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THE EFFECTIVENESS OF AN ENHANCED ANTENATAL CARE SERVICE PACKAGE FOR THE CONTROL OF MALARIA AND ANAEMIA IN PREGNANCY IN GHANA

BY

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A THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES, KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY, KUMASI, GHANA, IN FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF DOCTOR OF PHILOSOPHY, PUBLIC HEALTH

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N0VEMBER, 2015

DECLARATION

I hereby declare that except for the references to other people's works which have been duly acknowledged, this work is the result of my own original research.

I hereby also declare that this work has neither in whole nor in part been presented for the award of a degree elsewhere.

Student	.....	.....
	Gifty Dufie Antwi	Date
Academic supervisor	.....	.....
	Dr. Harry Tagbor	Date
Head of Department	.....	.....
	Dr. Samuel Newton	Date

DEDICATION

This research is dedicated to all women in Ghana who have ever suffered malaria and/or anaemia during pregnancy.

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ABSTRACT

Background

Recommended efficacious interventions for malaria prevention and control during pregnancy have been implemented for over two decades yet malaria and anaemia prevalence during pregnancy remain high. This may be due to sub-optimal uptake of these interventions. Patient participation in their own health care improves health outcomes by improving adherence to treatment recommendations. We conceptualised that when pregnant women participated in their antenatal care it would improve their adherence to antenatal care recommendations and treatment and promote better health outcomes.

Methods

A cluster randomized controlled trial to assess the effectiveness of pregnant women's participation in their antenatal care on the risk of malaria and anaemia during pregnancy, the risk of low birth weight and the risk of sub-optimal pregnancy outcomes was conducted. The study was conducted in 14 antenatal clinics (7 clinics per arm) in the Ejisu-Juaben Municipality and Sekyere-East District of the Ashanti Region of Ghana. The intervention consisted of staff showing pregnant women their malaria rapid test and haemoglobin colour scale test results to facilitate their participation in their care in addition to standard antenatal care. The feasibility and acceptability of this intervention to antenatal care staff and pregnant women were also assessed.

Results

The overall mean age, gestational age and Hb concentration at baseline were 26.4yrs, 17.3 weeks and 11.0 g/dl respectively and similar in both groups; 10.7% had asymptomatic parasitaemia; 74.6% owned an ITN, only 48.8 % sleeping under it the night prior to enrolment. The adjusted risk ratio by 8 weeks of follow up in the intervention vs. control group was 0.97 (95% CI: 0.78-1.22) for anaemia and 1.17 (95% CI: 0.68-2.04) for parasitaemia. At 36-40 weeks gestation, the adjusted risk ratio was 0.92 (95% CI: 0.63-1.34) for anaemia and 0.83 (95% CI: 0.27-2.57) for parasitaemia in the intervention vs. control group. The adjusted risk ratio for low birth weight was 0.93 (95% CI: 0.44-1.97) while that for sub-optimal pregnancies was 0.77 (95% CI: 0.17-3.52). Using the haemoglobin colour scale and malaria rapid test to facilitate participation within routine antenatal care was feasible and acceptable to the pregnant women and staff members. The pregnant women saw and believed the test results and felt motivated to take action to improve their health. Antenatal care staff and pregnant women perceived some improvement in pregnant women's adherence to antenatal recommendations with regards to malaria and anaemia.

Conclusion

It was feasible and acceptable for pregnant women to participate in their antenatal care using the malaria rapid test and the haemoglobin colour scale. Their participation appeared to have potential benefit during pregnancy although clear evidence of a biologic effect was not found. The effect may have been diluted out by the concurrent introduction of malaria rapid tests into routine ANC during the time of the study and possible methodological and implementation challenges of the intervention. More research is thus recommended.

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ABBREVIATIONS

ACCESS	Access to clinical and community maternal, neonatal and women's health services programme
ACT	Artemisinin Combination Treatments
AFRO	African Regional Office of WHO
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
ASSURED	Affordable, **S**ensitive, **S**pecific, User-friendly, Rapid and robust, Equipment-free and Deliverable
CHPS	Community-based Health Planning and Services
DHMT	District Health Management Team
DOI	Diffusion of Innovations
FANC	Focused Antenatal Care
FGD	Focus Group Discussion
G-6-PD	Glucose-6-Phospahte Dehydrogenase
GDHS	Ghana Demographic and Health Survey
GHS	Ghana Health Service
GSS	Ghana Statistical Service
Hb	Haemoglobin concentration
HCS	Haemoglobin Colour Scale

HIV	Human Immunodeficiency Virus
ICC	Intra cluster correlation co-efficient
ImPACT	Improve Persistence And Compliance with Therapy
IPTp	Intermittent Preventive Treatment of malaria in pregnancy
ITN	Insecticide Treated Net
KNUST	Kwame Nkrumah University of Science and Technology
LBW	Low Birth Weight
MalERA	Malaria Eradication Research Agenda
MCDC	Malaria Capacity Development Consortium
MDG	Millennium Development Goal
MHMT	Municipal Health Management Team
MHRB	Maternal Health Record Book
MOH	Ministry of Health
NHIS	National Health Insurance Scheme
NMCP	National Malaria Control Programme
*pf*HRP2	*Plasmodium falciparum* Histidine-Rich Protein 2 antigen
PMTCT	Prevention of Mother to Child transmission
POA	Percentage of Agreement
POC	Point-of-care

RCT	Randomised Controlled Trial
RDT	Rapid Diagnostic Test
SMI	Safe Motherhood Initiative
SP	Sulphadoxine-Pyrimethamine
TT	Tetanus Toxoid
UN	United Nations
UNICEF	United Nations Children's Fund
VAS	Visual Analogue Scale
VDRL	Venereal Disease Research Laboratory
WHO	World Health Organisation

CHAPTER 1 INTRODUCTION

1.1 Antenatal care as a maternal and child survival strategy

Improving maternal and child health have been on the global development agenda for more than two decades. This has led to the promulgation of two Millennium Development Goals (MDG) directly linked to maternal and child survival, MDG 4 and 5 (UN 2006). Governments and the international communities have committed to reducing the maternal mortality ratio by three-quarters and under five mortality rate by two-thirds between 1990 and 2015 (UN 2006). They agree that a woman should receive quality of care throughout her reproductive life (Nour 2008) which will reduce the risk of maternal and perinatal morbidity and mortality. Health strategies focus on improving outcomes during the ante partum (during pregnancy), intrapartum (during labour and delivery) and postpartum period (after delivery) and include antenatal care (ANC), emergency obstetric and neonatal care, skilled delivery, post natal care and family planning services and safe abortion (Campbell and Graham 2006, Nour 2008).

Although more efforts are being concentrated on the intrapartum and immediate postpartum strategies to speed up reaching the millennium development goals 4 and 5 (W.H.O. 2005a), the place of ANC cannot be underestimated. ANC's role in improving maternal health during pregnancy is well documented and it impacts positively on the health of the unborn child and thus contributes to the reduction of perinatal morbidities and mortalities (AbouZahr C and Wardlaw T 2003). The pregnancy period provides a longer period of interaction between the pregnant woman and health care providers for health care to be given. In addition to the provision of the routine range of services provided by well-trained health professionals during ANC (including obstetric, physical and laboratory examinations and risk assessments) (W.H.O. 1996), the antenatal period also offers the opportunity for a variety of other interventions that may be essential to

the health and well-being of the mother and her unborn child to be delivered. These other interventions include giving of information about the danger signs and symptoms of pregnancy, and the risks of labour and delivery. This may encourage the women to deliver with the help of a skilled birth attendant (Bloom S. S, Lippeveld T et al. 1999, Mishra V and Retherford 2004). Information about birth spacing, which contributes to the survival of the infant, may also be given. Identification and treatment of infections such as malaria, tuberculosis, HIV and AIDS and syphilis and the giving of tetanus immunization also contribute to improved maternal and infant survival. For example, the Prevention of Mother to Child Transmission (PMTCT) of HIV screens pregnant women for the HIV infection, treats positive mothers and gives prophylactic anti retroviral treatment to the babies born to positive mothers. This has been proven to be effective in reducing the risk of transfer of the disease to the unborn child (Taha, Kumwenda et al. 2003, Volmink, Siegfried et al. 2007). Tuberculosis, a common co-infection with HIV, is screened for and managed alongside PMTCT of HIV, in areas of high HIV prevalence (Kali, Gray et al. 2006, Gounder, Nikolas I. Wada et al. 2011). Intermittent preventive treatment of malaria in pregnancy (IPTp), prompt and effective treatment of malaria episodes and encouraging the use of insecticide treated nets (ITN) by pregnant women are ANC interventions for the control of malaria in pregnancy. They have been proven to be efficacious in reducing maternal anaemia and low birth weight infants (Greenwood, Greenwood et al. 1989, Bergsjø and Villar 1997, Villar and Bergsjø 1997, Shulman, Dorman et al. 1999, Carroli, Villar et al. 2001, Gamble, Ekwaru et al. 2006). Similarly, iron and folic acid supplements when given throughout pregnancy reduce the prevalence and effects of anaemia (Sanghvi, Harvey et al. 2010).

1.2 Antenatal care in Ghana

In Ghana, ANC is predominantly the responsibility of the district, sub-district and community levels of healthcare; referring pregnant women to higher levels if they are

identified to have any complications. Pregnant women are encouraged to do a minimum of four visits by the 10th, 20th, 30th and 36th week of gestation (M.O.H. 1999). This is being operationalised through the focused ANC approach where ANC personnel are expected to take comprehensive medical histories; do general physical and obstetric examinations including temperature, pulse, blood pressure and weight measurements and palpation and auscultation of the abdomen. Laboratory investigations expected to be conducted include a urine dipstick and urine routine examination, stool routine examination and blood tests for haemoglobin concentration (Hb), sickling status, blood group type, Venereal Disease Reagent Laboratory test (VDRL) for syphilis , HIV and malaria. In addition, there should be routine iron and folic acid supplementation, IPT and tetanus toxoid immunization. The pregnant woman should also receive some education on diet and nutrition, use of ITN, rest and exercise, personal hygiene, danger signs in pregnancy, medicine intake and the purpose of ANC (M.O.H. 1999).

1.3 Rationale for the study

Antenatal care and delivery services have been free under the National Health Insurance Scheme (NHIS) since its introduction in the year 2005 through to 2008; improving financial accessibility to pregnant women and increasing ANC attendance (Dzakpasu, Soremekun et al. 2012, Dixon, Tenkorang et al. 2013). About 95% of pregnant women attended the ANC clinic at least once during their pregnancy and 78% four or more times according to the 2008 Ghana Demographic and Health Survey (GDHS) (GSS, GHS et al. 2009). However the high ANC clinic attendance has not translated into high uptake of ANC interventions and improved pregnancy outcomes. The effectiveness of the ANC interventions measured by the coverage of ANC interventions and their effect on the health outcomes of the mother and baby (Webster, Chandramohan et al. 2010) is low. For example, only 44% of pregnant women received the recommended two or more doses of IPT and only 32% slept under an ITN the night before the survey (against

a world target of 80%). Although 87% reported taking iron supplements during pregnancy, only 42% of were reported to have taken their iron supplements for three months or more. Thirteen percent did not take any iron supplements at all during pregnancy. Only a little above half (56%) of the women received the recommended 2 doses of tetanus toxoid immunization during pregnancy and a similar proportion (57%) delivered at health facilities. For testing of HIV during pregnancy, only 24 % of women who had given birth in the two years preceding the GDHS had been offered and voluntarily accepted testing during their pregnancy (GSS, GHS et al. 2009). The prevalence of anaemia (haemoglobin concentration < 11g/dl) in pregnancy is almost 50% at 36-40 weeks gestation; asymptomatic malaria parasitaemia at term is 12% and the prevalence of low birth weight is 11% (Tagbor, Bruce et al. 2010).

The low ANC intervention effectiveness could be due to a number of factors including inaccessibility and unavailability of the ANC clinics, unavailability of resources needed for intervention implementation at the ANC clinics including lack of well-trained health personnel, lack of laboratories and equipment for diagnostics and lack of medicines, lack of compliance of the ANC staff to the implementation of the interventions at the ANC clinics and poor adherence of the pregnant women to the ANC interventions (malERA 2011).

A range of strategies have been implemented in the past few years to improve coverage of and uptake of ANC interventions. These have included community-based antenatal and intrapartum interventions involving personnel such as traditional birth attendants, community health workers and community health nurses. There is evidence that these community-based intervention packages improve maternal and child survival through improving home practices, creating demand for skilled care and improving health care

seeking behaviours of pregnant women and mothers (Darmstadt, Bhutta et al. 2005, Lassi, Haider et al. 2010). For example, access to ANC has been improved through the establishment of more Community-Based Health Planning and Services (CHPS) compounds with commensurate numbers of health personnel in Ghana (GHS 2011). Community health nurses and community health workers embark on outreach programmes including home visits and educational campaigns to encourage pregnant women to attend ANC clinics. Health providers at the ANC clinics have been involved in training and supervision programmes aimed at improving their knowledge, skill and compliance to the delivery of ANC strategies while health managers have tried to ensure regular supply of medicines and ANC logistics. Very few studies have targeted strategies at improving adherence of pregnant women to the ANC interventions with good results (Mbonye, Yanow et al. 2013). New strategies aimed at improving adherence of pregnant women to ANC interventions may commensurably improve maternal health and hence pregnancy outcomes.

Patient participation in their own healthcare has been shown to improve patient outcomes (Greenfield, Kaplan et al. 1985, Greenfield, Kaplan et al. 1988) by improving communication and shared decision making between the health provider and the patient. This leads to improved adherence of patients to treatment recommendations and hence improved health outcomes (O'Malley, Forrest et al. 2002). The WHO recommends that patients and their families take active roles in their healthcare to improve patient outcomes (W.H.O. 2005b). This concept has been used in some aspects of patient care including decision making during the medical consultation, patient safety and the management of chronic diseases such as diabetes (Martin, Jahng et al. 2003, W.H.O. 2005b, Longtin, Sax et al. 2010), however no known literature exists on its application to antenatal care.

Point-of-care (POC) tests used in ANC offer an avenue for encouraging the pregnant woman to participate in her ANC. When the pregnant woman is encouraged to be part of POC testing and sees the results of her tests, and through her communication with the provider comes to know and understand the implications of the test results, she is likely to take the ANC recommendations given her by the health provider seriously and adhere to them thus improving her health and pregnancy outcomes.

This study was designed to evaluate the use of POC tests as tools to facilitate the pregnant woman's participation in her ANC with the aim of improving adherence to treatment and recommendations given by ANC staff and thus yield better pregnancy outcomes. It introduces two POC tests, the haemoglobin colour scale (HCS) for screening anaemia and the rapid diagnostic test (RDT) for malaria. The aim is to enhance the delivery and uptake of ANC interventions for malaria and anaemia in pregnancy by providing the ANC staff and pregnant women the means of communicating better about the pregnant women's health using these POC tests. When this concept proves successful, it will support the evidence of client participation in their healthcare as a means of improving health outcomes. This approach can be extended to other POC tests used during ANC. Pregnant women participating in their ANC through the use of POC tests can also be scaled up as a means of improving ANC intervention effectiveness towards achieving MDG 4 and 5 in Ghana and other countries in sub-Saharan Africa.

1.4 Conceptual framework

This study uses the RDT and the HCS as tools in an enhanced ANC package to facilitate the process of pregnant women's participation in their ANC. The RDT and HCS are portable, attractive, simple and easy to use and interpret POC tests that rely on

visible colour changes. The ANC staff personnel perform these tests with the pregnant women. The colour of the test results appeals to the visual senses of the pregnant women as they see for themselves their Hb and malaria parasitaemia status. They can then be encouraged to ask questions based on the results and engage in a conversation with ANC staff. When treatment recommendations are then given by the ANC staff, they are more likely to agree to them and adhere to their treatment recommendations. Adherence to treatment recommendations is a desired end product of the ANC delivery system. For malaria and anaemia in pregnancy, it means pregnant women complying with their antimalarial treatments, routinely taking their iron and folic acid supplements, regularly sleeping under the ITN and regularly visiting the ANC clinic for IPTp and ANC. The pregnant women would want to see an improvement in their health status as measured by the HCS and the RDT the next time they visit the ANC and this may also encourage them to adhere to the recommendations given. Hence prevalence of malaria parasitaemia and anaemia will reduce and contribute to increased haemoglobin concentration of the mother and improved outcomes of pregnancy, a measure of improved effectiveness of their ANC. Below (Figure 1) is a diagram showing the conceptual framework of this study

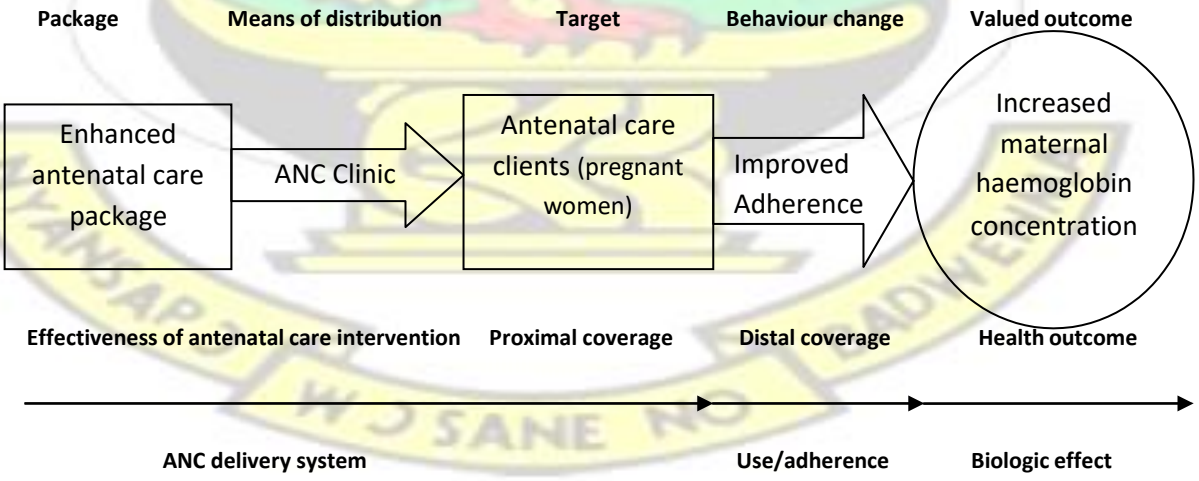


Figure 1: Schematic representation of an enhanced ANC strategy aimed at increasing maternal haemoglobin concentration during pregnancy. (Adapted from Campbell and Graham, 2006; Webster et al., 2010.)

The proximal and distal coverage and the biologic effect measure the effectiveness of the ANC intervention through the ANC delivery system. The proximal coverage of the intervention measures the outcomes that are intrinsically linked to the delivery of the intervention to the target population. The distal coverage measures the use of the intervention once it has been delivered to the target group and does not depend solely on the delivery system (Webster, Chandramohan et al. 2010). Thus the percentage number of pregnant women to be reached with the enhanced package is a measure of the proximal coverage whilst the level of adherence to or use of the recommendations and treatment given through the intervention will measure the distal coverage. In this study, distal coverage outcomes include the level of adherence to iron and folic acid supplementation and the proportion of pregnant women using the ITN. The prevalence of anaemia during pregnancy, the birth weight and adverse pregnancy outcomes will measure the biologic effect of the intervention.

1.5 Study aim and objectives

1.5.1 Aim

To determine the effect of pregnant women's participation in their antenatal care using the RDT and the HCS during antenatal clinic sessions on malaria and anaemia prevalence during pregnancy.

1.5.2 Objectives

1. To determine the effect of pregnant women's participation in their antenatal care using the RDT and the HCS during ANC sessions on
    a. Maternal haemoglobin concentration
    b. Malaria parasitaemia
    c. Birth weight and

d. Sub-optimal pregnancy outcomes- Preterm deliveries, abortions and still births

2. To describe the feasibility and implementation fidelity of the use of the RDT and HCS as tools to facilitate pregnant women's participation in their antenatal care during antenatal care clinic sessions
3. To describe the acceptability of pregnant women's participation in their antenatal care using the RDT and the HCS during ANC sessions to
    a. pregnant women and
    b. ANC staff

1.6 Organisation of thesis

The thesis is divided into the following chapters:

Chapter 1 Introduction

The chapter presents a brief background to the study, the rationale for the study, the study hypothesis, the conceptual framework, the aim and objectives and a general overview of the organisation of the thesis.

Chapter 2 Literature review

This chapter gives a brief review of initiatives to improve maternal health in developing countries and antenatal care as a maternal and child survival strategy. Initiatives to improve maternal health and ANC in Ghana are briefly reviewed next, including antenatal care strategies for malaria and anaemia in Ghana. Patient participation in health care and its effect on health outcomes through improved adherence to treatment recommendations is also briefly reviewed in addition to the use of POC tests as tools to facilitate patient participation in health care.

Chapter 3 Methods and materials

In this chapter, a general overview of all the study activities is first presented. The study was conducted in three phases: the pre-intervention, the intervention and the post intervention phase. Next, a detailed account of whole conduct of the study including all the activities and ethical issues is presented.

Chapter 4 Results 1:- Cross sectional survey of study population

This chapter describes results from the pre-intervention phase of the study. The first section gives a brief description of antenatal care services in the Ejisu-Juaben Municipality and the Sekyere-east district while the second section describes the results of a cross sectional survey that was conducted to describe the study population with respect to asymptomatic parasitaemia and anaemia and their associated factors.

Chapter 5 Results 2:- Cluster randomised controlled trial

The first section of this chapter describes the screening, enrolment and the participant flow of study pregnant women into the cluster randomised trial. The baseline socio-demographic and obstetric characteristics of the study participants, their most frequently reported symptoms at enrolment and their baseline parasitaemia and anaemia states are described next. These are followed by a description of the intervention effect of the trial. The intervention effect is estimated by comparing the risk of parasitaemia, anaemia, low birth weight and sub-optimal pregnancy outcomes between the intervention and the control arms of the trial.

Chapter 6 Results 3:- Feasibility and implementation fidelity of the use of the RDT and HCS as tools to facilitate pregnant women's participation in their ANC.

The first section of this chapter describes the feasibility of the implementation of the intervention to encourage pregnant women's participation in their ANC. It describes the ability of the ANC staff to use the RDT and HCS during ANC sessions and its effect on

the work flow at the ANC clinic. The second section describes the results of an independent monitoring of the implementation fidelity of the intervention.

Chapter 7 Results 4:- Acceptability of the use of the RDT and HCS as tools to facilitate pregnant women's participation in their ANC.

This chapter is presented in two sections. The first section describes how acceptable the use of the HCS and the RDT to encourage participation during ANC sessions are to the pregnant women while the second describes the acceptability to the ANC staff.

Chapter 8 Discussion and conclusion

This chapter is a presentation of a discussion of the principal findings from the study in comparison with the results of similar studies. The strengths and weaknesses are also discussed in addition to the implications for practice and policy, and research.

CHAPTER 2 LITERATURE REVIEW

2.1 International initiatives to improve maternal health in developing countries

Maternal health, the health of women during pregnancy, child birth and the postpartum period (up to 28 days after delivery)(W.H.O. 2012) is very crucial to the very survival of both the mother and her baby. Unfortunately many women end up with preventable complications during this period, resulting in increasing suffering and ill-health that may even take away their lives.

Improving maternal health with subsequent reduction in maternal morbidity and mortality has been on the global agenda for more than two decades now. The international community has increased its attention towards the health status of women in developing countries through improved legislation and services directed towards women. The first ever Safe Motherhood Conference which was sponsored by the WHO, United Nations Population Fund and the World Bank was held in Nairobi, Kenya, February 1987. Here the Safe Motherhood Initiative (SMI) was launched and aimed to improve maternal health through its programmes and research activities (Mahler 1987). It helped to raise awareness about the high rate of women dying from pregnancy and child birth and challenged the world to do something about it starting with heads of states and governments. In 1990, at the World Summit for Children, over 150 countries identified maternal health to be very critical to child survival and endorsed the plan of action to half maternal mortality by the year 2000 (AbouZahr 2003). The Cairo International Conference on Population and Development and the Beijing Fourth World Conference on Women were held in 1994 and 1995 respectively. Both re-iterated the fact that maternal deaths and disability were a total violation of women's human rights while being grossly linked with the status and economic status of the woman in society. In the year 2000, at the Millennium Summit of the United Nations, the United Nations

Millennium Declaration was adopted by all of the then 189 member states and 23 organisations. The heads of the member states and the organisations committed to achieving 8 MDGs by 2015. These MDGs were time-bound, achievable blue prints for reducing poverty and improving lives among the world's poorest countries. The fifth MDG directly linked to maternal survival and aimed to improve maternal health by reducing the maternal mortality ratio by three-quarters between 1990 and 2015 and achieve universal access to reproductive health by 2015 (UN 2008). Maternal health thus gained strong international attention and support with the MDGs that served as the basis of assessing the overall health and development of nations worldwide.

It had also been realised that it was unrealistic to separate maternal care from new born, infant and child care as factors that had been identified to contribute to a majority of maternal deaths overlapped with those causing maternal morbidity, still births and neonatal morbidity and mortality (W.H.O. 1994). In September, 2005, the Partnership for Maternal, Newborn, and Child Health was born hosted by the WHO. It comprised of the Partnership for Safe Motherhood and Newborn Health which had evolved from the Safe Motherhood Inter-Agency Group; the Healthy Newborn Partnership and the Partnership for Child Survival. It was launched to speed up efforts aimed at achieving the fourth (reduce by two-thirds, between 1990 and 2015, the under-five mortality rate) and fifth MDGs. It aimed to encourage international advocacy and leadership to help make maternal, newborn, and child health more public; to introduce and promote a continuum of care for mothers and children; and to coordinate country-level support and action towards improvement in maternal, newborn and child health (WHO 2014).

An infant is at the greatest risk of dying in the neonatal period. The WHO estimates that 44% of all child deaths occur within the first 28 days of life; half of these in the first 24

hours of life and 75% in the first week of life (UNICEF, WHO et al. 2013). Thus when skilled care is provided to mothers during pregnancy, delivery and after birth, it positively influences child survival. Skilled care for the mother and the infant includes antenatal care for pregnancy, skilled birth attendance, emergency obstetric care for delivery and post partum care for the puerperium.

2.2 Antenatal care as a strategy for maternal survival

2.2.1 Background of Antenatal care

Antenatal care, also known as prenatal care, is identified as one of the four main pillars of safe motherhood in addition to Clean/Safe delivery, Emergency Obstetric Care and Family Planning. It is the health care that a woman receives during pregnancy. It is believed to reduce maternal and perinatal mortality if carried out properly (W.H.O. 1994). It helps to improve the survival of both the woman and the newborn as its primary aim is to achieve a healthy mother and a healthy baby at the end of pregnancy.

ANC programmes, as they are now, take their roots from models that were developed in Europe in the past century. There was the belief at that time that maternal, foetal and infant death could be avoided if antenatal examinations were carried out frequently. The UK Ministry of Health then recommended that antenatal examination should begin at around the fourth month of pregnancy and be followed by monthly visits till the 7th month; then 2 weekly to 9 months and then weekly thereafter till the woman delivered (Oakley 1982). During these times, the antenatal examinations were to include the measurement of the height of the uterus, weight of the mother, listening to the foetal heart beat and testing of urine. They also recommended that a medical officer examined the pregnant woman at the 8th and 9th month visits. ANC throughout the whole world has followed these recommendations and has been only modified to embrace new

components based on advances in medical knowledge and technology. These new components have been mainly for screening purposes to improve identification of high-risk women.

During ANC, pregnant women are able to receive a wide range of services to promote their health and prevent disease. They are reached with a variety of interventions which are essential to their general well-being and that of their babies. They receive appropriate assessment of risk factors and health examinations by well-trained health professionals to identify conditions in the pregnant woman that may be harmful to her and her baby during pregnancy. These conditions are then treated or monitored with the aim of achieving a better outcome of the pregnancy (W.H.O. 1996). Pregnant women and their families also receive information about danger signs and symptoms during pregnancy, labour and its associated risks and the delivery process. Information about family planning and subsequent birth spacing is also shared as this is also recognized as an important contributor to improving infant survival and maternal health.

2.2.2 Antenatal care in developing countries

Diseases such as malaria, tuberculosis, HIV and AIDS and malnutrition exist in developing countries and contribute significantly to indirect causes of maternal deaths (20%) (W.H.O. 2007). The antenatal period offers the opportunity for programmes such as for nutrition, malaria, HIV/AIDS, tuberculosis and tetanus to be implemented to improve pregnancy outcomes in addition to the regular physical assessment and management of the pregnant women. The ANC system thus incorporates screening for and treatment of these infections and advice on improving the women's nutritional status according to the endemicity of these conditions in the various countries. These measures seek to improve maternal health and pregnancy outcomes and reduce adverse

pregnancy outcomes such as low birth weight (LBW) and maternal anaemia (Bergsjø and Villar 1997, Villar and Bergsjø 1997, Carroli, Villar et al. 2001).

2.2.3 The new approach to antenatal care

Antenatal care had become more of a ritual rather than tailoring the care to the individual health needs of the pregnant woman. It emphasized the timing and frequency of visits which led to a large number of visits with no proven advantage. It assumed that more visits meant better health outcomes for the woman and her child. The content relied on the measurement of some risk indicators such as maternal height and weight, foetal position at 36 weeks and ankle oedema. The women were then classified based on their risk of developing complications during pregnancy and their level of care based on these identified risks. However, many women who were identified as being high-risk for the development of complications never developed complications whilst those low-risk women rather developed complications during pregnancy (Lilford and Chard 1983). Thus this risk approach to antenatal care did not necessarily improve pregnancy outcomes. And frequent visits to the antenatal clinic were a burden both to the pregnant women and health system financially and logistically (Villar and Bergsjo 2001). This traditional approach to ANC had been adopted by many countries without them examining the scientific basis and also considering the strain that it could have on the scarce resources that were available (Villar and Bergsjo 1997). In 2001, the WHO proposed a different approach to ANC, the Focused Antenatal Care (FANC). It was based on the fact that during ANC, every woman had the opportunity to be diagnosed and treated early for any conditions that could potentially threaten the life of the mother and the baby, that the majority of pregnancies would end without complications and that all women are at risk for complications and so should receive the same basic care and monitoring for complications according to individual needs (Maine 1991). It emphasizes quality of visits over quantity (Kinzie and Gomez 2004). For normal

pregnancies, made up of some 75% of the total population of pregnant women, basic ANC is recommended. The WHO recommends only four antenatal visits during basic ANC; the first occurring in the first trimester, ideally before 12 weeks but no later than 16 weeks, the second at 24-28 weeks, the third at 32 weeks and the last at 36 weeks (Villar and Bergsjo 2001). During these visits, assessments of the pregnant woman should aim at the identification of pre-existing health conditions, early detection of complications arising during the pregnancy, health promotion and disease prevention and birth preparedness and complication readiness to help to maintain normal pregnancies (Kinzie and Gomez 2004). The FANC model relies on evidence-based, goal-directed interventions that are appropriate to the gestational age of the pregnancy, and specifically address the most prevalent health issues affecting women and newborns (Maine 1991, Gomez and Kinzie 2002). FANC therefore means that providers of ANC provide individualised care that focuses on assessment and actions needed to make decisions, and provide care for each woman's individual needs. Thus according to the WHO guidelines, 'only examinations and tests that serve an immediate purpose and that have been proven to be beneficial should be performed'(W.H.O. 2002). The frequency and scope of visits are only increased if problems or potential problems that could affect the pregnant woman and her baby are detected. FANC follows the principles of woman friendliness, individualisation of care, cultural appropriateness and integration of appropriate services. FANC thus offers a better opportunity for the health provider and the individual woman to be in close communication about her health needs and provides a platform for sharing of ideas for the remedy of these health needs. It should be part of the household to hospital continuum of care where linkages between the formal health care system and community based care should be ensured. It should also be inclusive of the woman's partner or other family members to grant the woman, her new born and her family a full and safe experience of child birth (ACCESS 2007).

