's shoulder with your finger tips. Bend the child's elbow to make a right angle. Place the tape at zero, which is indicated by two arrows, on the tip of the shoulder and pull the tape straight down past the tip of the elbow. Read the number at the tip of the elbow to the nearest centimetre. Divide this number by two to estimate the midpoint with a pen on the arm.

3. **Measurer:** Straighten the child's arm and wrap the tape around the arm at the midpoint. Make sure the numbers are right side up and the tape is flat around the skin.

4. **Measurer and Assistant:** Inspect the tension of the tape on the child's arm. Make sure the tape has the proper tension and is not too tight or too loose. Repeat any steps as necessary.

5. **Measurer:** When the tape is in the correct position on the arm with the correct tension, read and call out the measurement to the nearest 0.1 cm.

6. **Assistant:** Immediately record the measurement on the questionnaire and show it to the measurer.

7. **Measurer:** While the assistant records the measurement, loosen the tape on the child's arm.

8. **Measurer:** Check the recorded measurement on the questionnaire for accuracy and legibility. Ask the assistant to erase and correct any errors.

9. **Measurer:** Remove the tape from the child's arm.

3. MEASURING THE HEIGHT USING THE STADIOMETER

1. Stand subject/child on the "feet" preferably barefoot with his/her heels together and touching the backstop. The head, buttocks, spine at the pelvis and shoulder level and calf should touch the upright. Shoulders should be relaxed, with arms to the side. Remove headgear (bows, ribbons etc.) where possible.

2. Lower the measuring arm onto the head and position the head so that an imaginary horizontal line runs between the ear hole and the lower border of the eye socket.

3. Ask the subject/child to stand up straight.

4. Apply pressure (slight) to abdomen.

5. Ensure calf is against backboard and feet firmly on the ground.

6. Read off the Metric height to the last completed millimeter. Do not round up! Measure with care.

7. Record the measurement.

8. Take another measurement and strike average.

APPENDIX 30 TRAINING MATERIAL 3

ANTHROPOMETRY FIELD CHECKLIST
MALARIA AND ACCESS STUDY

1. WEIGHT MEASUREMENTS

Child cooperates and stands on scale

1. Zero scale
2. Child stands on scale
3. Read the child's weight
4. Note it carefully and record to the nearest 0.1kg
5. Record the new weight to the nearest 0.1kg

Child refuses to cooperate

1. Zero scale
2. Mother stands on scale
3. Read the mother's weight
4. Note it carefully and record to the nearest 0.1kg
5. Give child to mother and note change in weight
6. Subtract the new weight from the mother's weight
7. Record the new weight to the nearest 0.1kg
8. This is the weight of the child.
9. Repeat the procedure and take the average if necessary

NB: Remember the scale is sensitive and both mother and child should remain calm during the measurement

BODY LENGTH MEASUREMENTS

1. Position head
2. Top of head (vertex) touching headboard
3. Body should lie straight on rollameter
4. Legs should lie straight on rollameter
5. Footboard to touch heels (perpendicular to rollameter)
6. Read to the last completed unit (mm)

HEIGHT MEASUREMENTS

1. Child stands against vertical backboard
2. Heels, calves, buttocks and shoulder blades in contact with backboard
3. Position head
4. Headboard touches top of head
5. Read height to the last completed unit (mm)

ARM CIRCUMFERENCE MEASUREMENTS

1. Position child
2. Arm bent at right angles
3. Mark mid-point between shoulder (acromion) and elbow (olecranon)
4. Straighten arm and ensure it is relaxed
5. Pass tape around arm
6. Cross-over tape ends
7. Ensure tape touches skin (but does not depress skin)
8. Read to last completed unit (mm)

APPENDIX 31 TRAINING MATERIAL 4

HOW TO USE THE BRAUN EAR THERMOMETER
<u>MALARIA AND ACCESS STUDY</u>

1. Always make sure a clean lens filter is in place. **THE THERMOMETER WILL NOT FUNCTION WITHOUT A LENS FILTER ATTACHED!!!!**

2. Press the "O/mem" button

3. When the ready symbol (the shape of the thermometer) is displayed, the thermometer is ready for use

4. An "ear tug" straightens the ear canal to give a clear view of the ear drum.

   a. **Children under 1 year – Pull the ear straight backwards**
   b. **Children above 1 year – Pull the ear up and back**

5. While tugging the ear fit the probe snugly into the ear canal and press the activation button. Release it when you hear a beep. This is the **TEMP BEEP** that confirms the end of the measurement.