The FANC model appears acceptable to both health care providers and clients because it can improve care and reduce cost (W.H.O. 2002) but may lead to some women feeling slightly less satisfied with their care (Villar, Carroli et al. 2001). Difficulties in implementation of this model do exist. Factors contributing to this include high staff turnover and scarcity of resources. To ensure sustainability in the provision of FANC, especially in sub-Saharan Africa, training of staff including strategies that address the high staff attrition rate, ensuring pregnant women compliance through outreaches and strengthening of infrastructure to ensure the availability of supplies, space and equipment for the service would have to be provided (Birungi 2008).

Generally, reducing the number of ANC visits could be implemented without any increase in adverse pregnancy outcomes (Villar, Carroli et al. 2001), but within the context of low resources, it may be advisable not to reduce the standard number of visits without close monitoring of the foetal and neonatal outcomes as the reduced number of visits may be associated with increased perinatal mortality (Dowswell T, Carroli G et al. 2010). Emphasis should be placed on maximising the benefits of each ANC visit through the implementation of quality ANC content.

2.2.4 Effectiveness of antenatal care strategies in developing countries

Campbell and Graham describe a health care strategy to consist of a package of interventions delivered to a target group of people through an identifiable means of distribution with the aim of producing a valued outcome (Campbell and Graham 2006). For ANC, the specific interventions delivered to pregnant women at the ANC clinic for a particular condition or disease to produce a valuable effect on the mother and her baby would constitute a strategy. For example, strategies for malaria and anaemia control, prevention of mother to child transmission of HIV and syphilis are implemented through the ANC system. The strategy for malaria control during ANC comprises

administration of sulphadoxine-pyrimethanine (SP) through IPTp to the pregnant women at the clinic, promptly identifying and treating effectively any cases of malaria and encouraging ITN use by the pregnant women during their antenatal care sessions. These interventions when effectively implemented lead to the valued outcome of decreased maternal anaemia, low birth weight babies, miscarriages and still births. When such strategies are implemented under controlled conditions, they are found to be highly efficacious in improving pregnancy outcomes and the health of the mother. For example, ANC strategies for the control of malaria in pregnancy have been proven to be efficacious in improving maternal anaemia and LBW and subsequently reducing maternal and perinatal mortality (D'Alessandro, Langerock et al. 1996, Shulman 1999, Lengeler 2000, ter Kuile, Terlouw et al. 2003). ITN use during pregnancy reduces malaria parasitaemia in the peripheral blood and the placenta, increases haemoglobin concentrations of the women, increases the mean birth weight of the babies and reduces the risk of abortions (Gamble, Ekwaru et al. 2006). Micronutrient and iron supplementation and the appropriate use of anti-microbial and anti-malarial drugs could reduce maternal mortality in sub-Saharan Africa by 8% (Collin, Baggaley et al. 2007).

But proven efficacy has not always been translated into high effectiveness of the strategies. The effectiveness of ANC strategies which is measured by the percentage number of the pregnant women reached with the interventions , the use or adherence to the interventions among the women and the biologic effects of the strategy on the women and their babies (Webster, Chandramohan et al. 2010) during normal routine antenatal care practices has been low compared to targets set. The use of ITNs among pregnant women is not encouraging at all as even the Abuja target of 60% coverage by 2005 had not been reached by 2008. The world malaria report revealed that only 27% of pregnant women slept under an ITN in 2008 the night before the survey was conducted.

Household surveys in Africa revealed that in 2007–2009, the percentage of women who received two doses of IPTp ranged from 2.4% in Angola to 62% in Zambia with a weighted average of 12% due to low coverage rates in Nigeria (W.H.O. 2010) . The diagnosis, treatment and subsequent prevention of mother to child transmission of syphilis during pregnancy is a feasible and cost-effective strategy yet an estimated 66% of adverse events that occurred due to syphilis infection in 2008 occurred in pregnant women who had attended ANC clinics but were either not tested or not treated for syphilis (Newman, Kamb et al. 2013).

There has been a gradual increase in ANC attendance among pregnant women. The WHO estimates that globally, between the years 2000 and 2008, less than half of pregnant women received the recommended 4 ANC visits compared to 56% between 2006 and 2013. Between 1990 and 2012, the proportion of pregnant women who attended ANC at least four times in developing countries increased from 37% to 52% (WHO 2014). Unfortunately, an increase in the percentage of at least four ANC attendances does not necessarily mean an improvement in the quality and content of care. Mere contact with skilled providers will not result in better health outcomes if the quality and content of the care is compromised. Although these pregnant women who attended the clinic on more occasions stand a better chance of receiving specific components of ANC than their counterparts who do fewer visits, they still have quality-coverage gaps (measured by the difference between expected coverage (100%) and the actual coverage for the specific component of ANC for pregnant women who have received four or more ANC visits during their current pregnancy for certain components of ANC. For example, Hodgins and D'Agostino identified a 5% and 18% median quality-coverage gap for blood pressure measurement and tetanus toxoid immunisations in women who had received 4 or more ANC visits when they considered demographic

and health survey reports for 41 developing countries. Also, they identified a 72% and 86% quality–coverage gap for iron-folate supplementation and malaria prevention respectively (Hodgins and D'Agostino 2014).

It has been suggested that one of the best things that ANC could accomplish would be to influence women to select a skilled birth attendant at delivery. Pregnant women who receive ANC stand a higher chance of utilising the services of skilled birth attendants (Bloom S. S, Lippeveld T et al. 1999, Mishra V and Retherford 2004). However, the utilization of antenatal care disproportionately transcends into the use of skilled birth attendants. Data show that less than two thirds (62%) of all women in developing countries receive assistance from a skilled health worker when giving birth (UNICEF 2008) compared to 98% in the developed world although at least 80% of women attended the ANC at least once during their pregnancy.

2.2.5 Barriers to effective implementation of antenatal care strategies

A multitude of factors influence the effective implementation of ANC strategies in developing countries. An efficacious ANC intervention may lose traction along the health delivery system (Figure 2) till its effectiveness is measured based on:

1. Heath system factors which influence the delivery process (supply factors) of the intervention
2. End-user factors which influence the use or adherence of the strategies by the pregnant woman (demand factors) and
3. Environmental factors, the external environment in which the above operate.

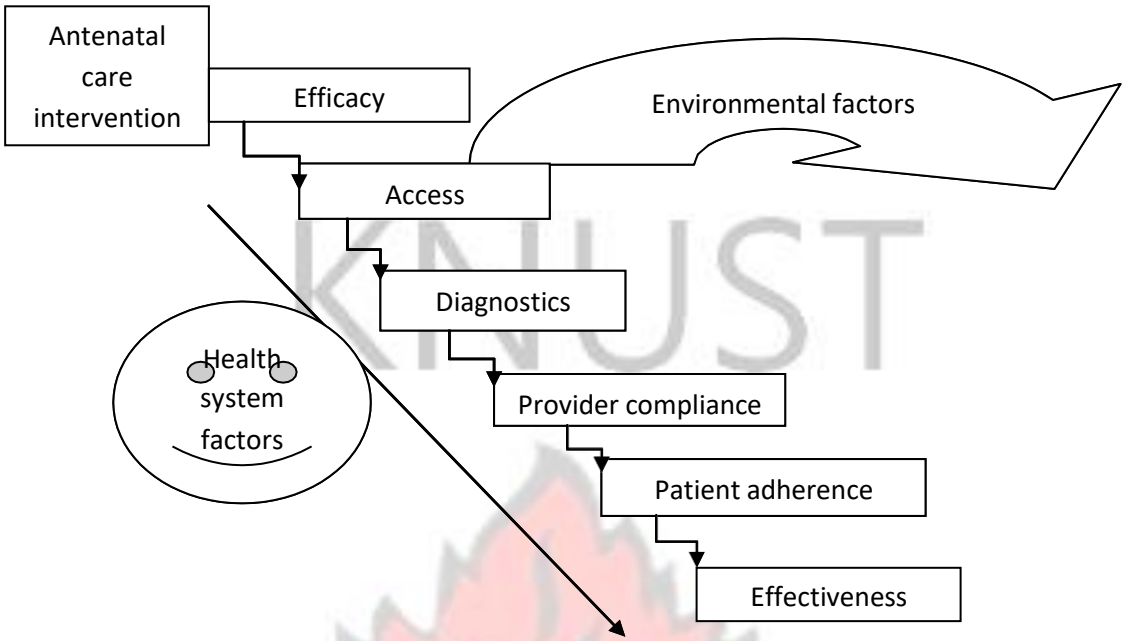


Figure 2: Diagram showing the interplay of health system factors, patient factors and environmental factors on implementation effectiveness of strategies. (Adapted from: malERA, 2011)

2.2.5.1 Health system factors

The WHO defines a health system to 'consist of all organizations, people and actions whose primary intent is to promote, restore or maintain health' with goals of ''improving health and health equity in ways that are responsive, financially fair and make the best, or most efficient, use of available resources' (W.H.O. 2000). Its components include the health workforce, medical products, vaccines and technologies, health financing, and information systems, leadership or governance and service delivery (WHO 2007) and they are needed for the smooth delivery of health interventions to the populace. Insufficient health system resources and inappropriate allocation of these resources across all levels of the ANC influence the quality and content of health care that will be received by the women at the ANC clinics. For the successful implementation of ANC strategies, adequate numbers and well-trained health providers in the ANC interventions who are highly motivated need to be present. A very

conducive environment for implementation also needs to be available. These coupled with good and efficient managerial/leadership systems that will ensure adequate and prompt supplies of medicines, laboratory materials, reagents and consumables needed for ANC. A well-functioning information management system is also essential to aid monitoring and evaluation of ANC services to help improve delivery of interventions at the ANC clinic. Constraints such as lack of or inadequate numbers of appropriately skilled and trained health personnel, poorly motivated health service providers, inappropriate provider behaviour towards users, poor acceptance and adherence of providers to strategy guidelines-provider compliance, persistent lack of appropriate resources for implementation of the strategy (for example, lack of equipment and medicines) coupled with weak planning and management of health services (Travis, Bennett et al. 2004) may contribute to poor results of ANC programmes.

Innovativeness, the degree to which new ideas, approaches or opinions are adopted differs from person to person (Rogers 2002). Health service providers' beliefs, perceptions and level of knowledge of the rationale and benefits about the intervention impacts on their acceptability and compliance to the interventions to be implemented (Mubyazi, Magnussen et al. 2008). Based on the theory of Diffusion of Innovation (DOI), (Rogers 2003) different health providers may react differently to new interventions and display different degrees of willingness to adopt them. They may belong to any of these five categories: innovators, early adopters, early majority, late majority or laggards. Innovators quickly adopt the innovation; early adopters are most amenable to change; early majority deliberate for some time to be convinced of the benefits before adopting a new intervention; late majority are sceptics and pressure from peers motivates them to adopt the innovation and laggards, who adopt innovations last. They are the most conservative, having some suspicions about the innovation and may

actively resist it. Thus different levels of acceptance and compliance may exist having a bearing on the general effectiveness of the interventions.

The attributes of the intervention also contribute to its adoption into the health system. Attributes important for an intervention to be adopted include its perceived relative advantage in relation to other options, its compatibility with existing values and practices, its trialability, that is, the degree to which the innovation can be experimented with on a limited basis, its perceived simplicity or ease of use and its observability, the degree to which the results of its use can be visualised (Rogers 2002). Thus it is only when an intervention is preferred to existing options, is compatible with the existing values and practices of the health provider and the facility culture, is easy to use and health providers are willing to try it out while the effects of it are readily seen, that it is most likely to be adopted and implemented.

The performance of the health worker is thus influenced by the above personal and intervention-attribute factors and affects the overall implementation and effectiveness of the interventions. An interplay of all the above mentioned health system factors may lead to a gap in successful delivery and hence implementation of evidence-based efficient practices. Hence across ANC clinics, there may be differences in the extent of delivery of the various interventions such that even when pregnant women present themselves for ANC, they may not be reached with appropriate and good quality interventions because of these constraints.

2.2.5.2 End-user factors

Firstly, the pregnant woman would have to visit the ANC clinic before the ANC interventions get delivered to her. Individual, social and cultural factors influence her utilization of ANC services. Factors like the age, parity, maternal education, husband's

education, marital status, place of residence: urban or rural, women's employment, household wealth and having a bad obstetric history have been found to influence pregnant women's attendance of ANC clinics (Simkhada, Teijlingen et al. 2008). Generally, in developing countries, women who are younger, who are pregnant for the first time, who live in urban areas, who have a higher level of education and who belong to richer households are more likely to attend the ANC clinic four or more times (Wang, Alva et al. 2011). Women of high parity tend to use ANC less although this also is influenced by the woman's age and religion (Simkhada, Teijlingen et al. 2008). The cultural beliefs and ideas that a woman has about pregnancy also influence ANC utilization. Cultural factors including issues like gender effects on behaviour and stigmatization associated with certain conditions of health (Travis, Bennett et al. 2004) affect pregnant women utilising ANC. In India, women perceived pregnancy as a natural process and hence visited the ANC clinic only when they thought there were some problems (Griffith and Stephenson 2001). In Zimbabwe, there was the fear that when their blood got into the wrong hands, it could be used to bewitch them and hence did not patronise the ANC clinics (Mathole, Lindmark et al. 2004). They also believed that the first trimester was most vulnerable to bewitchment and hence if they would attend the ANC clinic, it would in the later stages of pregnancy. Perceived shame associated with pregnancy also deterred some women from seeking ANC (Mathole, Lindmark et al. 2004, Mumtaz and Salway 2005). Level of education was as a key factor in helping women to understand the importance of ANC (Mumtaz and Salway 2005) and women with higher educational levels were more likely to receive the recommended number of ANC visits (Nielsen, Liljestrand et al. 2001, Erci 2003). Thus low levels of education and some cultural factors may blind the pregnant woman from identifying the potential benefits of ANC. When this is coupled with financial and geographical inaccessibility and non-availability of ANC services, ANC utilization and

hence coverage of the ANC interventions will be less. However, studies have shown that pregnant women are motivated to visit the ANC because of the health benefits they anticipate for themselves and their babies. In Ghana, women visited the ANC to know if there were any problems with themselves or their babies. They believed that the ANC staff could help identify and solve such problems and as such avoid losing their babies (Smith, Jones et al. 2010). Thus in-spite of the challenges they may face, they make an effort to visit the ANC clinic.

Secondly, the pregnant women's beliefs and perceptions about the ANC interventions after they have been delivered to her are also important in determining her level of acceptance and subsequent adherence. In Nigeria, the individual women's beliefs and their lack of understanding of the IPTp intervention contributed to its low uptake and adherence. Many of pregnant women did not see why they had to seek care for an illness they did not have (Diala, Pennas et al. 2013). Pregnant women who perceived that they themselves are responsible for the health of their babies were more likely to be adherent to the taking of iron supplementation during pregnancy than those who believed that it was chance or the influence of powerful others that affects their babies' outcomes (Wulandaria, Craig et al. 2012). In Ghana, some pregnant women believed that routine drugs given at the ANC clinic increased their appetite to help them to eat well and obtain strength and energy; made them sleep well and also urinate a lot for impurities to be flushed out. This encouraged them to take their routine medicines regularly and visit the ANC clinic for refills (Smith, Jones et al. 2010).

2.2.5.3 Environmental factors

These are factors that lie external to the health system but yet have a tremendous effect on the functioning of the health system. They include the overall policy environment that regulates the implementation of the strategies, political stability and the quality of

governance of the country (Travis, Bennett et al. 2004). Political will contributes significantly to the success or failure of implementation of nation-wide health interventions (Catford 2006). High level political commitment to healthcare policies and programme implementation is needed to ensure uninterrupted supply of resources and equipment needed for health care. Budgeting for and spending appropriately on health care is necessary to maintain adequate resources to improve access to and delivery of healthcare and this is the responsibility of the government of the day. Political commitment is also needed to provide support to various ministries of health for planning, implementation, monitoring and evaluation of the programmes at the health facility levels.

Creating a supportive socio-economic environment is also very important. Government's commitment to poverty reduction, education, water and sanitation and women empowerment also affects maternal health outcomes. Maternal mortality has been found to be inversely and significantly correlated with adult literacy rate, primary female enrolment rate, access to an improved water source, the Gross National Income per capita and the per-capita government expenditure on health in sub-Saharan Africa (Alvarez, Gil et al. 2009).

2.3 Maternal health in Ghana

2.3.1 Initiatives to improve maternal health in Ghana

A number of interventions have been adopted since the 1990's to help improve maternal health and reduce maternal morbidity and mortality in the country. The SMI, Prevention Maternal Mortality Programme, Making Pregnancy Safer Initiative, Maternal and Neonatal Health Programme, Ghana Vitamin A Supplementation Trial Survival Programme, Maternal Health Project, Prevention and Management of Safe Abortion

Programme, High Impact Rapid Delivery Programme, Roll Back Malaria Programme, IPTp and PMTCT of HIV and syphilis (UN 2010) have all been implemented at a point in time in an attempt to improve maternal health in the country.

The SMI programme in Ghana started immediately after the SMI conference in Nairobi and was piloted in 12 districts in 1987 and later on extended to all districts in the country. It was delivered through the primary health care concept by the district hospitals, health centres, clinics and later, the CHPS compounds. Its components included ANC, labour and delivery care, post natal care, family planning, prevention and management of unsafe abortions and health education to make pregnancy safer.

In 1988, the Prevention Maternal Mortality Programme started as a component of the SMI with the overall aim of promoting maternal health. It was made up of a network of clinicians, social scientists and public health physicians who conducted studies on maternal mortality with focus on emergency obstetric care. The programme sought to develop and implement interventions that improved the availability, quality and utilization of emergency obstetric care.

The Making Pregnancy Safer Initiative was also born out of the SMI. It had four parts namely care during pregnancy (ANC, treatment of severe anaemia, treatment of syphilis, treatment of other sexually transmitted diseases like gonorrhoea and Chlamydia and the treatment of malaria); care during and after delivery (delivery by skilled birth attendant including routine newborn care, management of pregnancy induced hypertension, management of postpartum haemorrhage, management of obstructed labour/Caesarean delivery including management of post-surgical care; management of sepsis, management of basic newborn complications, postpartum care,

management of abortion complications); postpartum family planning promotion and a community component focusing on the role of the CHPS and traditional birth attendants in maternal health at the community level. Thus, one after the other, new names evolved trying to solve the same problem of improving maternal health in Ghana.

Neonatal health was also integrated into maternal health issues like the Maternal and Neonatal Health programme. The Ghana Vitamin A Supplementation Trial Survival Programme aimed at reducing maternal and child mortality associated with vitamin A deficiency. Vitamin A became part of standard treatment for measles in children and mothers within 4 weeks of delivery.

The IPTp and Roll Back Malaria programmes are targeted specifically towards malaria control in Ghana. In 1999, the country adopted the Roll Back Malaria initiative and has since been implementing a combination of curative and preventive interventions for malaria control. IPTp was adopted as policy in 2003 after WHO recommendation with nation-wide implementation through the ANC system by the year 2005. The High Impact Rapid Delivery programme promotes high-priority, cost-effective interventions to improve maternal and child health at the district level. It provides specific funding for service delivery with an aim to increase focus on and funding for reproductive and child health services by District Health Management Teams (M.O.H. 2008).

Currently, the Ghana Reproductive Health Strategic Plan (2007-2011) has six high-level objectives under its Safe Motherhood Policy, the first of which is to “reduce maternal morbidity and mortality”. Under this objective, to “increase antenatal care and postnatal care coverage, content, and quality of services” features as one of the five intermediate objectives (G.H.S. 2007).

In 2007, a maternal health policy entitling all pregnant women to receive free ANC under the national health insurance scheme (NHIS) was instituted. This is aimed at improving financial access to health care for pregnant women to help bridge the access barrier that previously existed in the country. It was a follow up to the user fee exemption policy instituted in 2003 which exempted all pregnant women from paying for delivery costs at public, mission and private health facilities (Witter, Arhinfu et al. 2007).

2.3.2 Antenatal care in Ghana

Antenatal care in Ghana has been guided by the Clinical Management Protocols on Safe Motherhood since its introduction by the Ministry of Health in 1999. Its objectives have been to promote and maintain the physical, mental and social health of mother and baby by providing education on nutrition, rest, sleep and personal hygiene; to detect and treat high-risk conditions arising during pregnancy, whether medical, surgical or obstetric; to ensure the delivery of a full term healthy baby with minimal stress or injury to mother and baby and to help prepare the mother to breastfeed successfully, experience normal puerperium and take good care of the child physically, psychology and socially (M.O.H. 1999).

The standard recommendation for ANC visits is that the pregnant woman should make monthly visits up to the 28^{th} week of pregnancy, then from the 28^{th} to the 36^{th} week, two weekly visits and then from the 36^{th} week, weekly visits till delivery. However a minimum of four visits was allowed at the 10^{th}, 20^{th}, 30^{th} and 36^{th} weeks in extreme conditions when the mother could not make the recommended number of visits (M.O.H. 1999). During the pregnant woman's first visit, it is expected that the woman is registered, a comprehensive medical history taken and a general, (temperature, pulse, blood pressure, weight, height, gait and/or deformity), physical (emphasising

examination of the conjunctiva and nail beds for anaemia), obstetrical and vaginal examination conducted. Laboratory investigations including a urine routine examination, stool routine examination and blood test for Hb, sickling status, blood group, VDRL test for syphilis and HIV tests are also conducted routinely. Any identified complications are then to be treated. In addition, there should be the routine administration of iron and folate, malaria chemoprophylaxis and tetanus toxoid immunization. The pregnant woman is also expected to receive some education on diet and nutrition, rest and exercise, personal hygiene, danger signs in pregnancy, birth preparedness, medicine intake and the purpose of ANC in addition to a brief explanation of the physiological changes and events in pregnancy and the effects of exposure to sexually transmitted diseases including HIV/AIDS. During subsequent visits, a medical history, general and physical examinations and urine for sugar and albumin, haemoglobin level determinations are to be carried out. Any complications noted are then treated accordingly.

2.3.3 Focused ANC in Ghana

The MOH believes that "The key to effective ANC is to use our (health workers) powers of observation to really look at the condition of each pregnant woman, using simple and effective tests and treating existing problems on the spot rather than trying to predict who is likely to have a complication" (M.O.H.a. 2010). Following the WHO recommendation in 2001, FANC has been piloted in Ghana in some health facilities including the Tema General Hospital which served as a model for the MOH (Birungi 2008).The ANC schedule was reduced from 13 to 4 comprehensive and personalized visits with emphasis on early detection and treatment of all complications arising during pregnancy, assessing birth preparedness and complication readiness, prevention of malaria in pregnancy and of mother-to-child transmission of HIV. Integrated services offered included history taking, physical and laboratory examinations (blood and urine

test, measurement of blood pressure, weight, height, and temperature), counselling on all health problems, behaviours, minor discomforts of pregnancy, danger signs, birth preparedness, counselling and testing for HIV, and postpartum family planning. In addition, ANC services were re-organized from an assembly-line type of model, in which clients would need to see a number of different providers (as many as six providers) during one consultation, to an individualized package of care from one provider. This ensured that the same providers attended to the same client during first and subsequent visits (Birungi 2008) ensuring continuity of service. The introduction of the FANC model was found to improve the overall quality of care of the pregnant woman and thus efforts are underway to scale up its implementation across the country. It was also found to be acceptable to both the ANC staff and the pregnant women involved. Clients appreciated the individualised care and the reduced number of provider contacts. However, for effective implementation, scale up and sustainability across the country, the challenges of staff attrition and training, funding insufficiency to support the delivery of the comprehensive range of services, poor infrastructure that limits availability of physical space to support the re-designing of client care process and functional laboratories need to be addressed (Birungi 2008).

2.3.4 Antenatal care coverage in Ghana

ANC coverage has improved over the past 20 years. Currently, more than 90% of pregnant women in Ghana attend ANC clinics at least once during their pregnancy. The coverage increased from 82% in 1988 to 95% in 2008 for all the deliveries in the five years preceding the survey (GSS/GHS/MacroInternational 2009). Only 4% did not receive any ANC during their pregnancies. The survey also showed that 95% of these received ANC from a health professional including doctors, midwives and community health nurses. The nurse or the midwife is the primary source of ANC in Ghana. Up to 78% of the women indicated having received ANC through them and 18% from

doctors. Only 1% indicated they received care from a trained or untrained traditional birth attendant. Although women in urban areas are more likely than women in rural areas to make four or more antenatal care visits, the increase between 2003 and 2008 was larger for women in rural areas (from 61% to 72%) than for women in urban areas (from 84% to 88%). Thus access to ANC especially in rural areas has improved over the years. (GSS/GHS/MacroInternational 2009). The WHO recommends that a pregnant woman under normal circumstances (without complications) should have at least four ANC visits with the first taking place during the first trimester. Among the women interviewed for the 2008 GDHS, 78% had four or more antenatal care visits for their most recent live birth, an increase of 9% over the 2003 figure. A total of 55% made their first ANC visit before the fourth month of pregnancy in 2008 compared to 46% in 2003 thus more pregnant women could be reached with a majority of ANC interventions to improve maternal health.

2.3.5 Strategies for the control of malaria and anaemia in pregnancy in Ghana

Malaria contributes significantly to morbidity and mortality in Ghana, especially among pregnant women and children under five years of age. The National Malaria Control Programme (NMCP) of the Ministry of Health has estimated that, among pregnant women, malaria accounts for 13.8% of out patients' attendance, 10.6% of admissions and 9.4% of maternal deaths (M.O.H.a. 2010). Malaria in pregnancy contributes 2-15% of maternal anaemia, 8-14% of low birth weight infants, 8-36% of preterm deliveries, 13-70% of intra uterine growth restriction and 3-8% of infant deaths (W.H.O. 2004). Currently, recommended interventions by the WHO for malaria prevention and control during pregnancy in areas of high or stable transmission include a package of intermittent preventive treatment (IPT), insecticide-treated nets (ITNs) and ensuring effective case management of malaria illness and anaemia (WHO/AFRO 2004). In response to the WHO recommendation, the NMCP and the Reproductive and Child

Health Unit, with support from partners, have developed and implemented strategies for the control of malaria in pregnancy. The general objective of the strategy is to reduce malaria related maternal and perinatal morbidity and mortality. The specific objectives include: to reduce malaria episodes among pregnant women attending ANC, to contribute to the reduction of maternal anaemia amongst pregnant women attending ANC and to contribute to the reduction of low birth weight amongst pregnant women attending ANC. These are to be delivered within the context of FANC as it has been identified as a one stop shop approach for the possible introduction of a varied range of services to the pregnant women (M.O.H.a. 2010, M.O.H.b. 2010). Specific components of the strategy include the integration of IPT with the following package of interventions within the Safe Motherhood Programme: Iron and folate supplementation, presumptive de-worming, prompt and effective case management of malaria, screening for anaemia and encouraging ITNs use among pregnant women; and increasing awareness at all levels about the integrated strategies for control and prevention of malaria during pregnancy. All pregnant women are screened for anaemia and malaria at registration and then for anaemia at 36 weeks gestation. Screening for malaria again during pregnancy only happens when the pregnant women present with symptoms suggestive of malaria. Here, treatment is to be based on only positive results using the RDT or microscopy. Presumptive treatment of malaria in pregnancy is allowed only when there are genuine stock outs of RDT and no microscopy is available (M.O.H.b. 2010).

Iron and folic acid supplementation is started at registration and are replenished at the next ANC visits. IPTp is started after 16 weeks gestation (or after quickening) and a single dose of SP (1500mg of sulphadoxine and 75mg of pyrimethamine) is administered by the health worker under direct observation at the ANC at not less than a

month's interval, three times during pregnancy. The pregnant woman is screened through history and where available through the laboratory to exclude the possibility of having Glucose-6-Phosphate Dehydrogenase (G-6-PD) deficiency (partial or full defect) before administering SP. In Ghana, the prevalence of G-6-PD deficiency in pregnancy has been found to be approximately 20% having implications for the IPTp programme. If a woman cannot take SP, she is encouraged to consistently use ITNs and other protective measures against malaria (M.O.H.b. 2010). Effective case management of a pregnant woman with malaria during the first trimester is by giving quinine for 7 days and if in the second and third trimesters, a three day course of Artemisin Combination Treatment (ACT) is administered (M.O.H.b. 2010).

2.3.6 Effectiveness of ANC strategies for malaria and anaemia in pregnancy in Ghana

Achieving high effectiveness of strategies for the control of malaria and anaemia in pregnancy has been a challenge. Even achieving the world 2005 target of 60% pregnant women being reached with strategies for the control of malaria in pregnancy (W.H.O. 2000) has been elusive. From the 2008 GDHS, less than half (44%) of pregnant women interviewed received two or more doses of IPTp and only 32% slept under an ITN the night before the survey. Only 42% of pregnant women were reported to have taken their iron supplements for three months or more during pregnancy while 13% did not take any iron supplements at all during pregnancy. Only 35% took de-worming medicine during pregnancy. It is not surprising then that an appreciable proportion of pregnant women still have asymptomatic malaria parasitaemia and anaemia during pregnancy.

2.3.7 Malaria parasitaemia and anaemia prevalence in pregnant women

The prevalence of asymptomatic malaria parasitemia among pregnant women is high and found to be associated with maternal age, gravidity, parity, gestation at first ANC

visit and income levels in Ghana (Tagbor 2005, Ofori, Ansah et al. 2009, Yatich, Yi et al. 2009) and in other African countries (Omer, Khalil et al. 2011, Valea, Tinto et al. 2012, De Beaudrap, Turyakira et al. 2013). The younger, primigravidarous, nulliparous and poorer mothers tend to be more prone to parasitaemia. Women in their second trimesters of pregnancy also tend to be significantly associated with malaria infection than those in the third trimester.

At ANC booking, asymptomatic malaria parasitaemia was found in 29.6% and 10.2% of primigravidae and multigravidae respectively in a semi-urban location. (Tagbor, Bruce et al. 2010). Tay et al, have reported malaria parasitaemia among pregnant women to be 12.6% (Tay, Agboli et al. 2013) in an urban area while Ofori et al reported malaria parasitaemia prevalence to be 19.7% in rural Ghana (Ofori, Ansah et al. 2009). At term pregnancy, 12.1% of all the women still harboured the parasite after going through ANC (Tagbor, Bruce et al. 2010) and 15% of women 32 weeks and above gestation had parasitaemia (Tutu, Browne et al. 2011) A higher proportion of pregnant women had malaria parasitaemia at delivery (36.3%) using Malaria Antigen Celisa assay instead of microscopy (Yatich, Yi et al. 2009) as it determined sub-microscopic parasitaemia levels in an urban area in Ghana.

High proportions of pregnant women suffer from anaemia during pregnancy. From the 2008 GDHS, 70% of pregnant women were found to be anaemic compared to 57% in non-pregnant women (GSS, GHS et al. 2009). Different proportions of anaemia have been reported in different populations. Tagbor et al, found 56.3% of pregnant women to be anaemic at ANC booking with 3.6% severely anaemic (Tagbor, Bruce et al. 2010). Tay et al have also reported 62.6% of pregnant women to be anaemic compared to 53.2% in non pregnant women (Tay, Agboli et al. 2013). In urban Ghana, 34% of

pregnant women had anaemia (Engmann, Adanu et al. 2008) while in Benin, a close neighbour of Ghana, the prevalence of anaemia was 39.5% at delivery (Koura, Ouedraogo et al. 2012).

Anaemia in pregnancy tends to be associated with a variety of factors. Multigravidity, multiparity, older age and infections such as malaria, HIV and hookworm increase the risk of anaemia in pregnant women (Ouedraogo, Koura et al. 2012, Agu, Ogboi et al. 2013, Alem, Enawgaw et al. 2013, Tay, Agboli et al. 2013). Poverty and limited access to nutrition and health education information also contribute to maternal anaemia (Mbule, Byaruhanga et al. 2013). Nutritional insufficiency has also been identified to be associated with anaemia in pregnancy (Ouedraogo, Koura et al. 2012, Obse, Mossie et al. 2013). Anaemia has also been found to decrease with increasing number of doses of SP received during pregnancy (Tutu, Browne et al. 2011).

2.3.8 Perceptions and knowledge about malaria in pregnancy

Cause

The perceived causes of malaria among community members have been identified to include excessive contact with external heat which upsets the blood equilibrium (Agyepong 1992); contaminated water, standing or walking in the sun, housefly, untimely eating, environmental and personal sanitation and hygiene, stale food, fatigue, eating contaminated food, dirty environments and weedy surroundings (Asante, Abokyi et al. 2010) in addition to mosquitoes. Malaria has also been perceived primarily to be a water-borne disease which was transmitted oro-faecally (Das, Das Gupta et al. 2013). To some women in Malawi, malaria in pregnancy was a common disease that was fairly harmless. They considered diseases such as cholera, diarrhoea, sexually transmitted diseases, AIDS and anaemia to be more serious than malaria in pregnancy. Malaria they thought could also be caused by hard work in addition to mosquitoes (Launiala and

Kulmala 2006). There was usually no perceived distinction between malaria and other feverish conditions shown by the use of common terminology for both malaria and fever.

Signs, symptoms and effect

Malaria has been associated with still births, death before or during delivery, excessive bleeding during and after delivery, anaemia in pregnant women and delivering a child with malaria. Also, dizziness, swelling of the legs, fever, joint pains, fatigue, loss of appetite, general body malaise, high blood pressure, palpitations, abortion, headache and vomiting have all been reported as symptoms of malaria in pregnancy (Nuwaha 2002, Mubyazi, Bloch et al. 2005, Mbonye, Neema et al. 2006, Menaca, Pell et al. 2013). However, in Uganda, anaemia and low birth weight babies were not associated with malaria and paleness was considered to be a normal sign of pregnancy (Mbonye, Neema et al. 2006). Because of social pressures that the women faced to get pregnant, they tended to hide a lot of probable symptoms of malaria such as fever, vomiting nausea and backache, until they were really sure it was pregnancy.

Treatment and prevention

Pregnant women may in addition to seeking treatment for malaria in the health facilities consult with traditional health practitioners and drug shops to obtain medicines (Mubyazi, Bloch et al. 2005). Strong cultural beliefs about signs and symptoms of malaria in pregnancy, especially in the early pregnancy, as normal, influenced the use of herbs and clay to treat all pregnancy related sicknesses (Mbonye, Neema et al. 2006). Knowledge of the benefits of the use of ITN during pregnancy does not translate into its use because of a variety of factors. In Uganda, ITN use was low because in addition to cost issues, the respondents believed that the chemicals used for treating the nets posed

a danger to the women and their foetuses (Mbonye, Neema et al. 2006). ITN were also said to cause a lot of heat and discomfort and so prevented the pregnant women from using them (Nuwaha 2002, Mbonye, Neema et al. 2006, Chukwuocha, Dozie et al. 2010). Other methods of malaria prevention were known including, weeding around homes, keeping the environment clean, disposing of empty tins and broken pots properly, not leaving stagnant water in the environment and closing windows and doors early in the evening, and eating properly make the body stronger however these practices were not observed usually by the pregnant women due mainly to laziness and economic constraints.

2.3.9 Perceptions and knowledge about anaemia in pregnancy

There have been very few studies which report on the perceptions and knowledge about anaemia in pregnancy. In a study conducted across 8 developing countries including Bolivia, Burkina Faso, Guatemala, Honduras, India, Indonesia, Malawi and Pakistan (Galloway, Dusch et al. 2002), anaemia was described as “no longer have any blood,” “have weak blood” or “their blood is pure water”. Symptoms such as headache, dizziness, paleness, “become yellow,” “decayed blood,” “thin blood,” fainting, “low blood,” weight loss, and loss of appetite were used to describe anaemia in the pregnant woman. Some women confused the concept of anaemia with low blood pressure.

Most of the women in the above study said that anaemia was caused by poor quality of food intake or lack of food intake due to poverty. Inadequate intakes of foods such as meat, green vegetables and competition with other members of the family for food were also mentioned. Sleeping too much, sleeping uncovered, sleeping during the day, hard work or working in the sun were also mentioned as some of the causes of anaemia in women. Some other causes that were mentioned included malaria, HIV, frequent births, worms, eating dirt and soap and young age.

Although the responses about the effect of anaemia were varied across the countries, conditions such as death of the mother and baby, giving birth to weak, thin, deformed or premature babies were reported. Not having blood was also associated with inability to push out the baby during the birthing process. Some of the women however said that too much blood could also be detrimental to the health of the woman. The women did not associate the risk of bleeding heavily after delivery with anaemia.

Taking in good and nutritious foods were recommended by women in this study as the treatment for anaemia in pregnancy. Roots, herbs and plants like radish, beets and carrots could also be taken to cure anaemia. The women recognised that rest and reducing their workload could also help treat anaemia. Some perceived anaemia to be caused by black magic or curses and therefore consulted soothsayers or religious leaders for treatment. Some women also mentioned blood transfusion to treat anaemia and associated the drink 'coca-cola' with treating anaemia because it was given to blood donors. Although most of the women recognised iron and multivitamin tablets, they hardly understood that they were for treating anaemia and thus may have affected their intake among the study women. Some women however reported some benefits of taking the tablets which included improved strength and blood, feeling less tired, becoming more active, having a better appetite and also having a healthy baby. Others reported discontinuing taking the tablets for fear of having big babies which could make delivery difficult. Some women were also worried that they would not have enough money to buy more food should their appetite increase with the taking of the tablets (Galloway, Dusch et al. 2002).

2.4 Patient participation in health care

2.4.1 General overview of patient participation in health care

The patient participation concept in health care is quite complex. Various terms exist for it including patient collaboration, patient involvement, partnership, engagement, patient empowerment, or patient-centred care and are used interchangeably (Longtin, Sax et al. 2010). The Oxford Advanced Learner's dictionary defines participation as 'the act of taking part in an activity or event'. Generally, patients take part in their health care by either being involved with the development of medical care at one level or being involved in their own medical care at another level. (Wensing and Baker 2003). Patient participation may thus include enabling patients to take an active role in developing, deciding about and planning their own primary medical care. They are helped to contribute to the development and implementation of healthcare, to decide about using health care, to support them as their own health advocates and encourage them to share responsibility for their own health (Wetzels, Harmsen et al. 2007).

For some few years now, the concept of patients participating in their health care has been gaining popularity. It is increasingly being identified as an important ingredient in the delivery of health care. Patients can be encouraged to participate in aspects of their own medical care such as decision making, self-medication and self-monitoring especially with regards to the treatment of chronic illnesses, patient education, goal setting, or taking part in their physical care (Weiss 1986, Cahill 1998, Guadagnoli and Ward 1998). Patient participation is also being recommended in the improvement of patient safety. The WHO World Alliance for Patient Safety is advocating for the active role that patients and their families could play to improve their health (W.H.O. 2005b). A lot of studies on patient's participation to improve patient safety have concentrated on adherence to medications and infection control practices such as hand washing.

However other ways that patients can be involved to improve their safety include making informed choices about who their providers should be, helping providers to reach accurate diagnosis of their conditions, checking how accurate their medical records are, actively checking and observing the health care processes themselves and discussing any suspicions, identifying and reporting any complications and adverse events of their treatments, and managing and treating themselves effectively (Coulter and Ellins 2007).

During the consultation process, the patient can be assisted to make as informed a choice as possible about the diagnosis and management of his medical condition (while weighing the benefits against the risks), and to take partake of an alliance with the health care provider about his treatment. He assumes some independence and takes part in the decisions made for his medical treatment and care (Wetzels, Harmsen et al. 2007).

Patients are becoming expectant to be involved in their health care (Verhoef, White et al. 1999). 'Patients have grown up-and there is no going back,' says Angela Coulter, the executive director of policy and planning, London, in an editorial to the British Medical Journal. There is now a movement from paternalism where the health care provider is responsible for all decisions of care for his patient to partnership where the healthcare provider and the patient work together to achieve a common goal. Both parties respect and recognise each other's skills and competencies and use these to achieve beneficial health outcomes(Coulter 1999).

When patients have been given information and explanations for or according to their health needs, have been shown respect as individuals or been allowed to take part in the

planning of their health care and when they are able to make decisions based on their knowledge and needs, they feel that they have participated in their healthcare (Eldh, Ekman et al. 2006).

2.4.2 Effect of patient participation in health care

There is supporting evidence that when patients participate in their healthcare, it leads to improved health outcomes. Some studies suggest that patients' active participation during the medical interview reflects in better health outcomes (Kaplan, Greenfield et al. 1989, Kaplan, Greenfield et al. 1996) and that when there is increased patient participation , some aspects of medical care are also improved (Liaw, Lawrence et al. 1996, Atkin, Stringer et al. 1998). When doctors encourage their patients to participate more actively in treatment decisions, there are more favourable health outcomes, physiologically and functionally compared to those whose doctors do not (Kaplan, Gandek et al. 1995). Diabetic patients were found to have significantly lower glycosylated haemoglobin levels and fewer function limitations when they participated in an intervention to involve them in treatment decision making (Greenfield, Kaplan et al. 1988). Also, patients in an intervention group reported fewer limitations in physical and role-related activities and preferred to take part more actively in medical decisions after being part of a programme to encourage them to ask questions, negotiate medical decisions and read their medical records during the consultation period (Greenfield, Kaplan et al. 1985). However a recent systematic review has revealed non-conclusive results for patients participating in their care. No overall effect of patient participation could be demonstrated on disease-related outcomes with some studies even showing deterioration in outcomes. Also some studies showed the control patients having better outcomes than the patient participation group (Sanders, van Weeghel et al. 2013). Possible explanations that were given included the varied definitions for patient participation that existed in the studies, the existence of only a few controlled studies,

the inability to fully blind health providers and the lack of actual behavioural differences between the experimental and control groups. It was also noted that it was not easy to change provider behaviour with respect to patient participation and this could also have contributed to the lack of effect. The complexity of the concept of patient participation could have contributed to the described weak quality of the trials and hence the inconclusive results that were obtained. In one of the studies reviewed above, doctors and nurses in the intervention arm were trained on evidence and skills for patient centred care. The diabetic patients were given a hand held booklet to encourage them to ask questions during the consultation process. All these were done as a means of increasing patient participation in their health care (Kinmonth, Woodcock et al. 1998). Although patients in the intervention group reported better communication with providers, greater treatment satisfaction and wellbeing, these did not reflect in the measurement of their body mass index, triglyceride concentrations and knowledge scores. Recorded differences in the lifestyles and glycaemic controls between the groups were of no significance. Probably emphasis had been placed on the consultation process to the detriment of the management of the diabetic disease itself in these patients. Another study in which general practitioners and their practice nurses were trained to administer patient centred care to type II diabetic patients found that although the practioners adopted the intervention with enthusiasm at the beginning of the trial, this was not sustained throughout the period of the trial. Thus no significant differences were found in biomedical or functional status between patients of the control and intervention arms (Pill, Stott et al. 1998).

2.4.3 Factors influencing patient participation in their health care

Longtin et al have identified acceptance of new patient role, level of health literacy and extent of knowledge, confidence in their own capacities, type of decision making required, stakes of the proposed outcome, type of illness and co-morbidity, age, sex,

socioeconomic level, ethnic origin, use of alternative medicine and health care worker professional specialty as some of the factors that influence the patient to participate in their health care (Longtin, Sax et al. 2010). For example, if a patient is willing to take up the responsibility of taking part in the decision making process concerning his or her health, then he or she will participate. A passive patient would care less about his involvement in his health care while a seriously ill patient may not be able to participate in his care.

Similarly, there are some healthcare worker factors that may influence patient participation in their health care. These include health care workers' refusal to delegate power, their perceived lack of time, the type of health situation the health care worker is dealing with, their personal beliefs, their specialisation level, the race, age and sex, and their training in patient-physician communications (Longtin, Sax et al. 2010). Thus the health care worker and the patient both have significant influences in the participation process and the success of it depends on how well both parties are willing to allow the process to be implemented.

2.5 Patient adherence

2.5.1 Adherence to treatment recommendations

'The extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider' is termed as adherence (WHO 2003a). Thus non-adherence occurs when the individual's behaviour towards health seeking or its maintenance is at par with what has been recommended by the health care provider. Issues of adherence are mostly found in situations where the patient is expected to administer treatment himself no matter the disease type, severity or the patient's accessibility to health resources.

Adherence has generally been studied in association with the management of chronic diseases like hypertension, diabetes mellitus, asthma, HIV/AIDS and depression, where a patient is expected to take medications for a long period of time, if not for a life time. It can however be applied to all health conditions where a patient is expected to 'follow' some recommendations given by a health care provider.

It has been estimated that only 50% of chronic disease patients adhere to their recommendations even in the developed world where access to health care and health resources is higher. In developing countries, adherence may be assumed to be poorer because of poorer access to health care and resources. For example, only 27% and 26% of patients with hypertension were found to adhere to their medications in the Gambia and the Seychelles respectively (van der Sande, Milligan et al. 2000, Bovet, Burnier et al. 2002).

2.5.2 Consequences of non-adherence to treatment recommendations

Adherence to treatment recommendations is associated with improved patient outcomes whiles poor adherence impacts negatively on the effectiveness of treatments given. This manifests as poor patient outcomes with increased risks of complications. For example, amongst hypertensive patients, poor adherence to medication will lead to poorly controlled blood pressure. Poorly controlled blood pressure increases the risk morbidity and mortality with increased risk of conditions such as stroke, myocardial infarction, and renal impairment (Jin, Sklar et al. 2008). Poor adherence is also associated with increased economic burden on the society. Non-adherence increases emergency care visits, in-patients admissions and hospital days with attracted higher costs of treatment (Svarstad, Shireman et al. 2001). Health providers tend to change the treatment regimen because of unperceived non-adherence and this increases the cost of treatments given and the complexity of the regimen further complicating non-adherence. The patient's

quality of life is compromised and there is associated loss of productivity (Jin, Sklar et al. 2008).

2.5.3 Factors associated with adherence to treatment recommendations

A patient is expected to adhere to aspects of his healthcare such as appointment-keeping, medication use, following protocols for behaviour change and obtaining inoculations (WHO 2003a). A complex interplay of many factors has been identified that fight against the patient's ability to adhere to treatment recommendations. These include patient-centred factors, the disease characteristics and treatment, factors related to the health care system and the delivery of the health service, therapy related and social and economic factors (Jin, Sklar et al. 2008).

Patient-centred factors such as the patient's health literacy rate; attitudes, beliefs and group norms; culture; psychological state; the patients involvement and participatory decision making level have all been found to affect the patient's level of adherence to treatment recommendations (Martin, Williams et al. 2005). Forgetfulness is also widely recognised as a sole patient factor that greatly influences adherence to medications or clinic appointments (Morisky, Green et al. 1986). It is expected that socio-demographic factors of patients such as age, ethnicity, marital status, educational level and sex may have a direct correlation with adherence level but this has been found to be non-conclusive (Vik, Maxwell et al. 2004, Jin, Sklar et al. 2008). Rather, patients who feel susceptible to the disease and its complications, who believe that the disease and its complications are a threat to their health and who believe that the treatments given will work and be beneficial to them, tend to have better adherence to treatment. However patients who have misconceptions and unfounded beliefs about the disease and/or treatment and believe that the disease cannot be managed and hence worry a lot, fear or get angry or depressed tend not to adhere to treatment (Jin, Sklar et al. 2008). This can

be explained by the Health Belief Model of health behaviour where a person's individual beliefs of perceived susceptibility to and severity of disease leads to a perceived threat of the disease (Glanz, K. et al. 2008). The perceived threat of the disease is also influenced by the socio-demographic characteristics and existing knowledge of the individual. The perceived threat influences the individual's likelihood of behavioural change. The individual also weighs the perceived benefits of behavioural change against the perceived barriers to take action and his own perceived self-efficacy (the conviction that one can successfully effect any behavioural change to influence to produce an expected health outcome) to change behaviour. Also, cues to action which the individual gets through education about the disease and recommendations from the health provider, symptoms he experiences and media information influence the individuals behaviour. (Glanz, K. et al. 2008). For example, some pregnant women's beliefs that routine drugs given at the ANC clinic would make them feel hungry unnecessarily and also cause their babies to grow big leading to difficult delivery deterred them from taking all their iron and vitamin supplements (Smith, Jones et al. 2010).

Therapy-related factors include how long the medication is supposed to be taken in addition to how complex the medication regimen is. Adherence reduces when the patient has to take the medicine long-term and when the medication regimen is made up of many different medicines that have to be taken simultaneously. The type of medicine, whether liquid, capsular, injections or tablets and the patient's own perception of the effectiveness of the medication prescribed also affect the level of adherence of the patients (Kusserow 1990). Frequency of dose of medicine per day also affects medication adherence (Claxton, Cramer et al. 2001) with once a day regimens having a higher adherence compared to multiple dosing.

Patient-provider relationships are essential for patient adherence. Patient knowledge, beliefs, motivation and negative attitudes towards the disease condition and treatment can all be influenced positively by a healthy patient-provider relationship. Good communication during the patient-provider encounter builds trust and trusting relationships highly affect adherence and hence health outcomes of patients. For example, physicians who encourage the building of trusting relationships, who have good communication and bedside manners and who are empathic with their patients tend to encourage adherence to a wide range of treatment recommendations in their patients (O'Malley, Forrest et al. 2002). The use of more than three medicines for a disease condition and poor patient–health provider relationships (including the use of more than one provider) have been found to also contribute to non-adherence among patients (Vik, Maxwell et al. 2004).

2.5.4 Patient participation improves adherence to treatment recommendations

Physicians who encourage their patients to take part in their health care often communicate well with their patients and win their trust. This improves the patients' satisfaction with their care which in turn positively impacts on adherence (Golin, DiMatteo et al. 2002, Martin, Williams et al. 2005). Lack of participation may have negative consequences such as non-adherence to treatment and possibly be linked with negative outcomes (Bikowski, Ripsin et al. 2001).When patients' preferences in treatment-related decisions are not considered, especially when there is minimal communication and hence limited participation in their care, they feel frustrated and hence less empowered to take up treatment recommendations. They have more negative attitudes towards prescribed treatments and report lower levels of adherence (Webb, Horne et al. 2001). But when patients are actively encouraged to participate in their own care and feel that their physicians communicated well with them, they tend to be more

motivated to adhere to treatment recommendations (Martin, DiMatteo et al. 2001, O'Malley, Forrest et al. 2002) leading to improved health outcomes. Patients who see themselves as active partners with health providers in the treatment process and who participate in the healthcare process have better health outcomes because of better adherence behaviour and health outcomes (Schulman 1979). During the participation process, knowledge about the disease, its management and the consequences of non-adherence when shared by the provider improves the patient's understanding of their disease condition promoting adherence to treatment medications (Gascon, Sanchez-Ortuno et al. 2004, Ponnusankar, Surulivelrajan et al. 2004). Pregnant women completed their course of anti-malarial medicines given in spite of the minor adverse events they had experienced because they had been involved in the diagnostic process through the use of rapid tests for malaria during their ANC and they knew they had malaria (Tagbor, Bruce et al. 2006).

2.5.5 Measurement of medication adherence in patients

Adherence is a behavioural process and the measurement of it remains an estimate of the patient's behaviour. Acceptable methods for measuring medication adherence are available but as yet, accurate measurement continues to be difficult as there is no gold standard (Vik, Maxwell et al. 2004). Various approaches have been used to measure medication adherence among patients. These include the use of subjective means where patients, family members, caregivers or health care personnel are asked to report medicine use; objective means by pill counting, examining pharmacy refill records or electronically monitoring the pills taken out of a container; or biochemical means where medication markers or metabolites of the medicine are measured in the patient's blood or urine (Brown and Bussell 2011). These measures are considered as proxy measures since it is not possible to observe continually patients taking their medicines (Garfield, Clifford et al. 2011).

When patients are directly questioned about their adherence to medications, they tend to give quite an accurate assessment (Vik, Maxwell et al. 2004). Thus patients' estimate of adherence can be effective in assessing adherence. A variety of scales exist for the estimation of patients' self report of medication adherence. The Morisky Medication Adherence Scale has been used for chronic medical conditions like hypertension (Morisky, Ang et al. 2008). The visual analogue scale (VAS) although originally used in pain management has been applied to HIV (Walsh, Mandalia et al. 2002, Giordano, Guzman et al. 2004, Oyugi, Byakika-Tusiime et al. 2004). It has been reported from existing studies that it is easier for patients to estimate general adherence to medicines rather than to report specific doses that they have missed. Also, that it may be easier for patients to use the VAS compared to other scales (Garfield, Clifford et al. 2011).

2.6 Point of care tests

2.6.1 Definition and properties of point-of-care tests

Point of care (POC) testing is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POC testing refers to any testing performed outside of the traditional, core or central laboratory" (NACB 2006). The site of patient care could be the bed-side, the consulting room, the emergency room, operating room or wherever patient care is conducted. The advantage is that the time interval between testing to diagnosis and treatment is shortened as the results of the tests are available more quickly compared to laboratory testing. It gives the health care provider and his patient immediate access to tests results and hence prompt action based on the results and spares the patient the cost and inconvenience of a return visit to present laboratory results. Hence POC tests offer short turnaround time and patients are willing to wait for the results (Anderson, Crowe et al. 2011). The tests devices are usually hand held and do not need permanent dedicated space. They are not as

sophisticated as laboratory machines and hence their accuracy may be compromised. They are thus developed to be as sensitive and specific to diagnosing the disease condition as possible. Simple, rapid point of care tests are also developed to be affordable, user-friendly, robust and rapid, giving results in less than 30 minutes, equipment-free (or reliance on minimal equipment that can be solar powered) and deliverable to those who need them according to the 'ASSURED' criteria (WHO, UNICEF et al.).

POC testing has been found to reduce hospital stay, improve adherence to treatment and reduce disease complications. In general, it is believed to be more expensive than laboratory testing but it has superior economic benefits in the long term (Price 2001b).

2.6.2 Point of care tests in antenatal care

One of the principles underlying the WHO FANC model is that "wherever possible, rapid and easy-to-perform tests should be performed at the ANC clinic or in a facility as close as possible to the clinic". And "when the test results are positive (e.g. positive for syphilis), treatment should be initiated at the clinic the same day". (W.H.O. 2002). This is to ensure the rapid diagnosis and subsequent treatment of disease among pregnant women to enhance the effectiveness of ANC programmes, for example, the PMTCT of HIV. There is improved uptake as a majority of women who get to the ANC get tested during their care. Pregnant women need not be sent to laboratories outside the ANC clinics hence loss to follow up is minimised. The number of pregnant women who would not have returned to the ANC clinic following laboratory requests is reduced and a lot more pregnant women are reached with appropriate care.

POC testing has been part of routine ANC for some time now. It was however being used for urine tests to confirm pregnancy and to detect protein or sugar in urine. With

the advent of rapid tests for the diagnosis of HIV and syphilis, these tests are also being conducted as part of routine ANC. Currently, rapid tests for malaria diagnosis are also available. This is welcome news, especially in endemic countries where malaria infection is asymptomatic most of the time in pregnant women. Screening of asymptomatic pregnant women using the rapid test for malaria and their subsequent treatment during their ANC is being advocated (Tagbor, Bruce et al. 2010).

2.6.3 Point-of care tests as decision aids to facilitate client participation in ANC

Various tools have been used to facilitate patient participation in their health care such as the provision of printed leaflets and health information packages to improve health literacy among patients, the use of computer based and internet health information, targeted mass media campaigns, patient decision aids, training of providers in communication skills and coaching and question prompts for patients (Coulter and Ellins 2007). Decision aids help provide health information to assist patients in deciding various aspects of their health care such as essential treatment options including their risks and benefits with the goal of influencing behavioural outcomes including improving adherence to treatment recommendations.

POC testing provides the platform for engaging patients in increasing their literacy about the state of their diseases or health conditions and helping them make informed choices about their role in managing them. It has also been shown that the use of the POC tests leads to improved patient activation and satisfaction and hence adherence with treatment and management strategies (Price 2001a). In Project ImPACT: Hyperlipidaemia, the use of POC testing to monitor fasting blood lipid profiles of patients at the community pharmacist's level produced a high level of collaboration between the pharmacists, the patients and their physicians. Regular and improved communication was kept between the providers and the patients based on timely test

results acting as a source of objective information about the patient's progress. Patients upon knowing their test results during the consultation process accepted referral to and from the pharmacists to the physicians based on clinical results and timely adjustments in the patients' medications were made. Patients were highly motivated to be part of their care and this resulted in their becoming more persistent and adherent with their medication and life style changes yielding improved patient outcomes (Bluml, McKenney et al. 2000).

Similarly, POC testing during ANC can be used to increase the pregnant woman's participation in her care. It has the potential of increasing the pregnant woman's level of activation: her knowledge about the condition being tested, her skill of interpreting the test results in relation to her health and that of her baby's and confidence in managing her own health. It offers the ANC provider and her client the opportunity of increased communication in addition to the advantage of producing rapid results for the initiation of immediate treatment. The test results can be used as a means to offer information to the pregnant women about the medical condition tested and how to treat or manage it thus increasing her knowledge. It can also provide the pregnant woman the opportunity to ask questions and receive answers concerning the test results and their implications for her and her baby's health. Treatment options can also be discussed and agreed upon between the provider and the pregnant woman and the POC test used to monitor progress of the pregnant woman during her subsequent visits. Seeing an improvement in the test results at subsequent visits will boost her level of confidence in being able to manage her health yielding better health outcomes.

2.6.4 Malaria Diagnosis

Malaria diagnosis using light microscopy remains the 'gold standard' with sensitivity of about 50 parasites/ µl of blood (assuming a total red blood cell count of 5×10^6/ µl of

blood) in expert hands. However, its use in areas where it is needed most is challenged by lack of microscopy expertise. Also there appears to be on-going changes in the known morphological appearances of malaria parasites which may be as a result of drug pressure, strain variation or the way in which blood is collected. These may decrease the diagnostic accuracy of microscopy even further in the absence of well trained and expert microscopists (Moody 2002). Well-trained technicians, a microscope in good condition, electricity and a well-functioning quality assurance system are needed for the microscopy to be effective. These are generally not available at peripheral health facilities especially in developing countries and therefore encourage presumptive treatment of malaria based on clinical signs and symptoms in these areas. Other forms of malaria diagnosis do exist and include fluorescent microscopy and polymerase chain reaction but these depend on more complex technology and are not readily available.

2.6.5 Malaria Rapid Diagnostic Tests

Rapid Diagnostic Tests (RDTs) for malaria offer the potential for accurate malaria diagnosis especially in areas where microscopy services are not available such as in remote locations or even after regular laboratory hours in areas where the laboratory may be present. They are simple to perform and interpret, do not require electricity or special equipment and can be stored under ambient conditions. Obtaining test results within 15 minutes of drawing blood from a pregnant woman with suspected malaria infection is now made possible by the use of RDTs (W.H.O. 2000).

They are blood-based lateral-flow immune-chromatographic tests which capture specific antigens (proteins) produced by malaria parasites that are present in the blood of infected or recently infected persons using monoclonal antibodies impregnated on to the test surface. Blood for the test is commonly obtained from a finger-prick. The dye-labelled antibody first binds to a parasite antigen from the blood of the patient, either

Plasmodium falciparum histidine-rich Protein-2 (*pf*HRP2) or *Plasmodium* spp. lactose dehydrogenase (pLDH). The complex that results, captured on the of nitro-cellulose strip by band of bound antibody, forms a visible coloured test line. The presence of a control line on the test strip gives information on the integrity of the antibody-dye conjugate. In its absence, the test is invalid. Because RDTs detect circulating parasite antigen, they may be better at detecting submicroscopic levels of parasitaemia increasing their reliability as detectors of placental malaria (Mockenhaupt, Ulmen et al. 2002). A third enzyme, the aldolase has also been identified for use in the manufacture of RDT but only a few studies have investigated its use. It has been found to have a lower sensitivity compared to the HRP2 antigen (Richter, Gobels et al. 2004, Ashton, Kefyalew et al. 2010).

Below is a picture showing test results using an RDT (Figure 3). Positive results show as a double band on the test cassette at the C (control) and T (test) spots. A negative test shows as a band at only the C spot. An invalid test result means that no band shows at the C spot even if T shows a band.