6. Remove the thermometer from the ear canal. The LCD displays the temperature measured.

7. Clean the lens filter after each measurement with an alcohol preparation pad

8. New measurements can be taken as long as the "ready" symbol is shown. If no no button is pressed within 2 minutes, the thermometer will turn off automatically

Temperature Hints

- The right ear may differ from the reading taken at the left ear. Therefore **ALWAYS TAKE THE TEMPERATURE IN THE RIGHT EAR**

- Sleeping on an ear may cause the temperature to be higher than normal. Therefore wait a few minutes if taking temperature after sleeping

- The ear must be free from obstructions or excess earwax buildup and should not be infected to take an accurate reading

Memory Clear

- Press the "O/mem" button for 5 seconds to clear the temperatures stored in memory.

- Release the "O/mem" button to return to the ready symbol.

APPENDIX 32 CQ EFFICACY STUDY INFORMATION AND CONSENT FORM

INFORMATION AND CONSENT FORM FOR CQ EFFICACY STUDY
DANGME WEST DISTRICT

The Ghana Health Service is interested in knowing how well the current treatment for malaria is working in the country. To do this, we are carrying out a study in which we are treating a group of children for malaria and then following them for 14 days to see if their infection is cured. This is not a new treatment formulation as the test drug is Chloroquine.

If you agree to participate in this study, we would like you to bring your child to the clinic 5 more times over the next 2 weeks, so that we can monitor the progress of the treatment. It is very important that we see your child on these days, so if you feel you will not be able to return on these days, please let us know now. At each visit, your child will receive a full medical examination and on 3 of these visits we will take a small amount of blood by finger prick to make blood smears to see if your child still has malaria parasites. In the process of collecting the blood sample, from the finger tip your child may experience mild discomfort. This does not represent a health risk to your child. None of these tests will cost you any money.

Your participation is completely voluntary. If you do not want your child to participate in this study, he will receive treatment as usual in this clinic. Participation in this study will not cost you or your family anything. You may also withdraw your child from the study at any time and for any reason.

Your child will benefit from participating in this study because he will be closely followed over the next 14 days. If your child continues to suffer from malaria, he will receive an alternative treatment which will cure the illness. There will be someone here at the clinic every day so that, even on days between scheduled visits and on week-ends you may bring your child in for check-up if you feel that he/she is ill.

Do you have any questions about the study?

The contact address for Dr. Evelyn Ansah is as follows:

District Health Administration/Research Center
Dodowa

Consent Form

I have been adequately informed of the purpose of this study, procedures, potential risks, benefits and consequences.

I also understand that if I agree to participate in this study, I have to bring my child to the clinic 5 more times over the next 2 weeks, so that the progress of the treatment can be monitored. And that on 3 of these visits a small amount of blood will be taken by fingerprick to make blood smears to see if my child still has malaria parasites.

I understand that I am at liberty to withdraw consent for my child's participation any time in the course of the study. I understand that the information obtained as a result of my child's participation will be treated as confidential and used only by the investigators, the LSHTM as well as the Ghanaian authorities.

The investigators have answered all my concerns.

Parent/Guardian Name   **Date** ☐☐/☐☐/☐☐

Signature/Thumb-print:

I have adequately informed the parents or legal guardians of the child/ren the purpose of this study, its procedures, risks, benefits and consequences. I have answered the parents' questions regarding the study conduct and explained their concerns about the child's participation in the study. I will be available to continue doing so in the course of the study if the need arise.