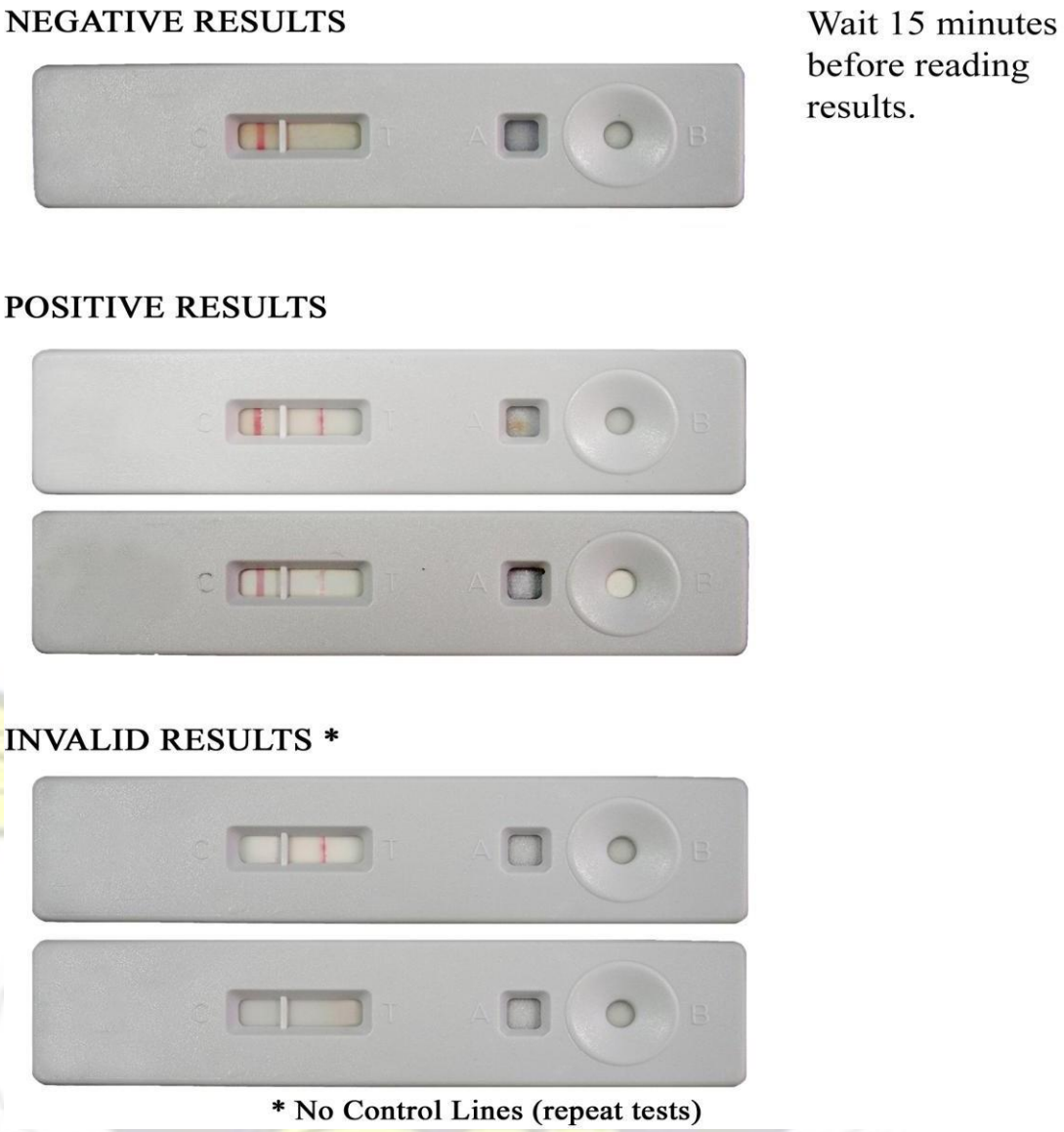


Figure 3: Malaria RDT test results (Adopted from W.H.O Generic Pf_Guide_White.pdf

The use of RDTs however has limitations. They are not sensitive enough to detect parasite densities of less than 100 parasites per µl (Moody 2002) however this is close to clinical laboratory staff performance and life-threatening infections will not be missed. Negative results in patients with symptoms however may have to be confirmed by microscopy. The HRP2-test based RDTs are preferred in areas where *Plasmodium falciparum* infection occurs in more than 90% of the population and are useful to us in sub-Saharan Africa. However, the presence of other plasmodium species (*Plasmodium ovale* and *Plasmodium malariae*) infections may be missed when the *pf*HRP2 test based RDT is used in such environments because it will give negative results (Moody 2002). The *pf*HRP2 antigen tends to persist in the blood of patients for variable periods of time, beyond the clearance of peripheral parasitaemia (Shiff, Premji et al. 1993, Beadle, Long et al. 1994, Kyabayinze, Tibenderana et al. 2008). Thus patients who have responded to treatment and are well may still be positive when the RDT is used in certain cases and may give confusing interpretations to the response to therapy. Genetic variations of the *pf*HRP2 antigen has been documented (Baker, McCarthy et al. 2005, Baker, Ho et al. 2010) in addition to lack of this antigen altogether (Kumar, Pande et al. 2013, Maltha, Gillet et al. 2013) . These, when they occur in the study population, reduce the sensitivity of the RDT and produces false negative results. RDTs are heat and humidity sensitive hence poor storage can affect the quality and hence performance of the tests which tends to influence the health worker's decision to prescribe an anti malarial medicine. Also, improperly performing the RDT according to manufacturers' instruction due to lack of health worker training and supervision can result in misdiagnosis of malaria (Mouatcho and Goldring 2013) . False negative results can also occur when there are very high parasite densities due to the 'prozone' effect (Gillet, Scheirlinck et al. 2011). The binding sites on the RDT cassette get flooded with excess *pf*HRP2 antigens from the patient's blood leading to a negative or very faint test line.

The RDT is also not able to quantify the density of parasitaemia present. This has implications for choice of management plan of the patient. Having a parasite count aids in prognostic assessment of the patient and gives information when suspected drug resistance is present in patients not responding to treatment (Moody 2002).

2.6.6 Acceptability of the use of the RDT in healthcare

Acceptability can be described as the attitudes, perceptions and beliefs that influence the use of a health intervention among implementers of the intervention and the users of it (Asiimwe, Kyabayinze et al. 2012, Tine, Ndiaye et al. 2013). It depends on attributes of the health intervention, the implementers and users of it and the health system. An intervention that is acceptable will be implemented and used by the population intended and vice versa.

The acceptability of the use of the RDT for malaria diagnosis has been assessed within different contexts. The use of the RDT in malaria diagnosis has been found to be acceptable to community health workers (CHW), health care providers, caregivers of children under five years, and community members. Numerous patient, provider and test specific factors influence the level of acceptability among different populations. In Senegal, the use of the RDT by CHWs was found to improve the diagnostic capabilities of the CHWs which attracted more community members to access their services. However RDT and anti malarial stock outs was noted as major barriers to the intervention (Tine, Ndiaye et al. 2013).

In Uganda, health workers and users of primary health care facilities noted an increased sense of professionalism, increased self confidence, improved provider-patient interaction leading to improved patient trust and confidence in the health workers and health system increasing the acceptability of the RDT's use. However, such factors as

the imposed threat to the health worker's clinical judgement, lack of clear guidelines for the management of patients with RDT negative results, increase in workload, stock outs of RDTs and antimalarials, not prescribing anti malarials to RDT negative patients and a relatively long wait for test results compared to using clinical judgement posed a threat to its continued acceptance (Asiimwe, Kyabayinze et al. 2012). The level of trust in CHWs and the educational level of CHWs were likely to affect the use of the RDT by community members in the Iganga district of Uganda. RDT use was likely to be acceptable only if the CHWs were properly trained and received regular supervision and supply of RDT and antimalarials. Perceived fear that their blood could be used for HIV testing and that the procedure could infect children with HIV, in addition to their blood used for witchcraft purposes, could be a hindrance to the RDT use among this population (Mukanga, Tibenderana et al. 2010).

In Ghana, improved patient's perceptions about the health facilities, increased willingness of patients to report to health facilities (Chandler, Whitty et al. 2010), perceived improved quality of care because of perceived improved communication between the health care worker and caregivers of children under five years (Baiden, Owusu-Agyei et al. 2012) have also been reported as factors increasing the acceptability of the use of the malaria RDT. In addition, patients were happy with the use of the RDT during their visit to health facilities because they believed the test could communicate their health problems better than they could verbally and that the test could identify any cause of illness in them beyond malaria (Ansah, Reynolds et al. 2013).

In rural part of central Cote d'Ivoire, socio cultural factors played a key role in the acceptability of the use of the malaria RDT. There was the perception that blood was a

sacred body fluid and hence they were unwilling for their blood to be drawn for the test. They also had fear of the test itself in addition to the fact that they believed the test could be used to check their HIV status (Comoe, Ouattara et al. 2012).

2.6.7 Screening for anaemia

During health assessments, the measurement of Hb is conducted routinely because of the recognised global problem of anaemia. During the course of pregnancy, an accepted standard of practice is that all women have at least one haemoglobin measurement which is usually carried out by electronic (automated) counter (Coulter). However, in many developing countries, this method is not readily available, especially at the peripheral health facilities level where ANC occurs. Thus, either screening for anaemia may not be carried out at all or may be limited to inspection of the conjunctiva, tongue and nail beds by the nurse or midwife for the presence of pallor during antenatal visits. Clinical inspection of the conjunctiva for anaemia in pregnant women has been found to have a sensitivity of only 33.2% for Hb of <11g/dl and 39.7% for Hb of <10g/dl (van den Broek, Ntonya et al. 1999) bringing into question the accuracy of such a method for detecting anaemia during ANC. Sensitivity however increases with severity of anaemia and was reported to be 62.0-69.0% for detecting Hb of <7g/dl in a study population of 16% incidence of severe anaemia (Shulman, Levene et al. 2001).

Other methods for the screening of anaemia are currently available. A simple, portable haemoglobin meter, the HemoCue with a sensitivity of between 80% and 97% and a specificity of between 79% and 99% depending on the cut-off points for haemoglobin concentration used is available (Neville 1987, Hudson-Thomas, Bingham et al. 1994, van den Broek, Ntonya et al. 1999). However, it relies on relatively expensive disposable cuvettes thus limiting their widespread use. An older method like the copper sulphate method has also been studied in ANC clinics and has been found to be accurate

(sensitivity 94%, specificity 95%) for Hb < 10 g/dl in pregnant women. It is inexpensive (<0.3% the cost of the Coulter counter), and was recommended for the screening of anaemia in pregnancy (Pistorius, Funk et al. 1996).

2.6.8 The haemoglobin colour scale

A colour scale for assessing Hb, the haemoglobin colour scale (HCS) (Figure 4) has been developed by WHO and is recommended for use in screening for anaemia in settings where resources are limited (van den Broek, Ntonya et al. 1999). It is very simple to use requiring only a very brief training period, rapid, and cheap (US$ 0.02 per test) (Lewis 2002). The HCS cannot compete with laboratory-based haemoglobinometry but it is a useful tool for identifying anaemia accurately and for assessing its severity. It works independently of electricity and can be used perfectly well in daylight or adequate artificial light. It is pocket-sized and can be extremely useful as a point-of-care test for anaemia anywhere (Lewis 2002). Even community health workers with minimal formal education (up to primary education) could use the HCS to diagnose severe anaemia and moderately-severe anaemia in real-life field conditions with minimal training (Shah, Desai et al. 2014).

With a finger prick blood sample, it relies on comparing the colour of a drop of blood absorbed onto a filter paper with standard colours on a laminated card, varying from pink to dark red. These colours correspond to haemoglobin levels of 4, 6, 8, 10, 12, and 14 g/dl. It allows Hb levels to be judged to 1 g/dl since intermediate shades can be identified.

Errors with its use can occur from inadequate or excessive blood being put unto the strip, reading the results too soon and /or too late (more than two minutes), poor lighting effects, or holding the scale at the wrong angle but the accuracy was improved

drastically when the tests were repeated under supervision, avoiding these errors (Ingram and Lewis 2000).

Mixed results of the HCS's diagnostic performance have been documented. It has been found to be more sensitive in detecting anaemia compared to clinical pallor in some studies but the opposite in others. Earlier assessments amongst antenatal women and general outpatients, showed that clinical judgement of pallor was frequently wrong, but the HCS gave correct diagnosis in 97 out of a 100 cases, with a 96% sensitivity and 86% sensitivity (Ingram and Lewis 2000). Amongst children 6-35 months, the HCS was found to have a sensitivity and specificity of 89% and 97% respectively compared to clinical pallor which had a sensitivity and specificity of 73% and 98% (Sinha, Deshmukh et al. 2008). It has also been found to be useful in determining anaemia and severe anaemia amongst preschool children (Montresor, Albonico et al. 2000). In Zanzibar, the sensitivity of the use of palmar pallor was found to be low but superior to the HCS. The HCS had 33% sensitivity in detecting anaemia and 14% in detecting severe anaemia whilst palmar pallor had a sensitivity of 58% in detecting anaemia. The HCS was however found to have a better specificity (87% vs 55%) (Aldridge, Foster et al. 2012). The sensitivity of the HCS was also found to be very low when used for anaemia screening during blood donation exercises compared to the cyanmethemoglobin method ranging from 55% in Hb of more than 13g/dl to 28% in Hb between 7g/dl to 9g/dl (Darshana and Uluwaduge 2014).

Although the accuracy of the scale is high in laboratory-based studies but tends to deteriorate as studies become more field-based and 'real life', it is still a promising tool for diagnosing anaemia, especially where there is no laboratory (Critchley and Bates 2005).

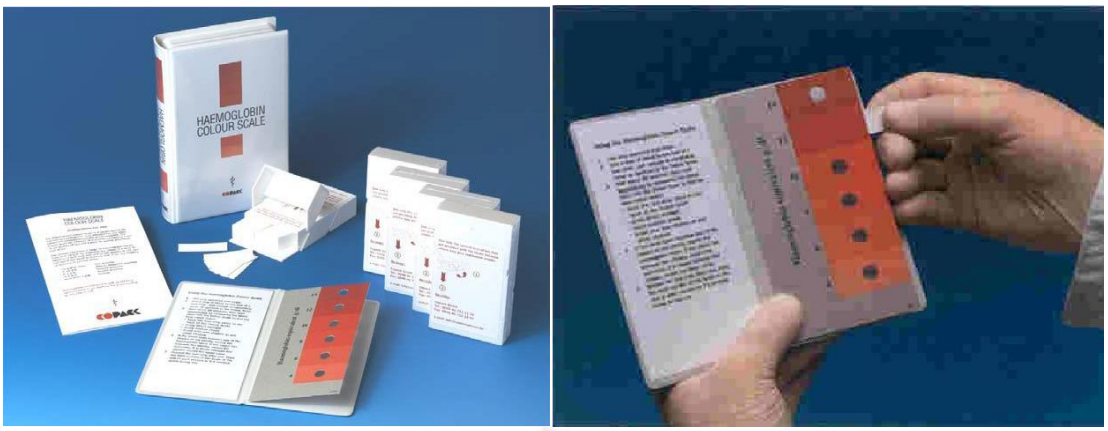


Figure 4: The WHO Haemoglobin colour scale (WHO 2004)

CHAPTER 3 METHODS AND MATERIALS

3.1 Introduction

This study was conducted to determine the effect of an enhanced ANC package on pregnancy outcomes. The enhanced package included pregnant women participating in their ANC using the RDT and the HCS during antenatal clinic sessions. A variety of activities were employed in order to achieve the study's objective. These processes were grouped into three phases:

Phase 1: The pre-intervention phase. This was the preparatory phase. The objectives of this phase included identifying and describing the characteristics of ANC clinics in the study area, describing the baseline characteristics of the study population, sourcing of materials for the study, recruiting and training research assistants for data collection, developing a desk guide and a pictorial guide for use by the ANC staff and training ANC staff to implement the intervention.

Phase 2: The intervention phase. The implementation of the enhanced package constituted the intervention. The objectives of this phase were to assess the feasibility of the use of the HCS and the RDT during ANC sessions and to determine the effect of the use of these tools during ANC on pregnancy outcomes.

Phase 3: Post-intervention phase. During this phase, the acceptability of the enhanced ANC package was explored among the pregnant women and ANC staff.

Table 1 below shows a summary of the objectives and activities conducted in each phase of the study and the methods employed.

Table 1: **Summary of study phases and objectives, activities and the methods employed**

Phase of study	Objectives	Activities	Method
Phase 1: Pre-intervention/ Preparatory	i. To recruit and train research assistants	i. Identifying qualified persons and training them in data collection	i. Training
	ii. To source for study materials	ii. Liaising with sponsors and local suppliers to purchase study materials	ii. Sourcing and procurement
	iii. To identify all ANC clinics in study area and select for intervention	iii. Mapping of all health facilities in study area, identifying ANC clinics and randomizing eligible ANCs for intervention	iii. Global positioning system and randomisation using Stata SE 11 computer software
	iv. To describe ANC in study area	iv. Observing ANC in study area	iv. Observational study
	v. To describe baseline characteristics of study population	v. Collecting baseline information from pregnant women attending ANC clinics	v. Cross sectional survey
	vi. To develop a desk guide and a pictorial guide for malaria and anaemia in pregnancy	vi. Drafting and finalising a desk guide and pictorial guide for malaria and anaemia in pregnancy	vi. Participatory development
	vii. To train ANC staff to implement enhanced ANC package during ANC sessions	vii. Identifying and training of ANC staff to implement enhanced package	vii. Training
Phase 2: Intervention	i. To determine the feasibility of the use of the enhanced ANC package during ANC sessions	i. Conducing supervisory visits to the ANC clinics for the integration of the use of the enhanced ANC package	i. Observation and supervision
	ii. To monitor the fidelity of implementation of the enhanced ANC package during ANC sessions	ii. Conducting monitoring visits to implementing sites to observe ANC sessions, discussing implementation with ANC staff, conducting exit interviews with pregnant women	ii. Non-participant observation of ANC sessions, focus group discussions, exit interviews
	iii. To determine the effect of the enhanced ANC package on pregnancy outcomes	iii. Collecting data from a cohort of pregnant women	iii. Cluster randomised controlled trial
Phase 3: Post intervention	i. To determine the acceptability of the enhanced package to pregnant women and ANC staff	i. Holding group discussions and interviews with pregnant women and ANC staff	i. Focus group discussions and in-depth interviews

3.2 Study location

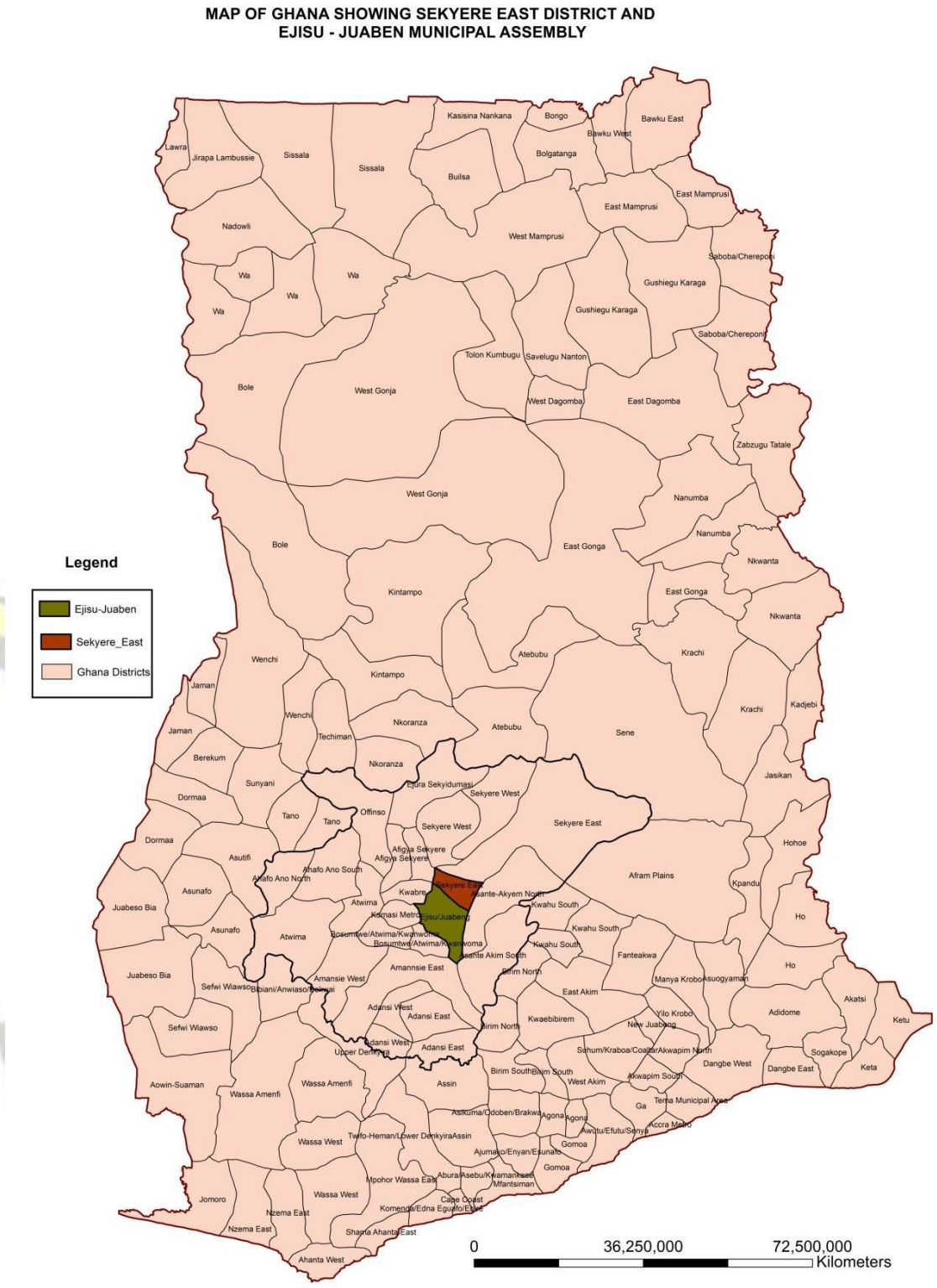


Figure 5: Map of Ghana showing the Sekyere-East district and Ejisu Juaben Municipality

The study was conducted in the Sekyere-East district and the Ejisu-Juaben municipality of the Ashanti region of Ghana. These are adjacent to each other and lie in the forest belt of Ghana. The Sekyere-East district is predominantly rural while the Ejisu-Juaben municipality has semi-urban and rural areas. The main economic activity carried out in both areas is subsistence farming. Malaria was the topmost disease reported at the outpatient's department (OPD) of both areas in 2010: 87.0% of all OPD attendances in the Sekyere East district and 47. 9% in the Ejisu-Juaben Municipality (DHMT 2011, MHMT 2011).

There are 4 sub-districts in the Sekyere East district namely Effiduase, Asokore, Nyanfa and Mponua with a total of 38 predominantly rural communities. The estimated 2010 population of this district was 87,284 and it covers an estimated land size of 730.5 square kilometres. An estimated 17, 456 women were in the reproductive age. The Effiduase Government Hospital, the district hospital is one of the two hospitals that serve the district, in addition to 4 health centres and 1 clinic. All the hospitals and health centres run ANC clinics. In the year 2010 the antenatal coverage was 70.6% with an average of 4.3 visits per pregnant woman. There were a total number 2471 new ANC bookings. A total of 23.4% of the pregnant women was anaemic (Hb < 11.0 g/dl) at their ANC booking visit and a similar proportion was anaemic at term (23.3%). A total of 1567 babies were delivered with 2.6% being still births and 14.2% being of low birth weight. Of all the deliveries in the district, only 44.7% were supervised by skilled birth attendants. One maternal death was recorded in the health facilities in the district in 2010 (DHMT 2011).

The Ejisu-Juaben municipality has 5 sub-municipals namely Achiase, Bomfa, Ejisu, Juaben and Kwaso. There are a total of 91 communities spread over an area of 637.2 square kilometres. Government health facilities include 3 hospitals, 4 health centres and

1 CHPS compound. There are a number of private hospitals, maternity homes and clinics too. The 2010 estimated population was 171,136 with a total of 39,703 women in the reproductive age. The antenatal coverage for the year 2010 was 96.1% with an average of 3.7 visits per pregnant woman. There were a total of 6616 new ANC bookings. Anaemia at 36 weeks gestation among pregnant women was 43.4% compared to 38.6% at first ANC booking. There were a total of 3846 deliveries with 11.9% being of low birth weight and 1.7% still births. In all, only 56.2% of deliveries were conducted by skilled birth attendants. A total of 7 maternal deaths were recorded in the year, 3 being due to post partum haemorrhage (MHMT 2011).

3.3 Pre-intervention phase activities

A description of the activities undertaken during the pre-intervention phase is given below.

3.3.1 Study team recruitment and training.

A total of 15 research assistants were recruited for the project. They comprised of post tertiary education graduates (post polytechnic or post-university) of varying backgrounds ranging from science to the arts and business. One of them acted as the supervisor of the team liaising between the researcher and other team members mainly for the supply of logistics for the study. Within a period of two weeks, the team underwent training in various aspects of the study (Figure 6). These included:

i. How to conduct the RDT
ii. How to use the HemoCue 301 analyser for Hb determination
iii. Blood slide preparation (thick and thin film) and air drying for malaria parasitaemia determination

iv. How to request for informed consent from pregnant women and to recruit into study

v. How to administer questionnaires to pregnant women for data collection

vi. How to conduct ANC clinic observations using a check list

The services of a post graduate laboratory technologist were employed to assist in training the research assistants with regards to how to do the RDT, HCS and prepare the blood slides for malaria microscopy. The research assistants were trained in how to obtain informed consent, administer questionnaires to the pregnant women and how to conduct the observations using the check list. Practical sessions were held in one ANC clinic in the Bosomtwe district to take the research assistants through the processes from consenting of the pregnant woman to collection of all relevant data for the study. The district is adjacent to the Ejisu-Juaben Municipality and has similar socio-economic characteristics as the study sites. The data collection tools were pre-tested in a day in one ANC clinic in the Bosomtwe district. All the research assistants had the opportunity of administering at least one questionnaire for the cross sectional survey and performing the RDT and Hb test. In addition, pretesting of the checklist for the ANC observation was done in pairs. The appropriateness of agreed local dialect for the questionnaire and the pregnant women's understanding of the questions were tested. The responses were discussed and any difficulties encountered clarified and used to modify the tools appropriately before the cross sectional survey and the ANC observations.

Figure 6: Training sessions of the research assistants

3.3.2 Sourcing of study materials.

The RDT, HCS, HemoCue 301 analysers and Foetal heart monitors were sourced with the help of the MCDC of the London School of Hygiene and Tropical Medicine. It was estimated that a total of 3000 RDT test kits would be needed for the baseline survey and the RCT. These were purchased in two batches from the manufacturers (PMC Medical India Pvt. Ltd., Mumbai, India) bearing in mind the expiry dates of the kits. The First Response brand was purchased. Also 14 starter kits each comprising of one HCS, 200 test strips and printed literature regarding its use and 2 refill kits, each comprising of 2000 test strips were purchased from COPACK GmbH Medical Branch, Osteinbek, Germany, the manufacturers. In addition 14 Sonoline B Foetal heart monitors with gel and 10 HemoCue 301analysers (from HemoCue AB, Angelholm, Sweden) were also purchased abroad and shipped to Ghana for the study. Blood slides, lancets, digital thermometers, stool containers and other laboratory consumables that were used were purchased locally by the researcher.

3.3.3 Identification of ANC clinics for study

In order to identify which ANC clinics would be used for the study, the following activities were undertaken:

i. *Mapping of health facilities.* The spatial distribution of all health facilities in the two districts were captured and displayed in Geographic Information System

environment using the Global Position System. This was done with the help of a geomatic engineer from the Kumasi Polytechnic. A total of 36 health facilities were identified. This was cross checked with data from the health authorities of the two health directorates. A familiarisation tour of all the health facilities was done to identify all health facilities that offered ANC services. These were noted and then identified geographically on the map. A total of 23 health facilities with ANC clinics in operation were identified; five in the Sekyere-East District and 18 in the Ejisu-Juaben district (Figure 7).

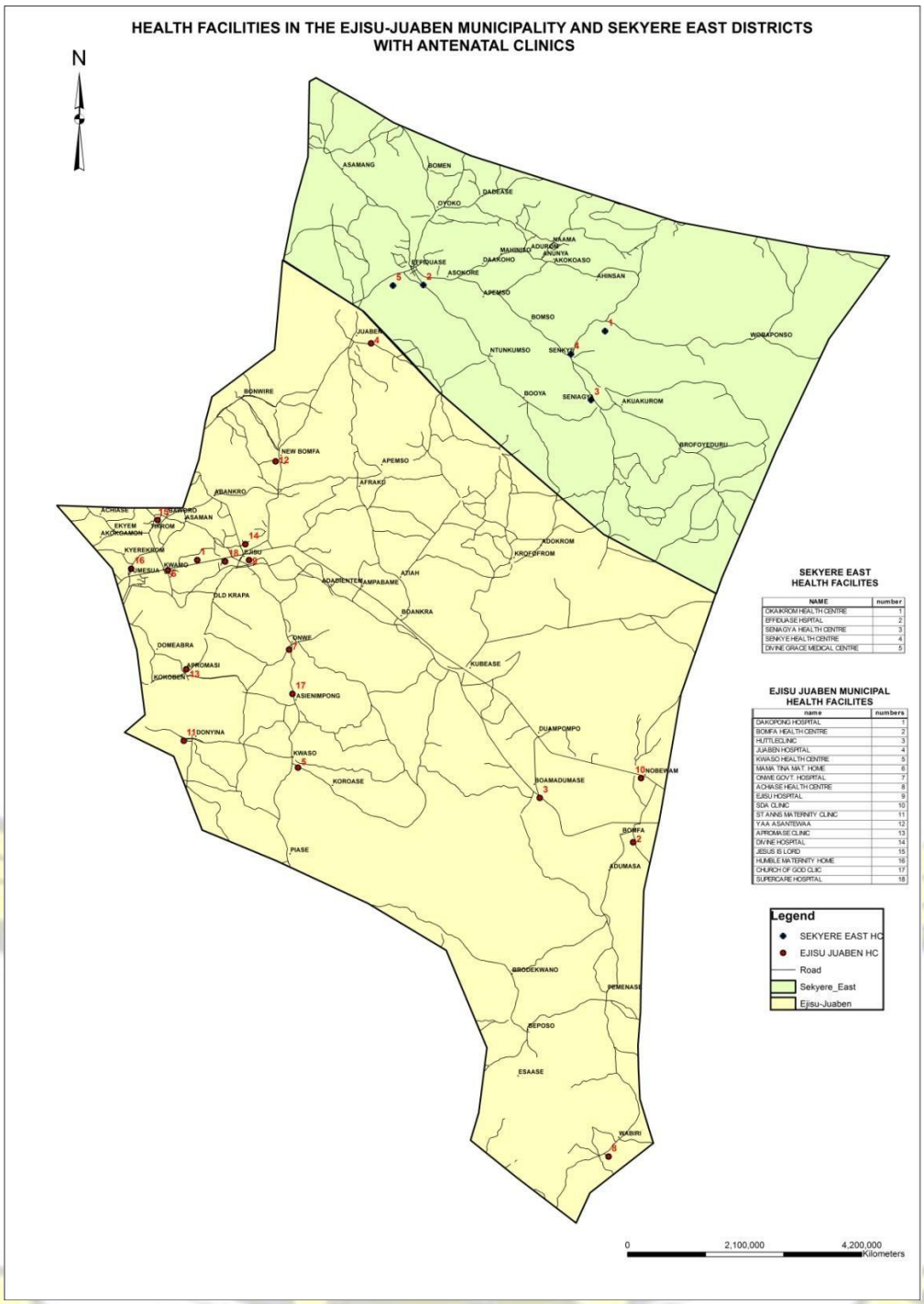


Figure 7: The distribution of all health facilities with ANC clinics in the Ejisu-Juaben Municipality and the Sekyere-East District

ii. *Observation of ANC in the districts.* All the 23 health facilities with ANC clinics were included for the ANC observations. However 2 of the health facilities were excluded later on because their heads did not consent to be part. The research assistants visited the remaining 21 ANC clinics in pairs to observe their characteristics in terms of practices and organization of ANC, category and number of staff available, laboratory and pharmacy services and maternity services available using a checklist (Appendix 1). The observation was done to confirm that ANC services were on-going in the clinics and also to describe ANC services in the study area before the introduction of the intervention.

iii. *Selection and randomisation of ANC clinics for RCT.* Information was sought from the municipal and district health administrations concerning the number of newly booked antenatal clients per month for the year preceding the survey for all the identified ANC clinics. Based on this information, ANC clinics that had newly booked antenatal clients of less than 10 per month for 2010 were disqualified. This was based on the fact that recruitment of study participants was anticipated to occur over a maximum of one year. Hence at a rate of at least 10 new ANC bookings per month, sufficient number of participants could be recruited even in the smaller clinics under the prevailing conditions. In addition ANC clinics that did not offer maternity services or had ANC services suspended were also eliminated. If 2 ANC clinics were situated within 1.5 kilometres of each other, the bigger ANC clinic was chosen over the smaller one in terms of the number of new ANC bookings per month. This was done to reduce the chances of pregnant women crossing over from one ANC to the other during the trial. In the end, a total of 14 ANC clinics were selected to participate in the cluster RCT after they had been demonstrated to be geographically

separate from each other by at least 1.5km radius. Initially, 12 ANC clinics were considered to be the minimum number of clinics needed for cluster nature of the study to be able to detect any differences in Hb between the intervention and control arms. However this number was increased to 14, within budget constraints, to allow for smaller numbers to be recruited per clinic over the estimated time frame. It had been observed that the current rate of ANC booking would not allow for the numbers required to be recruited over a one year recruitment period per clinic. Using Stata SE 11 software, the 14 ANC clinics were then randomised into either the intervention or control arms, 7 in each arm. These ANC clinics were then visited to discuss the study with the managers and to seek their permission for the study to be conducted in them. Their randomisation into either the intervention or control arm was not disclosed to them. Below (Figure 8) is a flow chart depicting the processes that led to the randomisation of the ANC clinics and Figure 9 shows the spatial distribution of the 14 ANC clinics randomised.

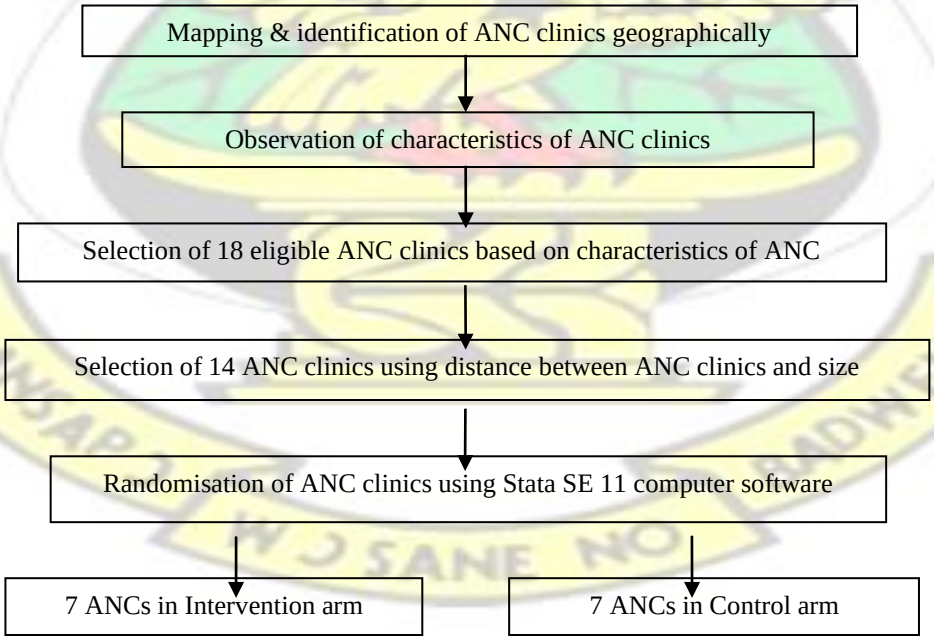


Figure 8: Flowchart of cluster randomization of ANC clinics

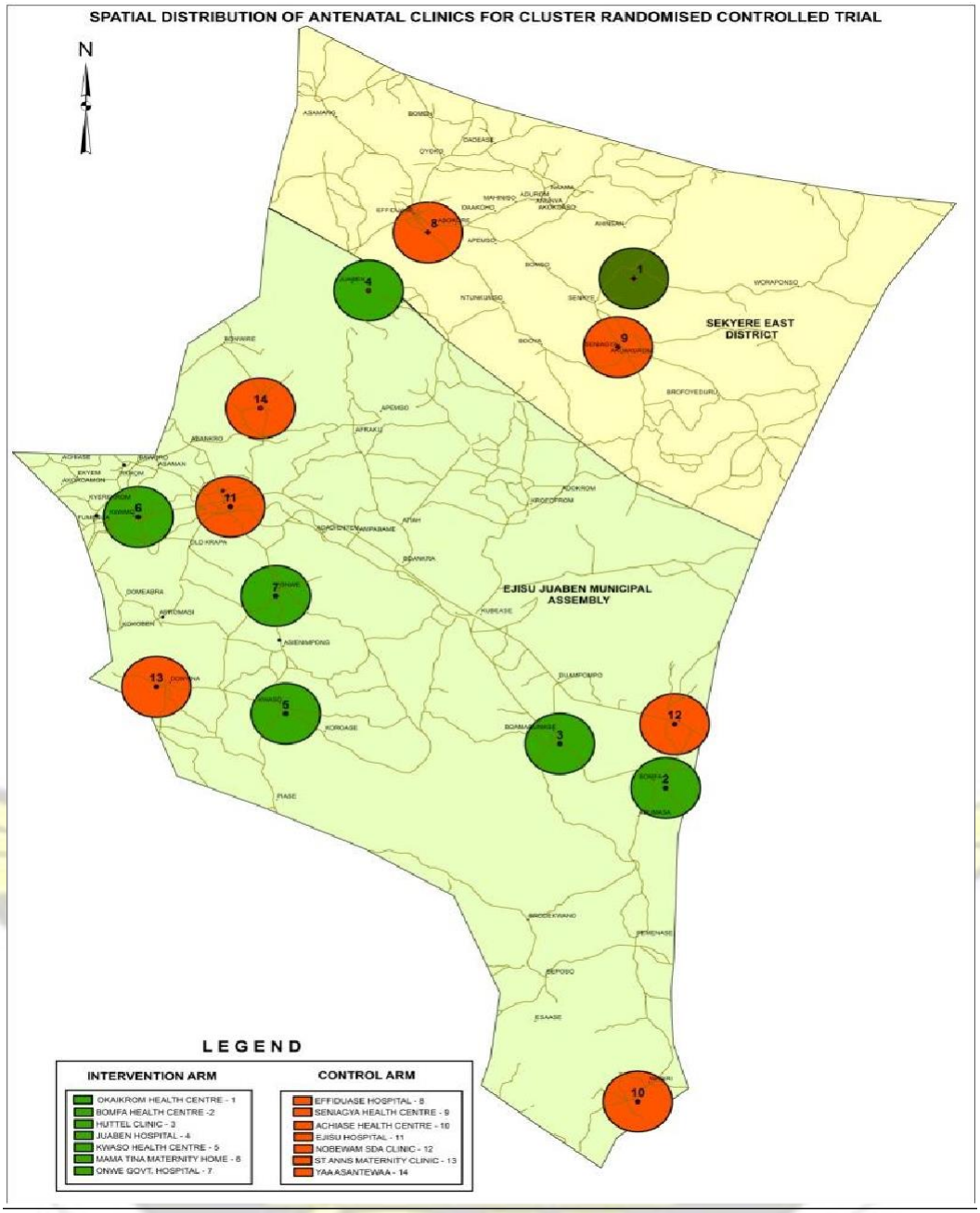


Figure 9: Map of Ejisu-Juaben and Sekyere-East districts showing the 14 selected ANC clinics for the RCT

3.3.4 Cross sectional survey.

3.3.4.1 Aim

The aim of this cross sectional study was to describe the characteristics of the study population and to determine the prevalence of asymptomatic malaria parasitaemia and anaemia and their associated factors within the study population.

3.3.4.2 Study population

Pregnant women of 32 weeks gestation and above visiting 21 ANC clinics in the Ejisu-Juaben Municipality and the Sekyere-East district were interviewed.

3.3.4.3 Methods

This survey was conducted from December 2011 to April 2012. All pregnant women ≥ 32 weeks gestation visiting the 21 identified ANC clinics and were willing to participate in the study were eligible. On each ANC clinic day for the health facilities, research assistants with the help of the ANC staff identified eligible pregnant women and approached them for their consent. A pre-tested structured questionnaire (Appendix 2) was then administered to those who consented as they exited the ANC clinic. Information was collected on their socio-demographic characteristics, level of self reported adherence to iron and folic acid supplementation, level of knowledge of malaria and anaemia in pregnancy, ITN use and the number of SP doses received for IPTp. Their Hb and malaria parasitaemia levels were also determined using the HemoCue 301 analyser and the First Response RDT for malaria as described in sections 3.6.1 and 3.6.2.1 respectively below.

3.3.4.4 Sample size calculation

A study conducted in the Ejisu-Juaben district (Tagbor, Bruce et al. 2010) found that the prevalence of anaemia (Hb <11.0g/dl) and asymptomatic malaria parasitaemia at 36-40 weeks gestation was 47.6% and 12.0 % respectively. The 2010 annual reports

(DHMT 2011, MHMT 2011) of the study area also estimated the prevalence of anaemia at 36-40 weeks gestation using the current ANC package to be 23.3% and 43.4 % for the Sekyere-East and Ejisu-Juaben districts respectively. An estimated prevalence of 50% of either anaemia or parasitaemia would allow for the maximum number of pregnant women to be sampled for the survey. Thus at a confidence interval of 95%, a precision of 5% and a power of 90%, the sample size was estimated to be 385 using the formula below:

$$n = Z^2 \frac{p(1-p)}{d^2}$$

Where n is the estimated sample size of the pregnant women

Z is the Z score at a confidence interval of 95% = 1.96

p is the estimated prevalence of anaemia = 50%

d is the precision = 5%

At a 20% non-response rate, the total number estimated was 482 pregnant women.

3.3.4.5 Data management and analysis

The information gathered from the pregnant women was recorded on the questionnaires. Two data entry clerks were engaged in entering the data electronically using Epidata 3.1 computer software. On completion of data entry, the Epidata 3.1 software was used to compare the data entered between the two clerks. All discrepancies generated were corrected using the questionnaires from which the data was entered. Stata SE 11 computer software was used to analyse the data. Data was summarized using frequencies and percentages, graphs, means and standard deviations or median and ranges. Tests of association between dependent and independent variables was

conducted using the log-binomial regression and reported as risk ratios set at a significance of ≤ 0.05 and a confidence interval of 95%.

The dependent variables were anaemia and asymptomatic parasitaemia. Anaemia was defined as haemoglobin level of < 11.0 g/dl. A positive RDT result was defined as asymptomatic parasitaemia in a pregnant woman who did not have symptoms for malaria. The independent variables were the age, gravidity, parity, highest level of education, ITN use, number of doses of SP recorded in the maternal health record book (MHRB), level of adherence to ANC health advice (which was measured by proxy by the level of self-reported adherence to iron and folic acid supplementation (section 3.6.3) and level of knowledge about malaria and anaemia (section 3.6.4).

3.3.5 Participatory development of pictorial guide and desk guide.

A desk guide for use by the ANC staff in implementing the enhanced ANC package and a pictorial guide to aid in the participation process of the pregnant women were drafted in collaboration with a graduate of the faculty of Art, KNUST, who drew the pictures used in the guides. A series of discussions were held with three different groups of ANC staff in the Bosomtwe district (the district where all pre-testing of study tools and materials was undertaken) to seek their opinion and contributions about the guides. Changes were made to some of the pictures in the pictorial guide, for example, using tablets instead of syrups for iron supplementation to reflect the current practise in ANC and clarity in some of the pictures depicting the signs and symptoms of malaria and anaemia. The pictorial guide was also shown to a few pregnant women and to lay persons in the Bosomtwe district to identify any difficulties in interpreting the pictures. Contributions made were also incorporated into the modification of the guide. The desk guide was edited for typographical errors and the general understanding of it by a lecturer of the Faculty of Art, KNUST. The guides were sent back to the ANC staff for

final comments and pre-testing before their use in the cluster randomized study (Figure 10). Figure 11 shows a picture of the final products of the desk guide and the pictorial guide and details are shown in Appendix 3 and Appendix 4.

Figure 10: ANC staff in Bosomtwe district participating in the development of the guides

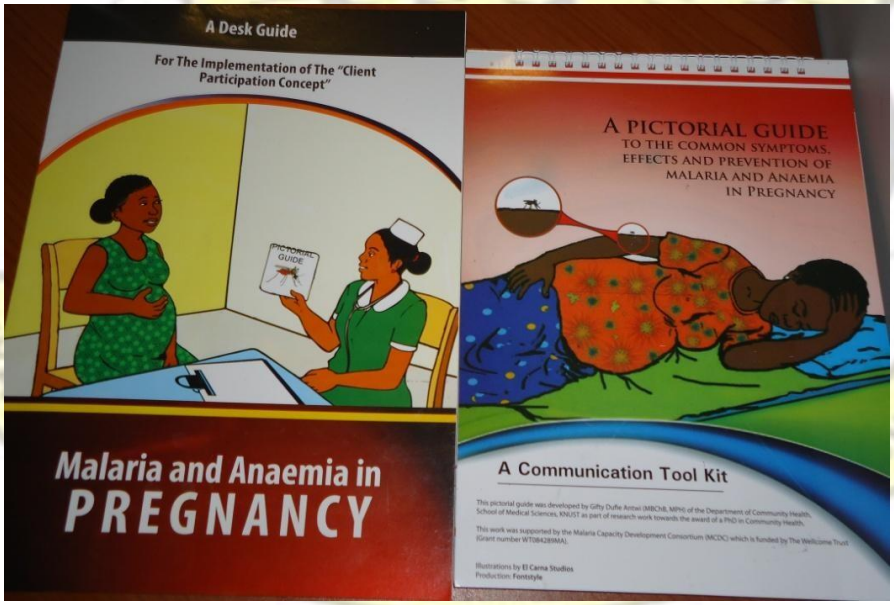


Figure 11: A picture showing the finished products of the desk guide and the pictorial guide

3.3.6 Training of ANC staff for implementation of the enhanced ANC package.

Two staff members per each of the 7 ANC clinics randomized into the intervention arm were invited for a one day training workshop. The head of the ANC of each of these clinics was strategically included in the training so as to facilitate the adoption of the intervention into their routine practices. With the help of a postgraduate laboratory technologist, the ANC staff members were trained under the supervision of the researcher's local academic supervisor. Training involved how to do the RDT and HCS tests; how to use the pictorial guide, HCS and RDT in the participation process; documentation of the RDT and HCS results; and the discussion of appropriate recommendations to give to the pregnant women based on the test results. The ANC staff practised how to do the RDT and HCS on themselves and staged role plays to demonstrate the use of the HCS, RDT and pictorial guide in the participation process in the first part of the training session. In the second part, pregnant women were invited from the site of training for practise. The ANC staff paired up and practised integrating the participation process using the pictorial guide, RDT and HCS into their routine practices on a pregnant woman for her ANC. Thus a set of 7 pairs of ANC staff practiced on 7 pregnant women, members of each pair contributing to the practise implementation process. The ANC staff was supervised during the practise process to offer further guidance and assistance when needed. At the end of the practise session, a final discussion to further clarify any difficulties was held to end the training.

Figure 12: ANC staff in a training session

3.3.7 Integration of the enhanced ANC package into current ANC practices

After the training session, RDTs, HCS, pictorial guides, desk guides and notebooks were supplied to the 7 intervention ANC clinics to start implementation. Within 2 weeks in September, 2012, all 7 ANCs in the intervention arm had started the implementation of the enhanced package. The implementation sites were visited on their days of ANC to observe and supervise the implementation process so as to ensure the smooth integration of the package into the current ANC. Data collection for both the intervention and control ANC clinics begun after 2 weeks of implementation of the enhanced ANC package in the intervention clinics. This time was to allow for all the ANC staff in the intervention sites to become familiar with the implementation of the enhanced package. During this period, trained staff passed on their skill and knowledge of the enhanced package to other ANC staff members involved with consultation under the supervision of the researcher. All 14 ANC clinics were supplied with foetal heart monitors to help with confirmation of foetal viability at each ANC visit.

3.3.8 Components of the enhanced antenatal care package

The enhanced ANC package included, in addition to the current ANC that was being implemented in the ANC clinics, the use of the RDT and HCS by trained ANC staff in the participation process, the availability of a desk guide to aid the ANC staff in implementation of the enhanced ANC, and a pictorial guide about malaria and anaemia

in pregnancy to aid in the participation process of the pregnant women in their ANC (Table 2).

Table 2: Intervention and control arms of randomized control trial

Intervention arm	Control arm
❖ Current ANC package • Medical and obstetric history • Physical examination: blood pressure, weight, height, temperature • Obstetric examination: symphysio-fundal height measurement, foetal viability • Routine urine and stool examination, blood group, sickling, VDRL, HIV. • Screening for anaemia and malaria at 1st visit and for anaemia at 36weeks gestation • IPTp, tetanus toxoid administration • Folic acid and iron supplementation • De-worming • ITN use, dietary, scheduled ANC visit, birth preparedness recommendation (Health education)	❖ Current ANC package • Medical and obstetric history • Physical examination: blood pressure, weight, height, temperature • Obstetric examination: symphysio-fundal height measurement, foetal viability • Routine urine and stool examination, blood group, sickling, VDRL, HIV. • Screening for anaemia and malaria at 1st visit and for anaemia at 36weeks gestation • IPTp, tetanus toxoid administration • Folic acid and iron supplementation • De-worming • ITN use, dietary, scheduled ANC visit, birth preparedness recommendation (health education)
❖ Trained ANC staff in the use and interpretation of the RDT and HCS	
❖ Desk guide to aid implementation and a pictorial guide for aiding participation of pregnant women in their ANC	

3.4 Intervention phase activities

3.4.1 The intervention: Participation of pregnant women in their ANC

All pregnant women who visited the ANC clinics in the intervention arm were invited by the ANC staff members to participate in their ANC at each ANC visit until they delivered. The ANC staff performed the RDT and HCS tests with blood from a single finger tip prick of the pregnant woman. The results of the RDT and the HCS were interpreted with the pregnant women (Figure 13 and Figure 14) and they were also encouraged to ask any questions they had about the test results. Based on the test results, the pregnant women were given recommendations including the use of ITN, adhering to iron and folic acid supplementation and or anti-malarial treatment, healthy eating and regular ANC clinic attendance. The pictorial guide assisted in the

participation process. It contained pictures of pregnant women showing signs, symptoms, effects and prevention of malaria and anaemia in pregnancy. The ANC staff showed the pictures to the pregnant women and asked for them to describe what they saw. In this way the ANC staff and the pregnant women were able to engage in a conversation about malaria and anaemia in pregnancy (Figure 15).

Figure 13: Pregnant woman participating in her care through the use of the RDT

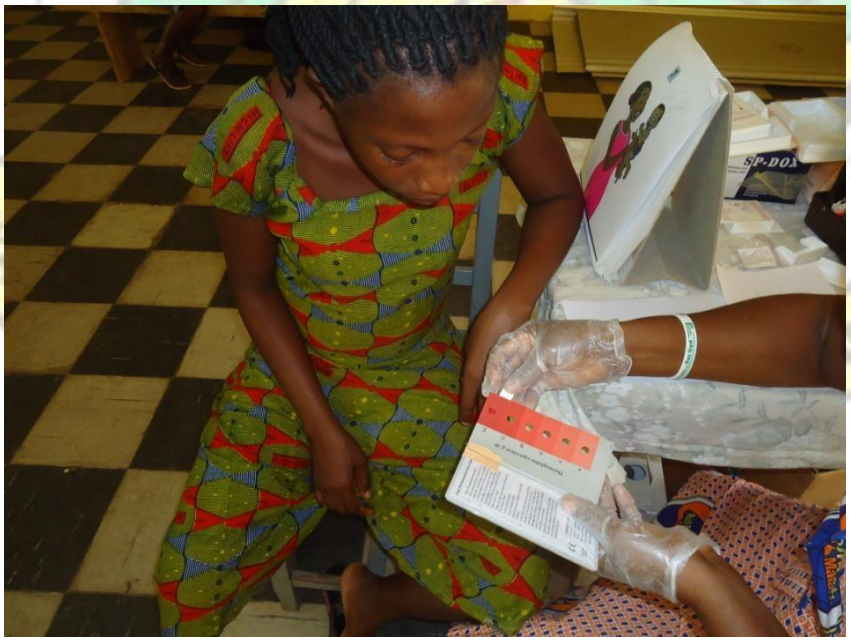


Figure 14: Pregnant woman participating in her care through the use of the HCS

Figure 15: Pregnant woman participating in her care through the aid of the pictorial guide

3.4.2 Feasibility and implementation fidelity of the use of the HCS and RDT in client participation in ANC

3.4.2.1 Aim

The aim was to describe how feasible it was for ANC staff to use the RDT, HCS and pictorial guide to facilitate pregnant women's participation during ANC sessions and to assess how this enhanced ANC package was being adopted and implemented during ANC sessions.

3.4.2.2 Method

During the first month of implementation of the enhanced package, all the implementing ANC clinics were visited regularly on their specific ANC days, at least once a week, to assist in the integration of the intervention into their routine ANC practices. In the following three months, monthly supervisory visits were made to each implementing ANC clinic to observe and discuss on-going ANC processes including the

intervention. During this time too, any discrepancies in implementation procedures noted were discussed and rectified. Supervisory visits were gradually reduced in frequency to once in two months after the 6th month of implementation.

The feasibility of the intervention was assessed in terms of the ANC staff's ability to use the RDT, HCS and the pictorial guide during ANC sessions to engage the pregnant women in their care without disrupting the workflow of routine processes at the clinic. The RDT, HCS and pictorial guides were supplied free of charge by the researcher. Stocks of the RDT and HCS strips were constantly replenished through the research assistants hence availability of the tools was assured. Also, the ANC staff members could call on phone if they anticipated stock outs for their supply to be replenished. Observations made during the supervisory visits in the first six months of implementation of the intervention were documented in the form of field notes for the feasibility assessment.

To assess how well the ANC staff adhered to implementation of the components of the enhanced ANC package and describe the factors that influenced the adoption and implementation of the enhanced ANC package by the ANC staff,

i. A trained independent observer conducted non-participant observations and exit interviews at the implementation sites for the assessment of fidelity.
ii. Focus group discussions were conducted amongst implementing ANC staff to describe the adoption and implementation of the intervention.

Non participant observations and exit interviews

The trained independent observer visited one ANC clinic per day and spent an average of 6 hours at each ANC clinic observing activities and interviewing the pregnant women. The observations were non participatory in nature using a checklist (Appendix 5) in the 9th month of implementation. By this time, it was assumed that the ANC staff members had become used to implementing the enhanced package and had adopted their own coping mechanisms for implementing it. All implementing ANC clinics were visited. The activities that were observed during the ANC sessions included whether the RDT and HCS were used to test for malaria and anaemia respectively in the pregnant women, whether the ANC staff involved the pregnant women in the interpretation of the results of the RDT and HCS, whether any recommendations were given to the pregnant women based on the RDT and HCS results, whether the results of the RDT and HCS were recorded and whether the pictorial guide was used to encourage pregnant women's participation in groups or on individual basis. In all 10 items were to be observed (Table 3). For each item on the checklist, the observer ticked as observed if she saw the activity take place in at least one of the ANC staff-pregnant women interactions in the clinic. Up to 5 ANC staff-pregnant women interactions were observed in addition to any group educational talks that were given by the ANC staff.

The independent observer also conducted short exit interviews with pregnant women, up to 5 per ANC clinic, during her visit to the clinics to ascertain the processes they had been through during their ANC using an interview guide (Appendix 6). The interviews were conducted in 'Twi'(our local dialect) and tape recorded with the consent of the pregnant woman. The interviews found out whether the pregnant women had seen the HCS, RDT and pictorial guide (which were shown to them by the observer) before, whether the RDT and HCS were used to test their blood during their ANC, whether they

saw and understood the results of the HCS and the RDT, whether the pictorial guide was used in participatory education with them or one-on-one and whether any recommendations with regards to malaria and anaemia in pregnancy were given to them. In all, there were 12 items that the pregnant women were to mention to describe what they had experienced (Table 4).

Table 3: Content of enhanced ANC package observed

	Activity Observed	**Yes**	**No**
1.	Group education of pregnant women about malaria and anaemia using the pictorial guide		
2.	One on one education of pregnant women about malaria and anaemia using the pictorial guide		
3.	ANC staff using the rapid diagnostic test (RDT) to test for malaria in pregnant women		
4.	ANC staff using the Haemoglobin colour scale (HCS) to test for anaemia in pregnant women		
5.	ANC staff engaging pregnant women in the interpretation of results of the RDT		
6.	ANC staff engaging pregnant women in the interpretation of results of the HCS		
7.	ANC staff giving recommendations to pregnant women based on the results of RDT		
8.	ANC staff giving recommendations to pregnant women based on the results of HCS		
9.	ANC staff giving the pregnant women the opportunity to ask questions about antenatal consultation		
10.	ANC staff recording results of the HCS and RDT in note book		

Table 4: Content of enhanced ANC package described by pregnant women

	Activity described by pregnant woman	Yes	No
1.	Seen RDT before		
2.	RDT used to test her blood during ANC session		
3.	Saw results of RDT		
4.	Results of RDT interpreted with her		
5.	Seen HCS before		
6.	HCS used to test her blood during ANC session		
7.	Saw the results of the HCS		
8.	Results of HCS interpreted with her		
9.	Seen pictorial guide before		
10.	Pictorial guide used during health talks and /or one-on-one		
11	Pregnant woman asked to talk about pictures in pictorial guide		
12	ANC staff gave pregnant woman recommendations based on blood results		

Focus group discussions

Two focus group discussions (FGDs) were conducted with the ANC staff of the implementing sites to discuss the implementation of the enhanced ANC package. The group discussions were held prior to the observations and exit interviews of the independent observer. Each ANC clinic in the intervention arm provided two members of staff who had been included in the implementation of the enhanced package, one of them being the head of the ANC clinic. The groups consisted of the heads of the ANC clinics in one (7 in number) and other ANC staff (a total of 8) in the other. This second group comprised of midwives, nurses with no formal midwifery training and ward assistants who worked in the ANC clinics. Topics discussed included their current ANC practices after the implementation of the enhanced package, their perceptions and experiences of the new package, any existing and/or perceived barriers to the implementation of the new package, how they had been able to solve any problems that

arose during the implementation and any recommendations for the future of the new package. The FGDs were moderated by 2 post graduate students who have experience with conducting FGDs but who were not part of the research team. They were assisted by 2 research assistants who were members of the research team. They were all trained in a day by discussing the enhanced package and its implementation and then the topic guide (Appendix 7) with them. The two research assistants, one for each group, were trained in note taking, observation of non-verbal behaviours of participants and operation of a tape recorder. The group discussions were held on the same day, simultaneously, after the ANC staff had been invited to assemble at the premises of one of the ANC clinics. The discussions were held in rooms, away from the ANC clinic to reduce the amount of interference from staff and pregnant women. The discussions were held mainly in English but translated to into 'twi', the local dialect from time to time to allow for easier expression of themselves as they held the discussions.

3.4.2.3 Data analysis.

Observations made during supervisory visits

At the end of each supervisory visit, observations made about how the ANC staff members engaged the pregnant women in their care using the HCS, RDT and pictorial guide during the antenatal care sessions were documented in a note book as field notes. Of particular interest was if there were any disruptions in the workflow at the clinics. These notes were then organised manually after reading through, summarised and written out as a brief report for the feasibility assessment.

Non participant observation and exit interviews

The recorded interviews of the pregnant women were transcribed verbatim into English by the independent observer. These were cross-checked for accuracy and clarity by the researcher. Reading through the transcripts for each pregnant woman, responses to the

12 item content of the enhanced pack was identified and ticked accordingly. A total score was computed for each pregnant woman interviewed per ANC clinic they visited. A total was also computed for each item observed on the 10-item content of the checklist for each ANC clinic.

The percentage of agreement (POA) between observed and mentioned activities and what was expected to be delivered by the ANC staff was used as the measure for assessing the level of implementation of the intervention. A goal of 90% was set as the limit to be reached to define acceptable POA (Wickersham, Colbert et al. 2011). For example, if the observer observed 8 out of the 10 items in an ANC clinic, then the POA was computed as (8/10) X 100% = 80%. Similarly, if 10 out of the 12 items were experienced by a pregnant woman, then the POA was (10/12) X 100% = 83.3%. The average POA was computed for each ANC from the average scores of the pregnant women interviewed and from the observations. These were presented in a table.

Focus group discussions

Tape recorded discussions were transcribed verbatim by the moderators into English and supported by the notes that were taken by the research assistants. They were checked for correctness and clarity and then imported in QSR NVIVO 10 computer software to assist in data analysis. The scripts were read and re-read for familiarisation with its contents and then the contents categorised under two main themes: Facilitators of implementation and barriers to implementation. The facilitators of the adoption of the use of these tools at the ANC clinics was described through the lens of the theory of diffusion of innovations (Rogers 2003) under the following subtitles: Perceived relative advantage in relation to other existing options; compatibility with the existing values and practices of the ANC system; trialability, that is, how the tests can be

experimented with on a limited basis; simplicity of use of the tests and observability, that is, the degree to which the results of the use of the tools can be visualized by the ANC staff and pregnant women.

3.4.3 Effect of the enhanced antenatal care package on malaria and anaemia in pregnancy

3.4.3.1 Aim

To determine the effect that the use of the RDT and HCS as tools to facilitate pregnant women's participation in their ANC has on malaria and anaemia during pregnancy.

3.4.3.2 Objectives

Primary objective

To determine the effect that the use of the RDT and HCS as tools to facilitate pregnant women's participation in their ANC has on malaria and anaemia prevalence at 4-8 weeks after enrolment.

Secondary objectives

To determine the effect of the use of the RDT and HCS as tools for pregnant women's participation in their ANC on

1. malaria and anaemia prevalence prior to delivery (36-40 weeks gestation)
2. birth weight
3. sub-optimal pregnancy outcomes (abortions, still births, preterm deliveries)
4. pregnant women's knowledge of malaria and anaemia in pregnancy
5. pregnant women's adherence to health advice

3.4.3.3 Study Population

The study involved pregnant women of all parities up to 32 weeks gestation who were visiting the ANC for the first time for their current pregnancy. After recruitment, they were passively followed up at the ANC clinics until delivery.

3.4.3.4 Study design

This study was a cluster randomized controlled trial (RCT). The unit of randomization was the ANC clinic.

3.4.3.5 Study sites

The study was conducted in 14 ANC clinics, 3 in the Sekyere-East district and 11 in the Ejisu-Juaben municipality. A total of 7 ANC clinics were randomized to each arm, the control and intervention arms. In all, 5 hospitals, 7 health centres and 2 maternity homes were included in the study.