Dr. Evelyn Ansah: **Date** ☐☐/☐☐/☐☐

APPENDIX 33 CQ EFFICACY STUDY PATIENT CASE RECORD FORM

DWDHA/RC/LSHTM ANTIMALARIAL THERAPEUTIC EFFICACY TESTING CASE RECORD FORM

NAME_____ CHILD ID: DES /____ ____ _____

AGE_____(mths)   SEX (M=1; F=2)____   WEIGHT_____Kg

ANTIMALARIAL TAKEN DURING THE PAST WEEK_____
(Chloroquine=1; Amodiaquine=2; Sulphadoxine-Pyrimethamine=3; Halofantrine=4; Artesunate=5; Herbal=5; No antimalarial=99; Other =88)

FORMULATION OF DRUG *(Tablet=1; Syrup=2;Not Applicable=99)*_____

TOTAL DOSE TAKEN TO DATE _____mls/tabs

GUARDIAN NAME_____OCCUPATION_____

HOME ADDRESS *(Detailed description)*_____

	Day 0	Day1	Day 2	Day 3	Day 7	Day 14	Day Other
Date							
History of fever (Yes=1;No=2)							
Diarrhoea (Yes=1;No=2)							
Cough (Yes=1;No=2)							
Difficult Breathing (Yes=1; No=2)							
Ear Problem (Yes=1;No=2)							
Convulsion (Yes=1;No=2)							
*Not able to drink/breastfeed (Yes=1;No=2)							
*Vomiting everything (Yes=1;No=2)							
*Lethargic/unconscious (Yes=1;No=2)							
*Unable to sit or stand up (Yes=1;No=2)							
Temperature (°C)							
Respiratory Rate (breaths/min)							

*Danger signs: - Do not recruit if they are present on Day 0. Remove from study and refer if present after Day 0.

	Day 0	Day1	Day 2	Day 3	Day 7	Day 14	Day Other
Parasite Count (per µl)							
Hb (g/dl)							
Drug administered							
Dose (No of tabs)							
Concomitant treatment							
Dose (No of tabs)							

Overall Assessment (tick)	ETF=1	LTF=2	ACR=3	Exclude=4	Loss to follow-up=5

Reasons for exclusion/loss to follow-up...

....

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PATIENT NOTES

Day 0

Day 1

Day 2

Day 3

PATIENT NOTES

Day 7

Day 14

Any other day: Day......

APPENDIX 34 CQ EFFICACY STUDY LABORATORY FORM

LABORATORY REQUEST FORM-DANGME WEST EFFICACY STUDY

Name_____ Screen No: ES_____, Study ID: DES/_____

Date: __ __ /__ __ /__ __   Day of Visit_____ Sex___   Age___ .mths

Laboratory Tests Requested   Lab Technician ID_____

Initial Screening (Thick Blood Film)

Species(see below)	No of parasites per wbc	Hb (g/dl)

Actual Microscopic Examination (Thick and thin blood)

Species (see below)	No of asexual parasites(a)	No. of leucocytes(b)	Parasitaemia (per µl) = No of parasites(a) X 8000/ No of leucocytes(b)

Species: P. falciparum = 1 P. malariae = 2 P. ovale = 3 Pf = + Pm =4 Pf + Po = 5

....

LABORATORY REQUEST FORM-DANGME WEST EFFICACY STUDY

Name_____ Screen No: ES_____, Study ID:DES/_____

Date: __ __ /__ __ /__ __   Day of Visit_____ Sex___   Age___ .mths

Laboratory Tests Requested   Lab Technician ID_____

Initial Screening (Thick Blood Film)

Species(see below)	No of parasites per wbc	Hb (g/dl)

Actual Microscopic Examination (Thick and thin blood)

Species (see below)	No of asexual parasites(a)	No. of leucocytes(b)	Parasitaemia (per µl) = No of parasites(a) X 8000/ No of leucocytes(b)

Species: P. falciparum = 1 P. malariae = 2 P. ovale = 3 Pf = + Pm =4 Pf + Po = 5

APPENDIX 35 STUDY ID CARDS

MALARIA AND ACCESS STUDY CHILD ID
CHILD NAME:..
STUDY ID: __ /__ __ __ __/__
DATE OF BIRTH.....................................
COMMUNITY..
COMPOUND NUMBER............................

....

EFFICACY STUDY CHILD ID
CHILD NAME:..
STUDY ID: DES /.............................
DATE OF BIRTH.....................................
COMMUNITY..
COMPOUND NUMBER............................

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