3.4.3.6 Sample size determination

The cross sectional survey conducted in the study area prior to the cluster RCT found the prevalence of anaemia and asymptomatic parasitaemia at term pregnancy to be 42.6 % and 15.5%. The prevalence of anaemia was chosen for the estimation of the sample size because using the prevalence of anaemia leads to the estimation of a logistically feasible and practicable sample size compared to that of parasitaemia. Using the low prevalence of parasitaemia would have led to an erroneously high sample size that would be impracticable to study. Thus using the formula by Hayes and Bennet:

$$c = 2 + (z_{\alpha/2} + z_{\beta})^2 \frac{\pi_0 (1-\pi_0)/m + \pi_1(1-\pi_1)/m + k_m^2(\pi_0^2 + \pi_1^2)}{(\pi_0 - \pi_1)^2}$$

Where:

c = number of clusters per arm

$z_{\alpha/2}$ = standard normal deviate corresponding to the upper tail probability of $\alpha/2$ where α is the probability of a type I error

z_{β} = standard normal deviate corresponding to the upper tail probability of β where β is the probability of a type II error

π_0 = true proportion in the control arm

π_1 = true proportion in the intervention arm

m = number of individuals per cluster

k_m = coefficient of variation

(Hayes and Bennett 1999), a total number of 1176 pregnant women, 84 per cluster and 7 clusters per arm (including a 20% loss to follow up) was estimated at a power of 80% to detect a 30% reduction in anaemia at 95% confidence interval assuming a co-efficient of variation of 0.15 and an estimated anaemia prevalence of anaemia of 45%. An intervention effect of 30% was assumed to be reasonable based on the documented effects of patient participation in previous studies (Greenfield, Kaplan et al. 1985, Greenfield, Kaplan et al. 1988, Lewis, Pantell et al. 1990). A co-efficient of 0.15 was estimated as a reasonable variation to assume for this study as there was no known reported co-efficient of variation for antenatal clinics in Ghana or other African countries that could be used.

3.4.3.7 Eligibility criteria

Inclusion criteria:

The pregnant woman was found to be eligible to participate in the study if:

1. She was attending her booking visit (visiting the ANC clinic for the first time for the current pregnancy)
2. She had ≤ 32 weeks gestation at booking
3. Her Hb ≥ 7g/dl
4. She stayed within the catchment area of the health facility
5. She was willing to participate in the study and give her consent.

Exclusion criteria:

A pregnant woman was excluded from the study if she had any of the following conditions that could contribute significantly to anaemia in pregnancy or that would not allow her to go through ANC routinely:

1. She had a known history or presence of sickle cell disease, G-6-PD deficiency and HIV/AIDs or tuberculosis
2. She had any significant illness at time of screening that required hospitalization (including severe anaemia)

3.4.3.8. Outcome measures

Primary outcome measures

a. Prevalence of malaria parasitaemia at 4-8 weeks after enrolment
b. Prevalence of anaemia 4-8 weeks after enrolment

Secondary outcome measures

a. Prevalence of malaria parasitaemia prior to delivery
b. Prevalence of anaemia prior to delivery
c. Prevalence of low birth weight
d. Prevalence of sub-optimal pregnancy outcomes
e. Level of knowledge about malaria and anaemia in pregnancy
f. Level of adherence to health advice

3.4.3.9. Study procedure

First ANC visit (Screening and Enrolment)

Screening and enrolment occurred simultaneously in all 14 ANC clinics randomized into the RCT on their specific ANC clinic days. The following activities were conducted at enrolment:

1. The research assistants identified all first time ANC bookers as they waited for their turn to be seen by the ANC staff. They then adequately explained the study to the pregnant women using the information sheet (Appendix 8a or 8b depending on which arm of the trial they belonged) to obtain their verbal consent for screening to proceed. Once the woman verbally consented, she was assigned a screening identification number and issued a screening form (Appendix 9). Screening involved using the inclusion and exclusion criteria and conducting Hb assessment with the HemoCue 301 analyser to identify eligible women for the study. A sample of their blood was also collected for slide preparation for the determination of baseline malaria parasitaemia.

Figure 16: A research assistant performs Hb assessment of a pregnant woman during the screening process

2. A written informed consent (Appendix 10), signed or thumb printed, was then obtained from all eligible pregnant women who were willing to be part of the study. A study identification number was then assigned to them. Each ANC

clinic had its own unique 2 digit pre-fix identity number which preceded a three digit consecutive number assigned depending on the number of women that had been recruited. This number was then written on the enrolment form (Appendix 11) of a case report form for the recruited woman. This case report form consisted of the enrolment form, a laboratory form (Appendix 12) and a treatment form (Appendix 13a or 13b) was used to record all the information that was collected for the pregnant woman during the study.

3. The research assistants then obtained information on socio-demographic characteristics: age, gravidity, parity, marital status, highest educational level and current occupation of each woman and recorded it on to the enrolment form. The history of any medical conditions that had been experienced with the current pregnancy as well as any on-going symptoms and their current use of ITNs was also obtained and recorded. The women were then allowed to go through their ANC.
4. If the ANC clinic belonged to the intervention arm, then in addition to the current ANC package that was delivered at the ANC clinic, the pregnant women participated in their care through the use of the RDT and HCS tests and the pictorial guide whilst going through the ANC session.
5. After the pregnant women finished their ANC, the research assistants obtained additional information from the pregnant women's MHRB. This included the administration of IPTp or treatment of malaria, administration of iron and folic acid and de-wormers and recorded these on the treatment form. For those in the intervention arm, information of the results of the RDT and HCS test were also obtained from MHRB and recorded.

Follow up at first scheduled ANC visit

Follow up at this time was passive. The research assistants waited for the enrolled pregnant women to report back to the ANC clinic for their ANC. This usually occurred anytime between 4-8 weeks after enrolment. The pregnant women went through their routine ANC. The research assistants then checked the Hb of those previously enrolled using the HemoCue 301 analyser and then prepared blood slides for microscopy. At the intervention sites, the pregnant women participated again in their care using the RDT and HCS tests and information on the results of these tests were obtained and recorded.

Follow up at 36-40 weeks

This was considered the last ANC visit for the study. Follow up was also passive. Here too, the pregnant women went through their routine ANC with participation if in the intervention arm. The research assistants then checked their Hb using the HemoCue 301 analyser and then prepared blood slides for microscopy. Results of the HCS and RDT of pregnant women in the intervention arm were again obtained from their MHRB and recorded on to the case report form. A questionnaire (Appendix 14) to assess the pregnant women's level of adherence to iron and folic acid supplementation and their knowledge about malaria and anaemia in pregnancy was also administered to the women at this visit.

Follow up at delivery

Information about deliveries of the women was obtained from the ANC clinics' maternity units. The research assistants also actively followed up on pregnant women in the communities if their estimated delivery date overdue but had no records at the maternity units. Information on the date and place of delivery, mode of delivery, birth weight of the baby and pregnancy outcome of the mother and baby was recorded on the delivery form (Appendix 15).

The questionnaire to assess the pregnant women's level of adherence to iron and folic acid supplementation and their knowledge about malaria and anaemia in pregnancy was administered at this active follow up visit if it had not already been administered at the follow-up visit at 36-40 weeks.

3.4.3.10 Data handling and analysis

Data collection and entry

Data collected for the cluster RCT was documented using a pre designed case report form for each pregnant woman by the trained research assistants. The data was then entered independently into an electronic database by two data entry clerks using the Microsoft Access 2007 computer soft ware. The data was matched between the two entries and any mismatches corrected using a manual crosschecking of the case report forms. After data was cleaned, it was analysed using Stata SE version 13 (StataCorp, College Station, Texas).

Data analysis

Introduction

This was a pragmatic trial designed to investigate the potential impact of pregnant women's participation in their antenatal care on anaemia and malaria infection during pregnancy, birth weight and pregnancy outcome.

Data analysis was planned to be conducted by both intention-to treat and per protocol. Re-attendance at antenatal clinics is a recognised limitation of interventions during pregnancy, and as part of routine antenatal care, steps were taken to schedule women for their next visit. As part of the intervention too, antenatal care staff members were to

emphasise scheduled antenatal visits and also comply with study procedures. Given that compliance among pregnant women and antenatal staff was not optimum and re-attendance remained a challenge, the data was analysed per protocol and is presented below. Data from all the women enrolled into the study and successfully followed at each time point of the study until delivery were included in the analysis. I would emphasis however that analysis on the basis of intention-to-treat produced similar results to the per protocol analysis.

Analysis of baseline data

The characteristics of the study sample were described at the individual and cluster level. Summary statistics of the baseline characteristics of the pregnant women included frequencies and percentages for binary variables and means and standard deviations or medians and ranges for continuous variables. The baseline characteristics measured included age, gravidity, parity, educational level, occupation, ITN ownership, ITN use, frequent symptoms reported, asymptomatic malaria parasitaemia and haemoglobin concentration of the pregnant women of both arms. The numbers in each arm and the follow up status, for example, number of non-missing endpoint measurements were also described. The data was then examined to identify any imbalances in covariates and potential confounders between the two study arms (randomisation failure or not as indicated by p-value).

Data analysis for intervention effect

The intervention effect was analysed at the cluster level employing the summary measure analysis. Each cluster (ANC clinic) was used as the unit of analysis. Cluster level estimates of risks of the outcomes were obtained. The averages of the risks per arm were then obtained. These were then compared between the intervention and control arms at the defined time points of the study as risk ratios using the Student's t-

test. P-values were estimated at 95% confidence interval to compare the effectiveness of the intervention with routine ANC practices for each end-point. The analyses of the primary end points were adjusted for recognised risk factors for low birth weight, malaria parasitaemia and maternal anaemia and included maternal age, parity, gestational age, ITN use, IPTp doses received, parasitaemia and Hb at enrolment.

3.5 Post-intervention activities

3.5.1 Acceptability of the use of the enhanced antenatal care package

3.5.1.1 Aim

To describe how acceptable the use of the HCS and RDT as tools to facilitate the pregnant women's participation in their care was to pregnant women and ANC staff.

3.5.1.2 Objectives

1. To describe pregnant women's general understanding of antenatal care
2. To explore pregnant women and ANC staff members knowledge and social perceptions of malaria and anaemia in pregnancy
3. To describe pregnant women and ANC staff experiences, attitudes, beliefs and perceptions of the use of the RDT and HCS as tools to facilitate the pregnant women's participation in their ANC

3.5.1.3 Methods

After a year of implementation of the enhanced ANC package, when all the needed participants had been recruited into the study, a total of 6 FGD of between 6 to 11 participants per group and 6 in-depth interviews were conducted with mothers and/or pregnant women who belonged to either arms of the study. This was to understand their perceptions, experiences and acceptability of the use of the HCS and RDT in their

participation in ANC. Initially, a total of 8 FGD (4 per arm of study), and 12 in-depth interviews (2 per each site not involved in the FGD) were planned but 4 FGD were conducted in the intervention arm compared to 2 in the control arm making a total of 6 FGD. It was believed that the intervention groups were the ones who had experienced the enhanced antenatal care and thus would be more illuminating of their experiences and how the enhanced care impacted them. The ANC sites for the FGD were chosen randomly from using STATA SE 11, four per arm. All the 4 ANC clinics of the intervention arm that had been chosen randomly therefore had FGD conducted in them but only the first two on the list for the control arm were visited for the FGD.

For the interviews, only 1 ANC clinic per arm out of the 3 remaining that had not been randomised for the FGD was visited. Three women were interviewed in each ANC clinic. Mothers and pregnant women who stayed close to these ANC clinics and had participated in the cluster RCT were purposively invited to participate in the FGD and interviews. It was proposed that they were more likely to have utilized the ANC because of proximity and hence were in a better position to describe what had gone on in the ANC clinics during their most current pregnancy. Secondly because of proximity, it was easier to arrange for them to be part of the interviews and discussions. All interviews and the FGD were conducted by the researcher with help from research assistants for each of the participating sites. The research assistants arranged for the mothers to be present on the days scheduled for the discussions and interviews.

The FGD and interviews with the mothers were held on the premises of the ANC clinics but in areas secluded from the ANC staff to limit the perceived influence of the ANC staff on the mothers' responses. Topic guides with semi-structured questions were used for the FGD (Appendix 16) and the interviews (Appendix 17). Topics explored included

the women's general understanding of antenatal care, their knowledge and perceptions about malaria and anaemia in pregnancy and their experiences with the use of the HCS and RDT as tools for them to participate in their ANC. The participants who had been invited to participate were identified by their study ID numbers which were stuck on their MHRBs. The numbers were recorded and used later to generate their socio-demographic and obstetric characteristics from the cluster RCT database.

Pregnant women in the control arm had the use of RDT and HCS as tools for participation in their ANC demonstrated to them during the discussions and interviews and their perceptions of them explored. All interviews and FGDs were recorded with verbal consent from the participants using a digital tape recorder. During the discussions, the participants were given pseudonyms belonging to the letters of the alphabet to assume anonymity. The topic guides were written in English but the questions were asked in the local dialect, Twi, with responses also in Twi. The research assistants operated the tape recorder and took notes of the discussions and non-verbal behaviours of the participants. The recorded conversations were transcribed verbatim back to English by two graduate students who had experience in transcriptions and filled in with the written notes of the research assistants. The transcripts were then proof-read against the recorded audio files to check for accuracy, to identify any missed or misheard words and also to clarify any areas of confusion or unclear terminology that was written out by the transcribers.

A total of 7 in-depth interviews were also conducted with ANC staff in charge of 7 ANC clinics that were involved with the study, 4 from the intervention arm and 3 from the control arm. This was also to understand their perceptions, experiences and acceptability of the use of the HCS and RDT during ANC. Topic guides in English were

also used (Appendix 18) which were intermittently translated to Twi when the need arose during the interviews. Topics explored included the providers understanding of antenatal care, their experiences with the use of the RDT and HCS in ANC in terms of their diagnostic abilities, doing and interpreting their results, and their ability to influence the behaviour of the pregnant women. ANC staff of the control arm had the use of the RDT, HCS and pictorial guide to encourage pregnant women participation in their ANC demonstrated to them. These interviews were also recorded with their verbal consent and later transcribed verbatim by the researcher herself. The process of proof-reading against the audio-files was also conducted to check for consistency and accuracy of the transcripts.

3.5 1.4 Data management and analysis

Transcribed data were transported to QSR NVIVO version 10 to assist in data analysis. Data was analysed using the inductive way of thematic analysis (Braun and Clarke 2006) and not according to an existing theory. The transcripts were read and re-read for familiarisation with the data and also to aid in the identification of an initial coding frame. The coding frame was built based on patterns that were actively identified from the interviews and discussions and then imputed into QSR NVIVO 10 as nodes. With this initial coding frame, extracts from the transcripts were grouped under the nodes, adding on new nodes that were not initially identified. Nodes of similar content and understanding were then grouped into potential themes and sub-themes. The potential themes were then reviewed against the collated data extracts and then finalised for report writing. Quotes that best described the various themes were added to help support the findings.

3.6 Measurements and tools used

3.6.1 Measurement of Hb using the HemoCue Hb 301 analyser

The HemoCue Hb 301 analyser was used by the research assistants to measure Hb during the cross sectional survey and the cluster RCT. It is a small and portable battery or electricity operated system (photometer) for point of care haemoglobin determination. It consists of a photometer and plastic microcuvettes for drawing the blood sample and also measuring the Hb. The procedure followed the manufacturer's instruction. After the finger tip of the pregnant woman was sterilised with an alcohol swab and allowed to dry, it was pricked with a sterilised lancet and then a blood sample was drawn into the cavity of the microcuvette by capillary action and inserted into the analyser. Within 10 seconds, the result of the Hb was displayed on the window of the analyser. Figure 17 below shows the HemoCue Hb 301 analyser with a recorded Hb assessment. Any pregnant woman whose Hb assessment was found to be < 7g/dl during any of the time points for measurement were referred to the ANC staff for management.

The HemoCue Hb 301 analysers were brought together once every week to a central laboratory at one of the ANC clinics to verify their precision and accuracy in measuring Hb using the HemoCue-Hb 301control. All the analysers recorded correct Hb at all times using the HemoCue-Hb 301control. Batteries were also changed once every month to ensure maximum performance of the analysers once on the field.

Figure 17: HemoCue 301 analyser showing the results of Hb of 10.5 g/dl of a pregnant woman

3.6.2 Measurement of malaria parasitaemia

3.6.2.1 Rapid diagnostic test for malaria

During the cross sectional survey, the First Response malaria RDT was used to detect asymptomatic malaria parasitaemia in the pregnant women. Also this same RDT brand was used by the ANC staff in the intervention arm for the pregnant women's participation in their ANC. The type that was used detected only the *pf*HRP-2 antigen. Each test kit contained a new cassette with two round windows; a smaller one into which blood is dropped, and a bigger one for adding the buffer solution and then one rectangular window for observing the test results. Also included was a pipette for collecting blood. Packaged alcohol swabs and buffer solution in a dropper were added to the test kits in its box. The manufacturer's instructions were followed by the research assistants and the ANC staff to test the pregnant women for malaria parasitaemia as detailed in the desk guide for ANC staff (Appendix 3).

3.6.2.2 Malaria microscopy

Malaria microscopy was done in both arms of the RCT to determine parasitaemia in the pregnant women at the enrolment and follow up visits at 4-8 weeks and 36-40 weeks gestation. The microscopy results were used in the determination of the effect of the intervention since no RDT were used in the control arm for the trial.

i. Blood slide preparation

The research assistants prepared thick and thin blood films for each pregnant woman at enrolment and then at follow up visits in both arms of the RCT according to standard operating procedure. These slides were labelled with the identity number of the pregnant woman and also the specific ANC visit number and date of slide preparation. The slides were air dried for about 30 minutes under netted wooden boxes on site to prevent flies from feeding on the blood. They were then stored away in slide boxes and deposited at a central laboratory in the Juaben Government Hospital on a daily basis after field work for microscopy.

ii. Microscopy

Two microscopists were in charge of double reading the slides according to standard operating procedures of the laboratory. The blood slides were stained using 10% GIEMSA stain for 10 to 15 minutes and then carefully washed off under running water and allowed to air dry. With a drop of immersion oil onto each slide, they were read first to determine any malaria parasitaemia and secondly to count the number of parasites per 100 high power fields for the calculation of the parasite density. Thirdly, the plasmodium species was also determined. Quality control of the blood slides read by the microscopists was assured by the laboratory's participation in the Kenya Medical Research Institute's External Quality Assurance programme.

3.6.3 Assessment of level of adherence to ANC health advice

Self reported adherence to iron and folic acid supplementation was measured during the cross sectional survey and the cluster RCT. A visual analogue scale (VAS) was used. It is divided into 10% points from 0 to 100% across a visual scale (Figure 18). The pregnant women were to make a recall of how they had taken their supplements within the last two weeks of their visit to the ANC clinic and point to its equivalent on the scale. For example, in their estimation, if they had consumed half the amount of the tablets they were supposed to have taken during the period, then they would point at 50%. After its use was described by the research assistant, the pregnant woman judged her level of adherence by pointing to a spot along the scale. This was recorded as her estimated level of adherence to iron and folic acid supplementation. High adherence was defined as 90% or greater and mid adherence as 60% to 80% and low adherence, as 50% and lower. To be able to compare the levels of adherence between the study groups, the levels of adherence were dichotomised: high and mid adherence were grouped together as adequate adherence while low adherence was renamed poor adherence.

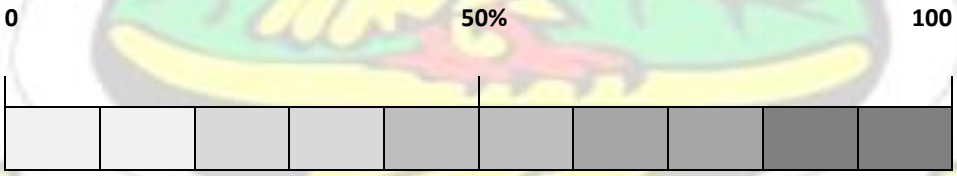


Figure 18: The visual analogue scale (VAS)

3.6.4 Assessment of level of knowledge about malaria and anaemia in pregnancy

The level of knowledge about malaria and anaemia was measured during the cross sectional survey and the cluster RCT.

Knowledge about malaria in pregnancy was constructed from the responses to 5 questions about the causes, signs and symptoms, effects of malaria on the mother, effects of malaria on the foetus and prevention of malaria. For each of the questions, the participant was given the opportunity to mention as many answers as she knew and could recollect and the interviewer ticked the corresponding answers among the options given. Each ticked answer attracted a score of 1 point and 0 when not ticked. If the respondent was able to mention at least one correct answer for each of the 5 questions, her knowledge about malaria was classified as adequate. If she was able to mention two or more correct answers per question, she was classified as having good knowledge. Poor knowledge was when the respondent was not able to mention at least one correct answer for any of the 5 questions.

Knowledge about anaemia in pregnancy was also constructed similar to that of malaria with 5 similar questions about the causes, signs and symptoms, effects on mother and foetus and prevention of anaemia. The pregnant woman was given the opportunity to mention as many options as she knew for each question and the interviewer ticked the answers accordingly. Adequate knowledge about anaemia in pregnancy was when the pregnant women could mention at least one correct answer per question and good knowledge was when she was able to provide at least two correct answers per question asked. The level of knowledge was poor if she was not able to mention at least one correct answer for each of the five questions.

To help determine the intervention effect, the levels of knowledge were dichotomised into adequate levels (represented by the sum of good and adequate level) and poor levels (represented by the original poor level).

3.7 Ethical issues

Ethical approval for the study was sought from the Committee on Human Research, Publications and Ethics of the Kwame Nkrumah University of Science and Technology (KNUST). The directors of health services of both districts and the heads of the health facilities that were included in the study were approached for brief discussions about the study to seek their support and permission to conduct the study in their facilities. Heads of the ANC clinics agreed for their clinics to be included by signing facility informed consent forms.

Written (or thumb printed) informed consent was sought from all the pregnant women before they were included in the cross sectional survey and the randomised controlled trial. Each pregnant woman who consented to be a part was assigned a study identification number to ensure confidentiality. They subsequently were not referred to by their names. All data collected were stored away in cabinets under lock and key and only the researcher, her academic supervisors, data entry clerks and research assistants had access to the case report forms on request during the data collection period. Only the academic supervisors and investigator have access to the final data set.

Verbal consent was sought from all the pregnant women and ANC staff during the FGDs and interviews and this was captured on the digital recorder prior to any discussions.

CHAPTER 4 CROSS SECTIONAL SURVEY OF STUDY POPULATION

4.1 Introduction

This chapter describes results from the pre-intervention phase of the study. The first section describes antenatal care services in the Ejisu-Juaben Municipality and the Sekyere-East district. The second section is the results of a cross sectional survey conducted among pregnant women in their third trimester to describe the study population with respect to asymptomatic parasitaemia and anaemia and their associated factors.

4.2 Antenatal care services in the Ejisu-Juaben and Sekyere-East districts

4.2.1 Geographic distribution of ANC clinics

A total of 23 ANC clinics were identified; five in Sekyere-East and 19 in Ejisu-Juaben. Figure 19 below shows the spatial distribution of the ANC clinics. Most of the ANC clinics were situated in the semi-urban areas of the two districts and only 6 were in the rural areas (to the right of the map; 2 in Sekyere-East, 4 in Ejisu-Juaben). The ANC clinics in both the rural and semi-urban areas could be reached by road although most of the roads in the rural areas were not tarred at the time of the survey. The farthest health centre in the rural area of the Ejisu-Juaben municipality (Bomfa) is 34.3 km from its nearest hospital (Ejisu) whilst in the Sekyere-East district, the farthest health centre (Okaikrom) is 9.2 km from its nearest hospital (Effiduase). Because of the distance, pregnant women in Bomfa are usually referred to a hospital in the adjacent Asante-Akyem district which is closer.

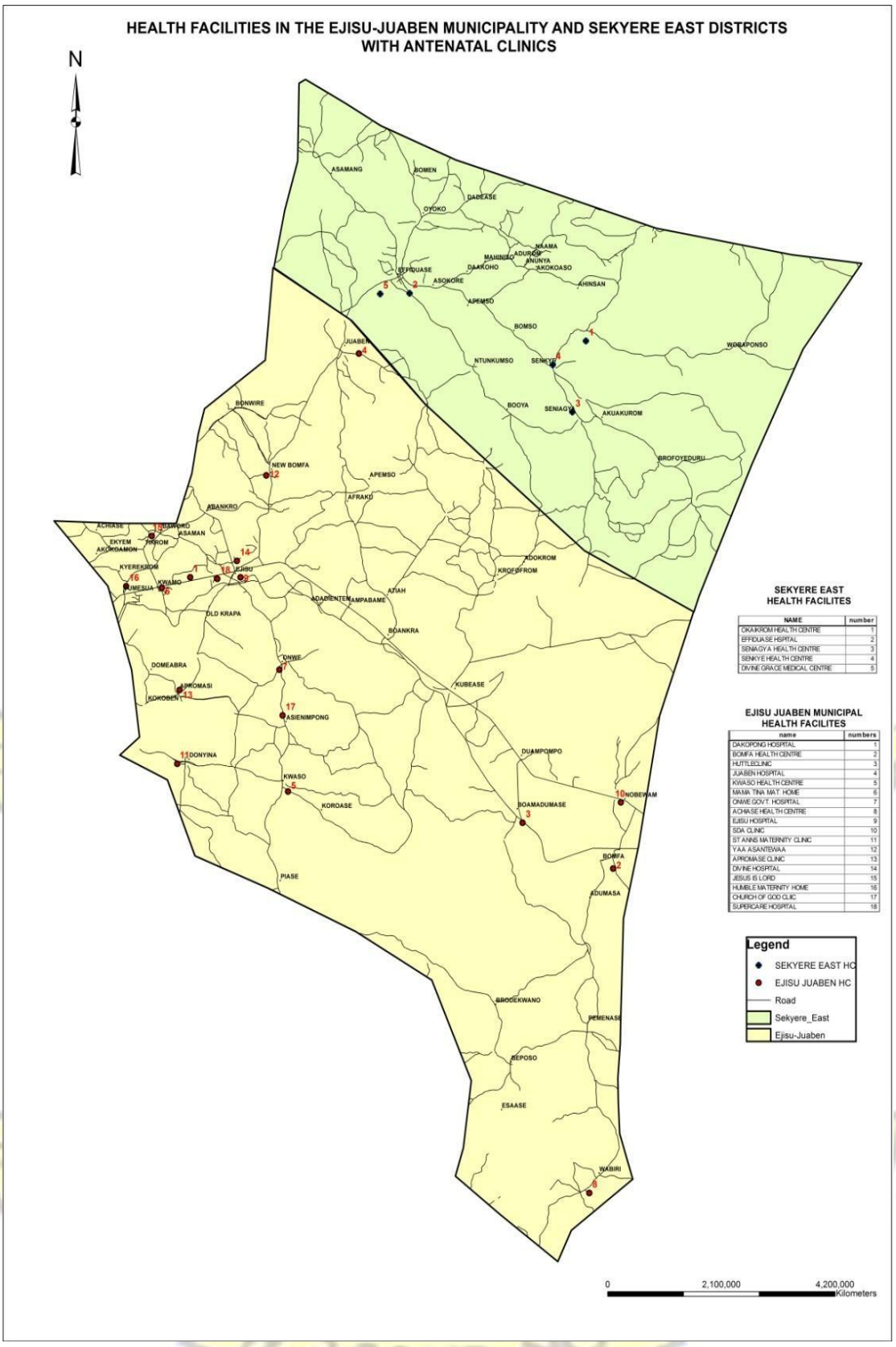


Figure 19: Distribution of antenatal clinics in the Ejisu-Juaben and Sekyere-East districts

4.2.2 Types of health facilities offering antenatal services

Twenty-one health facilities consented to be part of the observational studies. Of the 21 health facilities, 9 were Health Centres (42.9%), 6 were hospitals (28.6%), 4 were maternity homes (19.0%) and two were clinics (9.5%) (Table 5).The hospitals comprised of 4 government facilities and two private ones. Of the health centres, 4 were government facilities and the rest mission facilities. All the maternity homes were privately owned and the two clinics were mission run. The Sekyere-East district had only 3 health centres and 2 hospitals (1 private and one government) offering ANC services with the rest in the Ejisu-Juaben Municipality.

The average number of first time attendees per month in the two districts ranged from a high of 153 to a low of 8. Categorising the health facilities into small or large by the average number of first time ANC attendees per month, there were 10 small ANC clinics (20 or less first time attendees registered per month) and 11 large ones (more than 20 first time attendees registered per month). Two hospitals registered more than a hundred new pregnant women per month and two of the maternity homes registered more than 60 new pregnant women per month in 2010 (Table 5).

4.2.3 Category of health personnel working at the ANC clinics.

The category of health personnel working in the ANC clinics is also shown in Table 5 below. At the time of the survey, all, except one health centre had qualified midwives as heads of the ANC clinics. The exception was headed by a physician assistant who was also the head of the health facility. The majority of skilled staff offering ANC services was midwives followed by nurses. All the ANC clinics had midwives present on the day of the survey. Seven out of the 9 health centres had only one midwife present and she was the only midwife who had been posted to the health centre. Only up to 2 nurses per

health centre were present to help deliver services on the antenatal clinic day. At one health centre, there was no nurse to assist the midwife.

The auxiliary staff consisted of health assistant clinicals who had undergone a one year formal training in basic nursing; health extension workers who are post-senior high secondary graduates with a maximum of 6 weeks health training or ward assistants who had been recruited with no health training but developed health knowledge and skills during their work on the job.

Two of the maternity homes had visiting doctors on site offering consultations for pregnant women in the ANC clinic but they were being attended to amidst general out patients. The hospitals had doctors at the outpatient's department and pregnant women could get access to their services if they were referred to them. All the health centres had to rely on the services of doctors outside their facilities when the need arose. None of the doctors in the health facilities observed in the 2 districts were specialists in obstetrics and gynaecology but their general training enabled them to offer the needed services to the pregnant women.

Table 5: Distribution of ANC clinics by type of health facility, category of health personnel and number of registrants

	Health facility	Type of Health Facility	Average no. of 1st time attendees/ Month (2010)- Registrants	Category of staff present on an ANC day		
				MW	Nurse	Auxiliary staff
1	Effiduase	Hospital	153	3	4	2
2	Ejisu	Hospital	114	4	1	3
3	Juaben	Hospital	84	3	0	4
4	Onwe	Hospital	38	1	1	3
5	Divine	Hospital	37	2	3	0
6	Divine Grace	Hospital	25	3	2	1
7	Bomfa	Health Centre	26	1	0	1
8	Achiase	Health Centre	40	1	2	1
9	Kwaso	Health Centre	16	1	0	0
10	Okaikrom	Health Centre	18	0	2	3
11	Apromase	Health Centre	9	1	2	2
12	St Lukes'	Health Centre	17	1	1	1
13	Senchi	Health Centre	17	1	1	2
14	St Annes'	Health Centre	17	2	2	1
15	Huttel	Health Centre	16	1	0	0
16	Nobewam SDA	Clinic	15	1	1	0
17	Essienimpong	Clinic	24	2	2	0
18	Mama Tina	Maternity Home	67	3	0	4
19	Yaa Asantewaa	Maternity Home	68	2	1	2
20	Humble	Maternity Home	8	2	3	2
21	Jesus is Lord	Maternity Home	8	1	4	2

PA-Physician Assistant, MW-Midwife

4.2.4 Organization of ANC services

All the ANC clinics had a waiting area where the pregnant women sat to await their turn for ANC. Also at this area, the pregnant women received educational talks and health advice concerning their pregnancies. In six out of the 21 ANC clinics, the pregnant women had contact with ANC staff at the waiting area and the consulting room only. In the rest of ANC clinics, the pregnant women had contact with more than two ANC staff per their visit for the different ANC services to be rendered. There was sharing of labour at these clinics because of larger numbers of pregnant women attending for care so that different staff offered different services at their stations to the pregnant women.

Seventeen ANC clinics stocked SP for IPTp. In the other 4 clinics, the pregnant women received prescriptions from the ANC staff members to collect SP from their pharmacies/dispensaries and brought them back to the ANC clinic for it to be taken under direct observation.

All the health facilities had dispensaries or pharmacies outside the ANC clinic where the pregnant women accessed their prescribed medicines except one hospital which had created a dispensary and a laboratory at the ANC clinic to serve pregnant women exclusively. Three of the health centres had no laboratories in their health facility.

The ANC clinics had designated days of the week on which ANC was delivered. At least, 2 days of the week were ANC days. However, a pregnant woman could visit the ANC clinic on any day with complaints and be taken care of. ANC clinics generally opened at 8am throughout the week and closed when the last pregnant women had been taken care of.

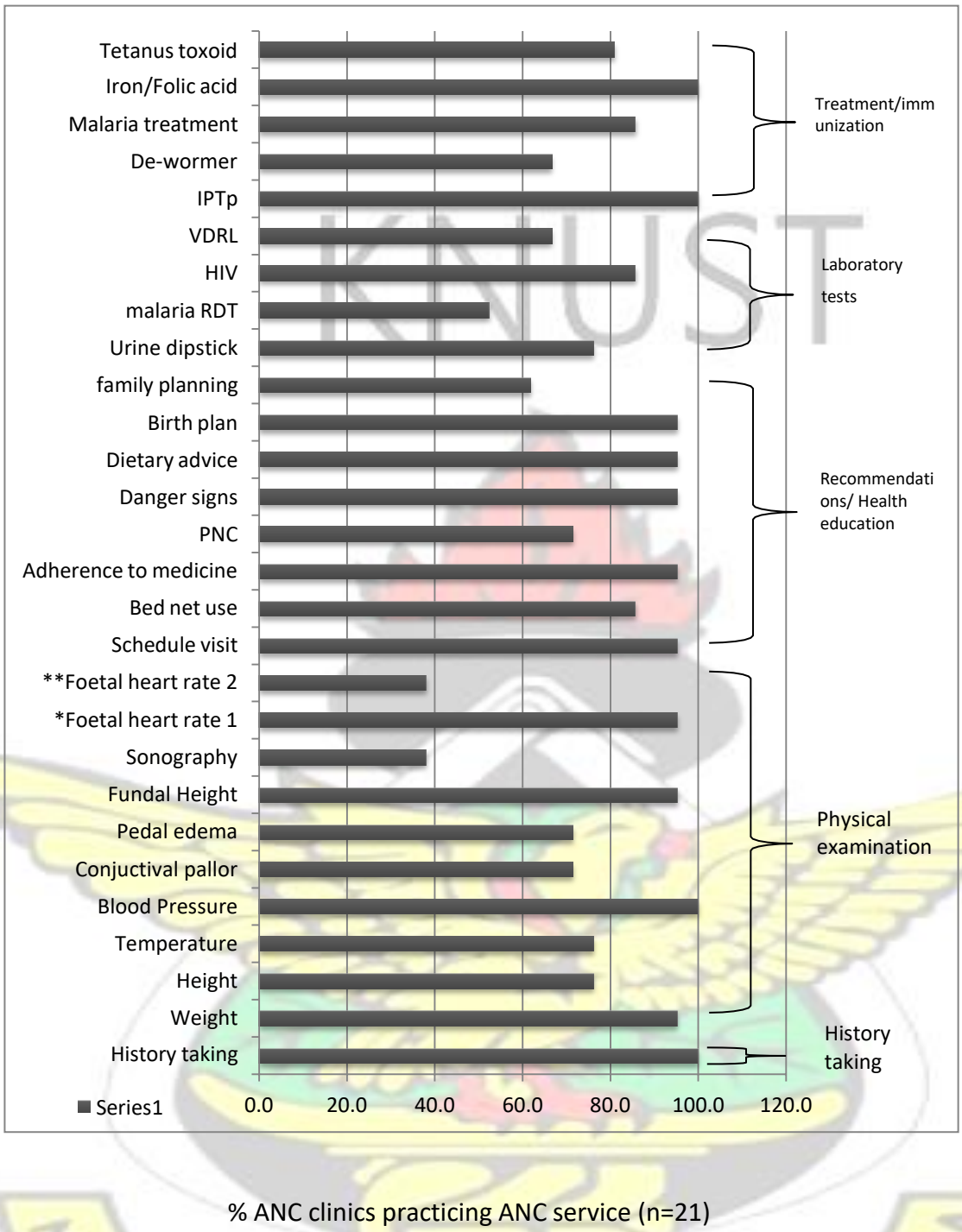
4.2.5 ANC services rendered

A wide range of services were observed at the ANC clinics. These can be grouped into history taking, physical examination, laboratory tests, treatments and immunizations and recommendations/health education. The type of services rendered depended on the type of health facility offering the ANC care. Figure 20 below shows the proportion of ANC clinics observed to have undertaken various ANC activities on the day of the survey. History taking, blood pressure measurements, giving of IPTp using SP by direct observation and writing prescriptions for iron and folic acid supplementation were observed in all the ANC clinics visited.

The ANC staff members were generally observed to conduct point-of-care (POC) tests including the urine dipstick for pregnancy confirmation and for protein and sugar, the HIV and the VDRL tests for prevention of mother to child transmission of HIV and syphilis respectively, at the ANC clinics. However in 3 of the hospitals, only the urine dipstick test was observed; in one of them, the pregnant women were referred to a nurse outside of the ANC clinic in their Voluntary Counselling and Testing centre to have the HIV and VDRL tests conducted while in the other 2, they were referred to the health facility's laboratories.

4.2.6 Maternity services

In addition to ANC services, all the health facilities offered delivery services. However at the time of the survey, delivery services had been suspended at one health centre because of the absence of a midwife. The hospitals offered essential obstetric care and served as referral centres for the health centres, maternity homes and clinics.



* Foetal heart rate measured by fetoscope ** Foetal heart rate measured by foetal heart monitor

Figure 20: Proportion of ANC clinics observed to have practiced ANC service

4.3 Asymptomatic malaria parasitaemia and anaemia and associated factors

4.3.1 Introduction

A cross sectional survey was conducted from September 2011 to January, 2012 among pregnant women in their third trimester attending 21 ANC clinics in the study area. Any pregnant woman visiting the antenatal clinics who was of 32 weeks and above gestation and was willing to participate in the survey was interviewed. This was aimed at describing the study population. In all, 570 pregnant women were interviewed.

4.3.2 Background characteristics and prevalence of parasitaemia and anaemia

Table 6 below shows the background characteristics of the pregnant women in addition to the prevalence of asymptomatic malaria parasitaemia and anaemia among them. A total of 88.6% of the women were 20 years and above. Their mean age was 27.0 years. Half of the women were nullips and primips. Approximately, 9 in 10 had acquired some formal education, a majority reaching the basic education level as their highest level. Seventy-seven percent of the study population were employed.

ITN utilisation the night before the survey was low. Only 39.3 % slept under an ITN. A high proportion of the women (79.6%) had received the recommended 2 or more doses of SP at the time of the survey. Five percent of the women had received no SP at all. Although anaemia prevalence was 42.6%, the mean Hb among the population was above 11.0g/dl. Asymptomatic parasitaemia prevalence by the RDT was 15.5%.

Table 6: Background characteristics of study population and the prevalence of asymptomatic parasitaemia and anaemia among them

Characteristic	n	%
Age group (years)		
under 20	65	11.44
20-29	310	54.58
30 and above	193	33.98
Mean age (sd)	26.97 (6.2)	
Parity		
Nullip	152	26.67
Primip	132	23.16
Multip	286	50.18
Gestational age (weeks)		
32-35 weeks	127	22.4
≥ 36	440	77.6
Mean gestational age	36.35 (4.74)	
Occupation		
No occupation	129	22.71
Salaried worker	24	4.23
Self employed	415	73.06
Educational Level		
None	73	12.81
Basic	420	73.68
Post basic	77	13.51
Slept under ITN the night of the survey		
No	346	60.7
Yes	224	39.3
No. of SP doses recorded in MHR book		
0	30	5.28
1	86	15.14
≥ 2	452	79.58
Asymptomatic Parasitaemia by RDT		
Negative	481	84.53
Positive	88	15.47
Maternal Hb level		
Hb =/> 11g/dl	327	57.37
Hb < 11g/dl	243	42.63
Mean Hb (sd)	11.13 (1.33)	
Median Hb (range)	11.2 (6.3-13.8)	

4.3.3 Adherence to health advice and knowledge of malaria and anaemia in pregnancy

The pregnant women's level of knowledge about malaria and anaemia in pregnancy and their self-reported adherence to health advice is shown in Table 7 below. A total of 77.7% and 78.1% had good and adequate knowledge about malaria and anaemia respectively. Only 22.4% of them reported low adherence to health advice.

Table 7: Level of self-reported adherence and knowledge about malaria and anaemia

Characteristic	n	%
Level of adherence		
Low	127	22.40
Medium	177	31.22
High	263	46.38
Level of knowledge about malaria		
Poor	127	22.28
Adequate	358	62.81
Good	85	14.91
Level of knowledge about anaemia		
Poor	125	21.93
Adequate	356	62.46
Good	89	15.61

4.3.4 Asymptomatic malaria parasitaemia and associated factors

Table 8 below describes the factors associated with asymptomatic malaria parasitaemia in the women. Parity, age and level of adherence of the women to health advice and maternal anaemia were significantly associated with asymptomatic malaria parasitaemia. The risk of asymptomatic parasitaemia reduced as level of adherence increased; the risk was reduced by 46% and 58% if the adherence was medium and high respectively. Similarly, the risk of parasitaemia reduced as parity increased by as much as 43% for those of parity 2 and above. Also asymptomatic parasitaemia decreased with increasing age (36% and 62% for women 20-29 years and 30 years and above respectively). Parasitaemic women were almost twice as likely to have anaemia compared to non-parasitaemic women [(Risk Ratio=1.77, (95% Confidence interval; 1.20-2.60)].

Increasing levels of education also decreased the risk of asymptomatic parasitaemia although the association was border-line for those with post basic education (53% reduction). Although the risk of asymptomatic malaria parasitaemia decreased with increasing knowledge about malaria, this association was not statistically significant.

Table 8: Factors associated with asymptomatic parasitaemia in the pregnant women

	Asymptomatic malaria parasitaemia						
	Yes		No				
Independent variable	**n**	**%**	**n**	**%**	**Risk ratio**	**95% CI**	**p-value**
Slept under a net previous night							
Yes	39	44.32	184	38.25	1.23	0.84-1.82	0.28
Number of SP doses recorded in MHRB							
0	3	3.45	27	5.63			
1	12	13.79	74	15.42	1.4	0.42-4.61	0.59
≥ 2	72	82.76	379	78.96	1.6	0.53-4.77	0.40
Level of adherence							
Low adherence	33	37.93	93	19.42			
Medium adherence	25	28.74	152	31.73	0.54	0.34-0.86	0.01
High adherence	29	33.33	234	48.85	0.42	0.27-0.66	< 0.001
Parity							
0	31	35.23	121	25.16			
1	24	27.27	108	22.45	0.89	0.55-1.44	0.64
≥ 2	33	37.5	252	52.39	0.57	0.36-0.89	0.01
Age group (years)							
under 20	17	19.32	48	10.02			
20 - 29	52	59.09	257	53.65	0.64	0.40-1.04	0.07
30 and above	19	21.59	174	36.33	0.38	0.21-0.68	0.001
Knowledge of maternal anaemia							
Poor	21	23.86	105	21.83			
Adequate	56	63.64	302	62.79	1.00	0.62-1.62	1.00
Good	11	12.5	74	15.38	1.11	0.60-2.06	0.74
Knowledge of malaria							
Poor	21	23.86	105	21.83			
Adequate	56	63.64	302	62.79	0.94	0.59-1.48	0.79
Good	11	12.5	74	15.38	0.78	0.40-1.53	0.46
Educational level							
None	14	15.91	59	12.27			
Basic	67	76.14	352	73.18	0.83	0.50-1.40	0.49
Post basic	7	7.95	70	14.55	0.47	0.20-1.11	0.09
Maternal anaemia							
Yes	50	56.82	193	40.12	1.77	1.20-2.60	0.004

4.3.5 Maternal anaemia and associated factors

Maternal anaemia and the associated factors are described in Table 9 below. Among all the factors listed, the risk of maternal anaemia reduced only with increasing doses of SP received and increasing level of education; however these were statistically insignificant.

Table 9: Factors associated with maternal anaemia in the pregnant women

	Maternal anaemia						
	Yes		No				
Independent variable	**n**	**%**	**n**	**%**	**Risk ratio**	**95% CI**	**p-value**
Slept under a net previous night							
No	199	60.86	147	60.49			
Yes	128	39.14	96	39.51	1.01	0.83-1.23	0.93
Number of SP doses recorded in MHRB							
0	16	4.91	14	5.79			
1	39	11.96	47	19.42	1.17	0.76-1.80	0.47
≥2	271	83.13	181	74.79	0.86	0.58-1.28	0.45
Level of adherence							
Low adherence	76	23.38	51	21.07			
Medium adherence	95	29.23	82	33.88	1.15	0.89-1.50	0.29
High adherence	154	47.38	109	45.04	1.03	0.80-1.33	0.81
Parity							
0	87	26.61	65	26.75			
1	76	23.24	56	23.05	0.99	0.76-1.30	0.95
≥2	164	50.15	122	50.21	1.00	0.79-1.25	0.98
Age group (years)							
under 20	35	10.7	30	12.45			
20 - 29	179	54.74	131	54.36	0.92	0.68-1.23	0.56
30 and above	113	34.56	80	33.2	0.90	0.66-1.23	0.50
Knowledge of maternal anaemia							
Poor	77	23.55	48	19.75			
Adequate	128	39.14	91	37.45	1.15	0.89-1.48	0.28
Good	122	37.31	104	42.8	1.11	0.80-1.54	0.53
Knowledge of malaria							
Poor	21	23.86	105	21.83			
Adequate	56	63.64	302	62.79	1.11	0.86-1.42	0.42
Good	11	12.5	74	15.38	1.25	0.92-1.71	0.16
Educational level							
None	42	12.84	31	12.76			
Basic	236	72.17	184	75.72	1.03	0.77-1.38	0.83
Post basic	49	14.98	28	11.52	0.86	0.58-1.28	0.45

Chapter 5 CLUSTER RANDOMISED CONTROLLED TRIAL

5.1 Introduction

A cluster randomised controlled trial was conducted to determine the effect of the use of the RDT and HCS as tools to facilitate pregnant women's participation in their ANC on maternal anaemia, parasitaemia and pregnancy outcomes. The first section of this chapter describes the screening, enrolment and the participant flow throughout the trial. This is followed by the baseline socio-demographic and obstetric characteristics of the study participants, their most frequently reported symptoms at enrolment and their baseline parasitaemia and anaemia states. Next, the intervention effect on maternal anaemia, asymptomatic parasitaemia, birth weight, sub-optimal pregnancy outcomes, level of knowledge of malaria and anaemia in pregnancy and adherence to health advice is presented.

5.2 Screening, enrolment and participant flow throughout the study

Figure 21 below describes the participant flow throughout the study. Screening and enrolment of the study participants began in September 2012 and ended in December 2013. A total of 1663 pregnant women were enrolled, ranging from 97 to 123 per cluster (ANC clinic). The mean cluster size was 120.7 pregnant women for the control arm and 116.9 for the intervention group (Table 10).

Follow up of the women ended in April 2014. More than 50% of the enrolled women were followed up at each time point in both arms. A relatively higher proportion of the pregnant women were followed up in the intervention arm compared to the control arm (64.1%, 52.4% and 61.0% versus 56.7%, 50.4% and 58.8% respectively at 4-8 weeks, 36-40 weeks of gestation and at delivery).

Table 10: Number of pregnant women enrolled per cluster, by study arm

Study arm	Control		Intervention	
	ANC clinic	Number of women enrolled	ANC clinic	Number of women enrolled
	Achiase	121	Kwaso	120
	Nobewam	123	Onwe	122
	Senchi	122	Mama Tina	118
	Donyinah	119	Okaikrom	97
	Yaa Asantewa	120	Juaben	120
	Effiduase	120	Huttel	121
	Ejisu	120	Bomfa	120
Total		**845**		**818**
Cluster size	Mean (Range)	120.7 (119-123)		116.9 (97-122)

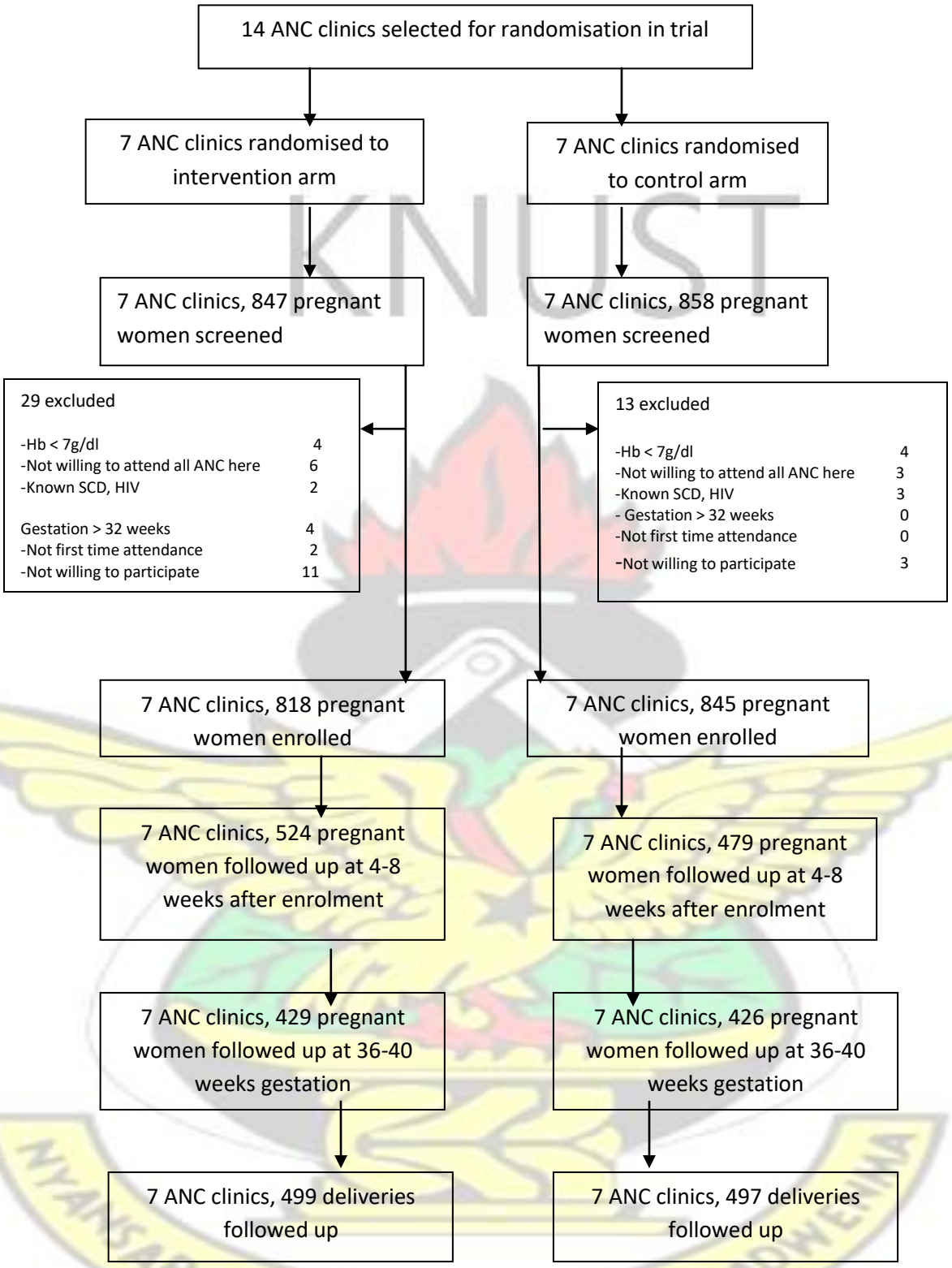


Figure 21: Diagram showing the flow of pregnant women throughout the trial

5.3 Baseline characteristics of study participants

5.3.1 Baseline characteristics; malaria parasitaemia and anaemia prevalence

The baseline socio-demographic and obstetric characteristics, malaria parasitaemia and anaemia prevalence calculated at individual level and at cluster (ANC clinic) level per arm are shown in Tables 11and 12 respectively below.

At the individual level, differences existed between the two arms with regards to parity, gravidity, gestational age at first ANC visit, educational level, ITN ownership and use and parasitaemia levels (Table 11) however at the cluster level, both groups were similar except with regards to gravidity, parity, ITN ownership and use (Table 12).

In both groups, more than half the women were in the 20-29 year range. The mean age was 26 years. Of all the study women, more than 60% had given birth to at least one child. Most of the women attended their first ANC clinic in the first and second trimesters; those attending in the third trimester accounting for only 12.1% and 12.9% in the control and intervention arms respectively. At least, 8 in 10 women had received some formal education; a majority having received education up to the basic level (Junior high school). More women owned ITN in the intervention group compared to the control group (81.3% versus 68.1%) however only 57.5% and 40.5% in the intervention and control groups respectively slept under an ITN the night before their enrolment. More pregnant women were anaemic at enrolment in the intervention arm compared to the control (49.3% versus 45.1%) however the mean Hb was the same (11.0g/dl) in both groups. Although the prevalence of parasitaemia was higher in the intervention group (13.7% versus 7.7%), the control group had a higher mean parasite density compared to the intervention group (653.5 versus 442.8). But statistically, these differences were not significant.

Table 11: Baseline characteristics of study participants (Individual level)

Characteristics	Control (N=845)		Intervention (N=818)		Total	
	n	%	n	%	n	%
Parity						
0	295	34.95	215	26.28	510	30.69
1	195	23.10	191	23.35	386	23.23
≥2	354	41.94	412	50.37	766	46.09
Gravidity						
1	238	28.20	176	21.52	414	24.91
2	189	22.39	182	22.25	371	22.32
≥3	417	49.41	460	56.23	877	52.77
Gestation at first ANC visit						
First	324	38.57	260	31.86	584	35.27
Second	414	49.29	451	55.27	865	52.23
Third	102	12.14	105	12.87	207	12.5
Mean (SD) gestational age	15.93	7.12	17.08	6.74		
Age group						
under 20	125	14.81	134	16.38	259	15.58
20-29	470	55.69	423	51.71	893	53.73
30 and above	249	29.50	261	31.91	510	30.69
Mean age (SD)	26.29	6.37	26.44	6.64		
Educational level						
None	87	10.32	127	15.54	214	12.89
Basic	617	73.19	611	74.79	1228	73.98
Post basic	139	16.49	79	9.67	218	13.13
ITN ownership						
Yes	574	68.09	665	81.3	1239	74.59
ITN use						
Yes	341	40.45	470	57.46	811	48.83
Anaemia						
Yes	381	45.14	403	49.27	784	47.17
Mean haemoglobin (SD) (g/dl)	11.03	(1.46)	10.99	(1.44)		
Parasitaemia						
Yes	64	7.69	111	13.70	175	10.66
GMPD (95% CI)	653.45 (481.56-886.68)		442.76 (332.01 - 590.46)			

Table 12: Baseline characteristics of study participants at cluster (ANC clinic) level

		CONTROL	INTERVENTION	p-value
	Number of clusters (ANC clinics)	7	7	
Hb	Mean of cluster summaries	11.03	10.99	0.83
	Standard Deviation	0.38	0.33	
	Median	11.06	11.01	
	Range	10.55-11.47	10.61-11.63	
Age	Mean of cluster summaries	26.29	26.40	0.83
	Standard Deviation	0.92	0.98	
	Median	25.88	26.11	
	Range	25.22-27.54	25.07-27.89	
Gestational age at enrolment (weeks)	Mean of cluster summaries	15.92	17.12	0.26
	Standard Deviation	1.95	1.86	
	Median	16.01	18.03	
	Range	13.07-18.95	14.42-19.18	
Parity	Mean of cluster summaries	1.60	1.95	0.03
	Standard Deviation	0.24	0.28	
	Median	1.54	1.84	
	Range	1.28-2.05	1.66-2.50	
Gravidity	Mean of cluster summaries	2.93	3.24	0.03
	Standard Deviation	0.21	0.27	
	Median	3.00	3.23	
	Range	2.61-3.16	2.92-3.80	
Parasite Density	Mean of cluster summaries	1202.95	1625.57	0.4
	Standard Deviation	601.19	1138.95	
	Median	989.33	1300.00	
	Range	543.33-2014	559.20-4087	
Anaemia	Mean of cluster proportions	45.08	49.23	0.50
	95% CI	(33.20-56.96)	(40.51-57.96)	
Felt unwell	Mean of cluster proportions	54.09	66.47	0.28
	95% CI	(31.76-76.42)	(52.02-80.92)	
ITN ownership	Mean of cluster proportions	67.90	81.55	0.004
	95% CI	(62.44-73.36)	(73.98-89.12)	
ITN use	Mean of cluster proportions	40.28	58.03	0.03
	95% CI	(31.58-48.97)	(42.09-73.96)	
Parasitaemia	Mean of cluster proportions	9.14	15.86	
	95% CI	(2.93-15.36)	(8.57-23.15)	0.11

5.3.2 Symptoms reported frequently at baseline

Table 13 below shows the distribution of frequently reported symptoms at enrolment for both arms of the study at enrolment. Although a higher proportion of women reported not feeling well in the past three days prior to enrolment in the intervention arm, statistically, the groups were the same in this regard. The prevalence of the specific symptoms related to malaria and anaemia that were reported was also similar in both groups.

Table 13: Frequently reported symptoms at enrolment

Frequently reported symptoms	Control (N=845)		Intervention (N=818)		Total	
	n	%	n	%	n	%
Felt unwell during the past three days	457	54.08	540	66.01	997	59.95
Fever	172	20.38	225	27.54	397	23.9
Headache	402	47.69	428	52.45	830	50.03
Weakness/Fatigue	390	46.15	391	47.80	781	46.96
Body pains	241	28.55	270	33.05	511	30.76
Joint pains	204	24.17	251	30.80	455	27.43
Lower abdominal pain	346	41.00	328	40.10	674	40.55

5.3.3 Intra cluster correlation co-efficient

The intra-cluster correlation co-efficient (ICC), a measure of how much similar the study outcomes are for individuals within clusters than for those in different clusters was calculated from the baseline data as 0.41. This was higher than the 0.15 that was assumed for the determination of the sample size for the RCT.

5.4 Intervention effect on malaria parasitaemia, anaemia and pregnancy outcomes

5.4.1 Intervention effects on malaria parasitaemia during pregnancy

The proportion of pregnant women who had malaria parasitaemia at 4-8 weeks after enrolment and at 36-40 weeks gestation per ANC clinic are shown in Table 14 and

Table 15 below and the overall effect of the enhanced package on parasitaemia by arm is shown in Table 16 below.

The risk of asymptomatic malaria parasitaemia generally decreased with progress of pregnancy in both groups. There was apparently no intervention effect (measured by the adjusted risk ratios) at 4-8 weeks after enrolment as the intervention group had a higher risk of parasitaemia compared to the controlled group (Adjusted risk ratio = 1.17, p-value = 0.51). Although prior to delivery at 36-40 weeks gestation, the intervention caused a decreased risk of 17% (Adjusted risk ratio = 0.83), the effect was not real (p-value = 0.73). Thus generally, there was no difference in the risk between the two groups at 4-8 weeks after enrolment or at 36-40weeks gestation (p >0.05).

Table 14: Proportion of pregnant women with parasitaemia at 4-8 wks after enrolment per ANC clinic

					95% Confidence Interval	
Study arm	ANC clinic	Number of women with parasitaemia	Number of women sampled	Proportion of women with parasitaemia	Lower Limit	Upper Limit
CONTROL	Achiase	10	78	12.82	7.12	22.02
	Nobewam	1	60	1.67	0.29	8.86
	Senchi	6	68	8.82	4.11	17.94
	Donyinah	5	74	6.76	2.92	14.86
	Yaa Asantewa	5	74	6.76	2.92	14.86
	Effiduase	3	62	4.84	1.66	13.29
	Ejisu	3	90	3.33	1.14	9.35
INTERVENTION	Kwaso	7	99	7.07	3.47	13.88
	Onwe	13	113	11.50	6.85	18.69
	Mama Tina	2	77	2.60	0.72	8.98
	Okaikrom	4	61	6.56	2.58	15.68
	Juaben	6	99	6.06	2.81	12.60
	Huttel	5	74	6.76	2.92	14.86
	Bomfa	4	61	6.56	2.58	15.68

Table 15: Proportion of pregnant women with parasitaemia at 36-40 wks after enrolment per ANC clinic

					95% Confidence Interval	
Study arm	ANC clinic	Number of women with parasitaemia	Number of women sampled	Proportion of women with parasitaemia	Lower Limit	Upper Limit
CONTROL	Achiase	3	20	15.00	5.24	36.04
	Nobewam	0	10	0.00	0.00	27.75
	Senchi	4	45	8.89	3.51	20.73
	Donyinah	0	30	0.00	0.00	11.35
	Yaa Asantewa	1	36	2.78	0.49	14.17
	Effiduase	5	34	14.71	6.45	30.13
	Ejisu	0	29	0.00	0.00	11.70
INTERVENTION	Kwaso	4	56	7.14	2.81	16.98
	Onwe	3	75	4.00	1.37	11.11
	Mama Tina	0	36	0.00	0.00	9.64
	Okaikrom	1	17	5.88	1.05	26.98
	Juaben	1	51	1.96	0.35	10.30
	Huttel	4	52	7.69	3.03	18.17
	Bomfa	1	27	3.70	0.66	18.28

Table 16: Effect of enhanced antenatal package on maternal anaemia, parasitaemia, birth weight and suboptimal birth outcomes

	Clusters	Risk (%)	95% Confidence Interval	Unadjusted Risk Ratio	95% Confidence Interval	p-value	Adjusted Risk Ratio[1]	95% Confidence Interval	p-value
Anaemia at 4-8 weeks after enrolment									
Control	7	48.39	33.33-70.00						
Intervention	7	48.04	36.74-62.63	0.99	0.73-1.34	0.96	0.97	0.78-1.22	0.79
Anaemia prior to delivery									
Control	7	50.25	22.73-78.95						
Intervention	7	47.40	20.41-65.38	0.94	0.60-1.49	0.78	0.92	0.63-1.34	0.62
Malaria at 4-8 weeks after enrolment									
Control	7	6.43	1.67-12.82						
Intervention	7	6.73	2.60-11.50	1.05	0.58-1.89	0.86	1.17	0.68-2.04	0.51
Malaria prior to delivery									
Control	7	5.91	0.00-15.00						
Intervention	7	4.34	0.00-7.690	0.73	0.24-2.26	0.59	0.83	0.27-2.57	0.73
Low birth weight									
Control	7	13.18	5.41-31.48						
Intervention	7	10.81	2.44-19.74	0.82	0.38-1.78	0.59	0.93	0.44-1.97	0.84
Suboptimal pregnancy outcome									
Control	7	8.35	0.00-39.22						
Intervention	7	6.32	0.00-10.53	0.76	0.16-3.48	0.72	0.77	0.17-3.52	0.73

[1] Risk ratios adjusted for baseline parasitaemia, anaemia, gestation at enrolment, age, educational level, ITN use, IPT and parity

5.4.2 Intervention effects on anaemia during pregnancy

Table 17 and Table 18 below show the effect of the enhanced ANC package on maternal anaemia at 4-8 weeks after enrolment and prior to delivery by ANC clinic. The combined intervention effect on maternal anaemia by trial arm is shown in Table 16.

The effect of the enhanced package on anaemia was very minimal; slightly greater prior to delivery than at 4-8 weeks after enrolment (adjusted risk ratios of 0.92 prior to delivery and 0.97 at 4-8 weeks) however these were not strong enough to reach statistical significance ($p>0.05$). Thus there was no difference in the risk of maternal anaemia between the two groups at both time points.

Table 17: Proportion of pregnant women with anaemia at 4-8 weeks after enrolment per ANC clinic

					95% Confidence Interval	
Study arm	ANC clinic	Number of women with anaemia	Number of women sampled	Proportion of women with anaemia	Lower Limit	Upper Limit
CONTROL	Achiase	46	82	56.10	45.32	66.33
	Nobewam	16	48	33.33	21.68	47.46
	Senchi	36	60	60.00	47.37	71.43
	Donyinah	27	75	36.00	26.06	47.30
	Yaa Asantewa	42	60	70.00	57.49	80.10
	Effiduase	27	63	42.86	31.40	55.14
	Ejisu	34	84	40.48	30.62	51.17
INTERVENTION	Kwaso	62	99	62.63	52.79	71.52
	Onwe	66	112	58.93	49.67	67.60
	Mama Tina	37	78	47.44	36.74	58.38
	Okaikrom	22	57	38.60	27.06	51.57
	Juaben	36	98	36.73	27.86	46.61
	Huttel	39	76	51.32	40.29	62.22
	Bomfa	26	64	40.63	29.46	52.86

Table 18: Proportion of pregnant women with anaemia at 36-40 weeks gestation per ANC clinic

					95% Confidence Interval	
Study arm	ANC clinic	Number of women with anaemia	Number of women sampled	Proportion of women with anaemia	Lower Limit	Upper Limit
CONTROL	Achiase	13	21	61.90	40.88	79.25
	Nobewam	5	22	22.73	10.12	43.44
	Senchi	32	45	71.11	56.63	82.27
	Donyinah	14	32	43.75	28.17	60.67
	Yaa Asantewa	45	57	78.95	66.71	87.53
	Effiduase	13	39	33.33	20.63	49.02
	Ejisu	10	25	40.00	23.40	59.26
INTERVENTION	Kwaso	32	58	55.17	42.45	67.25
	Onwe	45	70	64.29	52.59	74.50
	Mama Tina	14	33	42.42	27.24	59.19
	Okaikrom	10	22	45.45	26.92	65.34
	Juaben	10	49	20.41	11.48	33.64
	Huttel	34	52	65.38	51.80	76.85
	Bomfa	12	31	38.71	23.73	56.18

5.4.3 Intervention effects on birth weight

Table 19 below shows the effect of the enhanced ANC package on the prevalence of low birth weight infants by ANC clinic. The prevalence was generally higher in the control ANC clinics compared to the intervention ANC clinics. This is reflected in Table 16, where the mean of cluster proportions of low birth weight was 10.8% in the intervention arm compared to 13.2% in the control arm. Although there was an apparent intervention effect of 7% (Adjusted relative risk = 0.93), this did not reach statistical significance. Hence there was no difference between the arms with respect to the risk of low birth weight.

Table 19: Proportion of women with low birth weight per ANC clinic

					95% Confidence Interval	
Study arm	ANC clinic	Number of women with low birth weight babies	Number of women sampled	Proportion of women with low birth weight	Lower Limit	Upper Limit
CONTROL	Achiase	3	51	5.88	2.02	15.92
	Nobewam	13	77	16.88	10.14	26.77
	Senchi	4	72	5.56	2.18	13.43
	Donyinah	17	54	31.48	20.68	44.74
	Yaa Asantewa	7	82	8.54	4.20	16.59
	Effiduase	15	81	18.52	11.56	28.33
	Ejisu	4	74	5.41	2.12	13.09
INTERVENTION	Kwaso	9	89	10.11	5.41	18.11
	Onwe	9	99	9.09	4.86	16.38
	Mama Tina	7	95	7.37	3.61	14.44
	Okaikrom	1	41	2.44	0.43	12.60
	Juaben	3	19	15.79	5.52	37.57
	Huttel	15	76	19.74	12.34	30.04
	Bomfa	8	72	11.11	5.74	20.42

5.4.4 Intervention effects on suboptimal pregnancy outcome

Table 20 below shows the proportion of women who had suboptimal outcomes per ANC clinic. The Achiase ANC clinic recorded a comparatively higher proportion in the control group (39.2%) compared with the highest of 10.5% from Mama Tina or Juaben in the intervention group. The risk of sub-optimal outcomes was thus relatively lower in the intervention arm compared to the control arm leading to an intervention effect of 23% (Adjusted risk ratio = 0.77). However this effect was also not statistically significant (Table 16).

Table 20: Proportion of women with suboptimal pregnancy outcome per ANC clinic

					95% Confidence Interval	
Study arm	ANC clinic	Number of women with suboptimal pregnancy outcome	Number of women sampled	Proportion of women with suboptimal pregnancy outcome	Lower Limit	Upper Limit
CONTROL	Achiase	20	51	39.22	27.03	52.92
	Nobewam	5	77	6.49	2.81	14.32
	Senchi	2	72	2.78	0.77	9.57
	Donyinah	0	54	0.00	0.00	6.64
	Yaa Asantewa	3	82	3.66	1.25	10.21
	Effiduase	4	81	4.94	1.94	12.02
	Ejisu	1	74	1.35	0.24	7.27
INTERVENTION	Kwaso	2	89	2.25	0.62	7.83
	Onwe	2	99	2.02	0.56	7.07
	Mama Tina	10	95	10.53	5.82	18.30
	Okaikrom	0	41	0.00	0.00	8.57
	Juaben	2	19	10.53	2.94	31.39
	Huttel	7	76	9.21	4.53	17.81
	Bomfa	7	72	9.72	4.79	18.74

5.4.5 Intervention effect on knowledge of malaria and anaemia in pregnancy and adherence to health advice

The level of knowledge of malaria and anaemia in pregnancy and adherence was measured at the pregnant women's last visit at the ANC clinic before delivery or at the delivery visit when she was expected to have completed her ANC. Table 21 below shows the cluster level proportions of pregnant women with adequate knowledge of malaria and anaemia in pregnancy while Table 22 shows the comparison of the mean cluster proportions of the levels of knowledge and adherence by arm. The mean proportion of pregnant women who had adequate levels of knowledge about anaemia and malaria was comparatively higher in the intervention arm compared to the control arm (43.8% versus 31.3% for anaemia 54.3% versus 34.2% for malaria). However these differences were not statistically significant (Table 22). Similarly, there was no difference between the levels of adherence to health advice between the two groups (Table 22).

Table 21: Proportion of women with adequate knowledge on malaria and anaemia and adequate adherence to health advice per ANC clinic.

Study arm	ANC clinic	Number of women	Malaria (%)	Anaemia (%)	Adherence (%)
CONTROL	Achiase	49	26.53	10.20	12.24
	Nobewam	82	56.10	41.46	21.95
	Senchi	75	61.33	45.33	54.67
	Donyinah	50	30.00	32.00	14.00
	Yaa Asantewa	82	21.95	20.73	75.61
	Effiduase	78	84.62	69.23	35.90
	Ejisu	28	3.57	0.00	25.00
INTERVENTION	Kwaso	85	97.65	80.00	4.71
	Onwe	94	89.36	87.23	25.53
	Mama Tina	95	31.58	31.58	56.84
	Okaikrom	48	70.83	72.92	31.25
	Juaben	47	25.53	6.38	44.68
	Huttel	53	35.85	18.87	50.94
	Bomfa	62	29.03	9.68	37.10

Table 22: Comparison of mean proportions of women with adequate knowledge on malaria and anaemia and adequate adherence to health advice by study arm.

	Arm	Mean of cluster proportions	SD	95% Confidence Interval	p-value
Anaemia	Control	31.28	23.37	9.67-52.89	
	Intervention	43.81	35.07	11.37-76.24	0.4468
Malaria	Control	40.59	27.80	14.87-66.30	
	Intervention	54.26	30.83	25.75-82.78	0.4005
Adherence	Control	34.20	23.31	12.63-55.76	
	Intervention	35.86	17.54	19.64-52.08	0.8822

CHAPTER 6 FEASIBILITY AND IMPLEMENTATION FIDELITY OF THE ENHANCED ANTENATAL PACKAGE

6.1 Introduction

This chapter is divided into two sections. The first section describes the feasibility of the use of the RDT and HCS (and the pictorial guide) as tools to facilitate the participation of the pregnant women in their ANC during ANC sessions and the second describes the fidelity of implementation of the use of the HCS and RDT (and pictorial guide) during the study.

6.2 Feasibility of the use of the HCS, RDT and pictorial guide during ANC sessions

6.2.1 Introduction

The feasibility of the use of the HCS, RDT and pictorial guide was observed during a period of 6 months during regular visits to the implementing ANC clinics. Feasibility was assessed in terms of the ANC staff's ability to use the RDT, HCS and pictorial guide during ANC sessions to engage the pregnant women in their ANC without the disruption of the workflow of routine processes at the ANC clinic. Stocks of the RDT and HCS were replenished through the research assistants hence availability of these tools was not assessed.

6.2.2 Use of RDT and HCS during ANC sessions

The use of the HCS and RDT were integrated smoothly into the routine processes of all the ANC clinics in the intervention arm without any disruptions with already existing ANC practices. Because of the existing PMTCT of HIV and syphilis, which also depended on POC testing by the ANC staff, the ANC staff was already familiar with conducting blood tests on the pregnant women during their ANC sessions. On a pregnant woman's first visit to the clinic, the HCS and RDT were conducted together

with the HIV and VDRL tests with blood from one finger prick. For subsequent visits by the pregnant woman, only the HCS and the RDT were conducted. The tests were usually conducted at the last station of the pregnant woman during her ANC. This was with a provider who would also prescribe medicines for her and so the tests results also informed the provider of the choice of medicines to prescribe.

When the pregnant woman entered the consultation room, all POC tests that needed to be conducted were explained to her and then blood drawn onto the test kits. Whilst waiting for the appropriate time to read the tests, other processes that had not already been conducted, for example, history and symptoms taking, blood pressure measurement and palpation of the abdomen was done. Afterwards, the results of the tests were read with the pregnant women, recorded in their MHRB and then prescriptions given. The actual time that it took to conduct the tests was not assessed but no undue delays of the pregnant women were observed as they went through the processes of their ANC. The ANC clinic closed latest by 3.30pm at the big facilities and this was usual.

6.2.3 Use of pictorial guide

It was observed that usually, the ANC staff used the pictorial guide for group health educational talks. This was held at the beginning of the ANC session when a number of the pregnant women would have gathered. The ANC staff called for interpretation of the pictures by the pregnant woman and in so doing engaged the pregnant women in a group discussion about malaria and anaemia. Some of ANC staff, however were observed on some occasions, to use the pictorial guide one-on-one with the pregnant women during consultation, especially when they realised that the test results of the RDT and the HCS demanded that. To this end, the ANC staff invited the pregnant women who usually had positive RDT results and/or low Hb to describe what they saw

in the pictorial guide in relation to the cause, effects, treatment and prevention of malaria and anaemia in pregnancy.

6.2.4 Other observations made

1. ANC staff situation

The number of and attitude of ANC staff present on an ANC day affected the implementation of the intervention. In ANC clinics where there were more than 3 senior ANC staff on duty on an ANC clinic day, especially at the hospitals, sometimes they were not certain of who to conduct the tests. The staff claimed no one had been appointed for the day to conduct the tests with the pregnant women. Thus constant on the job training and motivation was needed for the ANC staff to inculcate the doing of the tests regularly with the pregnant women. On the contrary, some ANC clinics lost their already trained health staff to further education and transfers and thus new ones needed to be trained to replace those who left. Constant monitoring of the staffing situation was thus very essential for implementation.

2. Health talks

It was observed that there were no clearly defined or planned guidelines for giving the educational talks. No planned schedule existed for various topics to be discussed for each ANC clinic day so the message for the day really depended on the ANC staff available for the health talk. Thus messages for malaria and anaemia in pregnancy were not co-ordinated but given out haphazardly.

3. Delays in provision laboratory tests and medicines

Pregnant women who were not registered with the NHIS by their first visit needed to get the registration done before their laboratory tests or medicines could be served. Those who could pay for the services had them done but a majority of the women had to go away without any medicines or laboratory tests conducted until they reported with their health insurance cards. This caused delays for the pregnant women who tested

positive with the RDT to receive anti-malarial medicine. Although the ANC staff wrote prescriptions for the pregnant women to buy, they could not guarantee that the medicines were bought and taken by the pregnant women. Also, SP and the routine haematinics were not served to women without health insurance who could not afford to pay for them. With the HCS giving an estimate of the Hb, the ANC staff was able to give dietary advice with regards to improving Hb levels.

6.3 Monitoring of implementation fidelity

6.3.1 Introduction

An independent monitoring of the implementation of the enhanced ANC package was conducted during the 9th month of implementation. A trained independent observer conducted non-participant observations using a check-list and also conducted brief exit interviews with pregnant women who had accessed ANC using a topic-guide. Also 2 FGDs conducted by two independent moderators were held with implementing ANC staff to describe the possible facilitators and barriers to the implementation of the intervention.

6.3.2 ANC clinic observations and exit interviews

All seven intervention ANC clinics were visited. Up to 5 ANC staff-pregnant women interactions were observed per clinic depending on the availability of pregnant women. Also, 1 to 5 pregnant women per clinic were interviewed on the day the ANC clinic was visited. A total number of 22 pregnant women were interviewed. Only 2 of the women reported that it was their first visit to the ANC clinic. The rest had visited the clinic between 2 to 7 times.

Table 23 below shows the results of the evaluation conducted. The total number of activities observed divided by the total number of activities expected to be delivered was presented as the percentage of agreement (POA).

Table 23: Percentage of agreement of intervention activities by ANC clinic

		Pregnant women responses			Observations		
ANC clinic	Intervie-wee	Activity conducted	Activity not conducted	POA	Activities observed	Activities not observed	POA
Kwaso	1	12	0	73.00	7	3	70.0
	2	10	2				
	3	7	5				
Onwe	1	2	10	17.0	2	8	20.0
	2	2	10				
	3	2	10				
Mama Tina	1	4	8	33.0	3	7	30.0
	2	4	8				
	3	0	12				
Okaikrom	1	2	10	17.0	2	8	20.0
Juaben	1	7	5	58.0	7	3	70.0
	2	8	4				
	3	4	8				
Huttel	1	7	5	38.0	4	6	40.0
	2	3	9				
	3	4	8				
	4	4	8				
Bomfa	1	4	8	70.0	8	2	80.0
	2	3	9				
	3	11	1				
	4	12	0				
	5	12	0				
Average POA				43.7			47.1

None of the ANC clinics reached the goal of 90% set for the POA. The POA ranged from a low value of 17.0% to a high of 73.0% for the exit interviews and 20.0% to 80% from the observations. The values from the observations and the interviews were comparable for each ANC clinic. The average POA for all the clinics was 43.7 % for the

exit interviews and 47.1% for the observations, implying that less than half the number of expected activities were observed to be implemented for the whole study.

The activities that the ANC staff fell short of mostly were involving the pregnant women in the interpretation of the results of the HCS and the RDT and the one-on-one interaction with the pregnant women using the pictorial guide. In only 2 out of the 7 sites were the ANC staff observed to involve the pregnant women in the interpretation of the results of the HCS and to engage the pregnant women one-on-one with the pictorial guide. Also, interpretation of the results of the RDT was observed in only one of the clinics although the use of the RDT was observed in 4 of the clinics. This was also evident in the responses the pregnant women gave. Only 7 out of the 22 women reported having been engaged in the interpretation of the results of the RDT while 14 admitted the RDT was used to test their blood. Similarly, only 5 of the women reported being engaged in the interpretation of the results of the HCS out of the 10 who admitted the HCS was used to test their blood. Only 4 out of the 11 that admitted having seen the pictorial guide at the clinic reported that they had been engaged on a one-on-one basis with it.

6.3.3 Possible facilitators and barriers to the implementation of the package

Two FGDs were held with ANC staff from the implementing ANC clinics to describe possible facilitators and barriers to their adoption of the use of the RDT and HCS as tools to facilitate the pregnant women's participation in their ANC. The facilitators of the adoption of the use of these tools at the ANC clinics is described under the following subtitles: Perceived relative advantage in relation to other existing options; compatibility with the existing values and practices of the ANC system; trialability, that is it can be experimented with on a limited basis; simplicity of use and observability,

that is, the degree to which the results of the use of the tools can be visualized by the ANC staff. The potential barriers identified are also described below.

6.3.3.1 Intervention attributes facilitating the adoption of the enhanced package

1. Relative advantage in relation to existing options

The use of the HCS and the RDT were perceived by the ANC staff to be beneficial to the activities of ANC for both themselves and the pregnant women. Especially for ANC clinics that did not have laboratories, the staff said that conducting the tests during ANC sessions saved time because they were able to get results quickly so as to take action instead of having to wait for the pregnant women to visit laboratories outside their facilities. It also saved time and cost for the pregnant women who had to travel to have the laboratory tests done. Sometimes the pregnant women did not have the laboratory tests done but reported to the clinic only after they had developed some complications which posed a threat to the health of the mother and their baby, sometimes making their management difficult. The use of the HCS and the RDT during ANC enabled the staff to manage their clients better without the onset of complications from malaria and anaemia. The staff also commented on the fact that the use of the tests during ANC sessions gave them the opportunity to have a one-on-one chat with the pregnant women. Based on the results of the tests, the staff said they were able to tailor their recommendations accordingly.

2. Compatibility with existing ANC values and practices

The ANC staff reported that according to policy in Ghana, all pregnant women were to have their blood tested for malaria parasitaemia and haemoglobin concentration at the first ANC visit. On subsequent visits, the Hb and parasitaemia were checked only when indicated but Hb needed to be checked again at 36 weeks gestation. Thus the use of the HCS and the RDT during ANC was compatible with the ANC practices and offered the opportunity for all the women who presented to be tested promptly for malaria and

anaemia and managed accordingly. Records of these test results that they kept were accurate for the time periods during which the tests were done and thus they were confident in reporting the figures to the authorities. The ANC staff welcomed the news that the RDT and HCS were available to them especially because for some of the pregnant women who had to go outside to have laboratory tests done presented their results far later than expected thus not reflecting the results of the time period for which the tests were requested. Sometimes too the pregnant women would not report back with the laboratory results at all. This posed some difficulties to the staff, especially of how to manage the pregnant women. The ANC staff also said that it became very difficult for them to ask the pregnant women to go to a laboratory outside their clinic to check only their Hb at 36 weeks and so the HCS had come to solve this problem for them.

3. Trialability

The ANC staff members were willing to try out the HCS and RDT during their clinic sessions. They reported that because the tests were available and free to use for the pregnant women, they were encouraged to use them anytime the pregnant women reported for ANC. Even if the women reported within 2 weeks of their last visit, they used the tests again because they believed that the condition of the pregnant women could have changed within the period. The ANC staff said they were happy that now they could conduct the tests themselves and see the results immediately to guide them in their treatment options. They also reported that the pregnant women were also willing for the tests to be conducted on them because they could see the results for themselves. The women sometimes reported to the ANC clinic just because they wanted the HCS and the RDT to be conducted for them and not that they had any specific problems. They actually requested for the tests to be done if they waited a while and realised that there were no signs of the staff conducting the tests. In the opinion of the ANC staff,

they perceived that the tests attracted the pregnant women to attend ANC clinics more than before.

4. Simplicity of use

The ANC staff saw the RDT and HCS as very easy to use and simple tools that enhanced their work not only at the ANC clinic but during their outreach programmes too. Because of their ease of use, they had been able to incorporate them into their routine activities in the clinic. The tools were also portable enough for them to carry along anywhere they went enabling them to take care of the pregnant women to their satisfaction. They reported that sometimes when they had visited the pregnant women at home, the women did not need to come back to the ANC clinic for further tests because they had all the tests they needed to carry out on the pregnant women. The results that both tests gave, to them, were easy to interpret and understand and it was also not difficult for the pregnant women to understand.

5. Observability

There were highly visible and immediate rewards for the use of the RDT and the HCS during ANC sessions. The staff reported that they were now able to diagnose and treat malaria in pregnant women who did not complain or show any symptoms because of the availability of the RDT at the clinic. Also, the staff members were particularly happy that they were able to differentiate between false and true labour in pregnant women who reported with labour symptoms before their due date. False labour, they claimed happened most of the time with malaria in the pregnant women. After diagnosing malaria in these women using the RDT at the ANC clinic, immediate treatment with an anti-malarial medicine with observation at the clinic aborted the symptoms and allowed the pregnant women to carry on the pregnancy to term. ANC staff in clinics with no laboratories said they felt more confident when they needed to refer a pregnant woman because of anaemia because they could now add a haemoglobin

level to the referral note. One staff said it had reduced the number of telephone calls she used to receive from the referral centre because she initially referred the women without an accompanying laboratory test report. Some staff in health facilities with laboratories also reported that the HCS helped them to get a better estimate of the pregnant woman's haemoglobin which usually correlated better with their clinical judgement. They said that sometimes, the laboratory results they received were deceptive of the pregnant woman's condition and thus were very excited to have the HCS with them to verify the Hb results. The ANC staff claimed that some of the women refused to attend ANC clinics even when they felt unwell because they could not afford the cost of the laboratory test that sometimes they had to pay. But since the introduction of the use of the test kits at the clinics, the women reported more often because they did not need to pay for the tests to be done for them.

Table 24 below shows some quotes from the ANC staff in support of the identified facilitators of adoption of the intervention by the ANC staff.

Table 24: Supporting quotes from the ANC staff for identified facilitators to the adoption of intervention

Intervention attribute	Meaning	Some supporting quotes from ANC staff
Perceived relative advantage	The degree to which an innovation is perceived as being better than preceding ideas	We for instance, we don't have a lab so it has really helped us in the sense that, the malarial kit that she introduced has made us able to check for malaria..... When somebody gets malaria, it helps us to diagnose quickly and take action. You can ask someone to go the lab and for three months she will not step foot in your facility. By the time she comes, she has complications ..So now, the women come to the hospital more than they used to. It enables me have a one-on-one talk. If the Hb is low based on the colour scale, then you talk to the woman about it. If you see malaria, you talk to her about sleeping in a mosquito net and taking her SP, else the malaria will come again.
Compatibility	The degree to which an innovation is perceived as being consistent with values, needs, and experiences of an adopting society	We use it for every new client. We prick once and take the blood for HIV, syphilis, Hb, everything is done at a go. The colour scale helps us a lot. When you ask some of the women to go check their Hb elsewhere, they won't bring you the report so the colour scale really helps us.
Simplicity	The degree to which an innovation is perceived as being easy to use and understand	It's easy to use, it's become routine to us. If I'm going out for outreach, I can put all the kits in my bag and render services outside. It's not necessary for the person to come to the lab. So it's very good. So if you meet her at home, what you would have done for her at the hospital, you can do that for her at home
Trialability	The degree to which an innovation may be experimented with on a limited basis	But now, you can conduct the test yourself and see that it is true that it is positive so when you are giving her treatment, you can see it directly and give treatment…and it is the same with anaemia. She will just be sitting there and saying 'today, won't we do it?' 'Are you sick in some part of your body?' 'No madam!' 'So then why have you come?' 'Madam, I am coming to have my blood tested.' They just come because it is now helping them.
Observability	The degree to which the results of the innovation are visible to others.	Some might come as if in labour but it will not be labour... So because we have the malaria kit, when we test her for malaria and she is positive, we give her an anti malarial. When she takes the anti malarial, the labour pains goes away and she can go on. With the colour scale, we've realized that the Hb results from the lab are defective. The difference can be so wide. You the midwife can tell that the woman is nowhere near 12. With the colour scale, her Hb will be around 9 but the lab result will be so high. ...but at first because she has no money for the lab, she will be at home and be using herbal medicines. By the time she comes to the hospital, there would be complications. So now, the women come to the hospital more than they used to. For those of us who don't have labs, now the women say that when they come, we will test their blood, so they are happy with it so they come.

6.3.3.2 Potential barriers to the adoption of the use of the RDT and HCS during ANC sessions

Although the RDT and HCS were being used during ANC clinic sessions, there were variations in the degrees of adoption at the various ANC clinics. These variations in level of adoption and implementation could be due to a number of factors that were reported during the FGD. These factors are grouped under the following categories:

1. Diagnostic tools factors

Although the HCS gave the ANC staff the opportunity to check the Hb of their clients, they were not satisfied with the divisions of the scale into categories of 2g/dl of Hb. They preferred divisions of 1g/dl so that their estimates of colours in-between the shades of Hb would be 0.5g/dl instead of 1g/dl. This they said would make them more specific in their estimations. Because of this, some of the ANC staff after conducting the HCS with the pregnant women requested for another Hb to be conducted at the laboratory. They also reported that sometimes they had some challenges with comparing the shades of the colours on the scale with that of the pregnant women. This made it difficult to estimate the blood level of the pregnant woman as they could not find any shade close to the woman's blood colour.

The colour scale, if you could grade it from 0-12 but you shouldn't make the differences 2, 4, 6. If you can do it 1, 2, 3, it will be better so that when it is not falling on it…it is either 3.5 or 2.5

For the RDT, the staff members were concerned with negative results in pregnant women suspected of having malaria. They said that such women usually had positive laboratory results after sending them for laboratory testing and so would have missed treating for malaria if they had stayed with the results of the RDT. They said that the RDT that was available to them could only detect one type of malaria parasite and so would miss diagnosing other strains.

Please, with the malaria kit, sometimes too it does not show positive but if you write the labs for the person to do it in a different hospital the next day, the results will come back with positive 'mps', about one or two plus but we would not have seen it when we did it.

They also had concerns with the RDT not being able to quantify the level of parasitaemia although it was able to diagnose malaria in some of the pregnant women. They would have preferred to know the quantity so that it would guide them in their choice of anti malarials for the pregnant women. However, they tried to quantify parasitaemia by the intensity of the test line.

But with this, you can at the spot detect if the woman has malaria, only that you would not know if she is 2+ or 3+. But I've realized that if the two lines are very deep, she is more than 2+. So we give her quinine and tell her to come in two weeks' time.

2. User factors

The ANC staff commented scarcely on the fact that using the RDT and HCS during ANC sessions had increased workload. One staff member said it impacted negatively on other components of ANC that they needed to deliver to the pregnant women. Although time was not mentioned explicitly in the discussions, it may have been implied by the report of increased workload.

No, it's only that it brings us the midwives more work. I'm not able to do the focused antenatal because what's involved is a lot.

Another staff also commented that the beginning of implementation was quite difficult but now it had become a routine and easier to do.

With every new thing, the beginning is very difficult but when you continue, it becomes routine and easier.

It was important for the pregnant women to be well informed about the tests otherwise they were reluctant to have their fingers pricked anytime they visited the clinics. The ANC staff reported that at the beginning of implementation, they faced this challenge but with continued education, explaining the reasons for conducting the tests to the pregnant women, they willingly offered themselves to be tested and even reminded the staff of their tests when they returned to the ANC clinic for their subsequent visits.

If you don't tell them the reason why, you will prick it alright but the next time when she comes, no matter how hard you try, she wouldn't allow you.

Now, some of the women even request for it. When you don't prick them, they'll remind you that you have not pricked them.

3. Health system factors

The type of health facility where the ANC clinic was conducted could influence the carrying out the tests. The ANC staff felt that the tests would be more useful in health facilities with no laboratories. Although the tests could be helpful when the laboratories in the hospitals were closed, they believed strongly that the smaller health facilities which usually had no laboratories needed them most. The ANC staff had some words of advice for the researcher.

She should concentrate on the [smaller] clinics because the hospitals, they have the labs and everything so it is the health centres that if they are really trying to expand then they should concentrate on them.

These should go to all the villages!

These thoughts were supported by the statement that one ANC staff made concerning the use of the tests in her clinic. She reported unreservedly that the tests were not done in her clinic because they had a laboratory.

We don't use the colour scale here ... because we have a lab.

The reported sentiments were also observed during the monitoring visits. Over time, it was observed that ANC staff in 2 of the health facilities that had laboratories sent the pregnant women to the laboratories for their tests for malaria and Hb instead of using the RDT and HCS at the ANC clinic. It was realised that according to the health facilities policies, the laboratories conducted the HIV and syphilis tests for the pregnant women in addition to all other tests and not the ANC staff and hence it was difficult to get the ANC staff to co-operate with conducting these two tests with the pregnant women as a routine. The RDT and HCS had been sent to the laboratories to be conducted there. Thus the tests were conducted alright but the element of participation by the pregnant women was missing. The ANC staff however sometimes conducted the RDT and HCS tests at the ANC clinic when the laboratories were closed or in emergency situations or sometimes to confirm questionable laboratory results. ANC staff members in clinics that had no laboratories were however observed to conduct the two tests quite religiously with the pregnant women throughout the study.

The constant supply of the tests kits was also discussed. Irregular supply, especially of the RDT, was reported by one staff member. She however had direct access to the telephone number of the researcher to call for stock to be replenished in anticipation of stock outs. She stressed the need for the tests kits to be readily available through identified supply channels if this intervention was to be scaled up.

We often get close to running out of stock. I'm always calling Dr. Gifty asking her for more supplies, because I have to do the tests for both old and new attendants. So the supplies should flow.

The issue with regular monitoring and support for the implementation was mentioned by the staff as key to the successful implementation of the package. They agreed that continued support and regular visits from the organisers of the project encouraged them

to continue with the implementation till it became routine for them. Lack of or irregular supervision and support would thus be to the detriment of adoption and implementation of the intervention.

...so we would ask that, you continue to pop in to see how things are going and polish us up.

CHAPTER 7 ACCEPTABILITY OF THE ENHANCED ANTENATAL CARE PACKAGE

7.1 Introduction

This chapter describes how acceptable the use of the HCS and RDT as tools to facilitate pregnant women's participation in their ANC was, first to the pregnant women and then to the ANC staff. Focus group discussions and in-depth interviews were held with the women while in-depth interviews alone were conducted with the ANC staff at the end of recruitment of study participants into the randomised controlled trial.

7.2 Pregnant women's acceptability of the enhanced antenatal care package

7.2.1 Selection of study participants

Figure 22 below shows the selection of the participants into this study. A total of 6 FGDs and 6 in-depth interviews were held with pregnant women and mothers from both arms. Participants were drawn from women who participated in the trial at 4 intervention and 2 control ANC clinics for the FGDs, and 1 ANC clinic from each arm for the in-depth interviews. The purpose of these discussions and interviews was to explore the pregnant women's perceptions and knowledge about ANC, malaria and anaemia in pregnancy and to describe their experiences with the use of the RDT and HCS to facilitate their participation in their ANC.

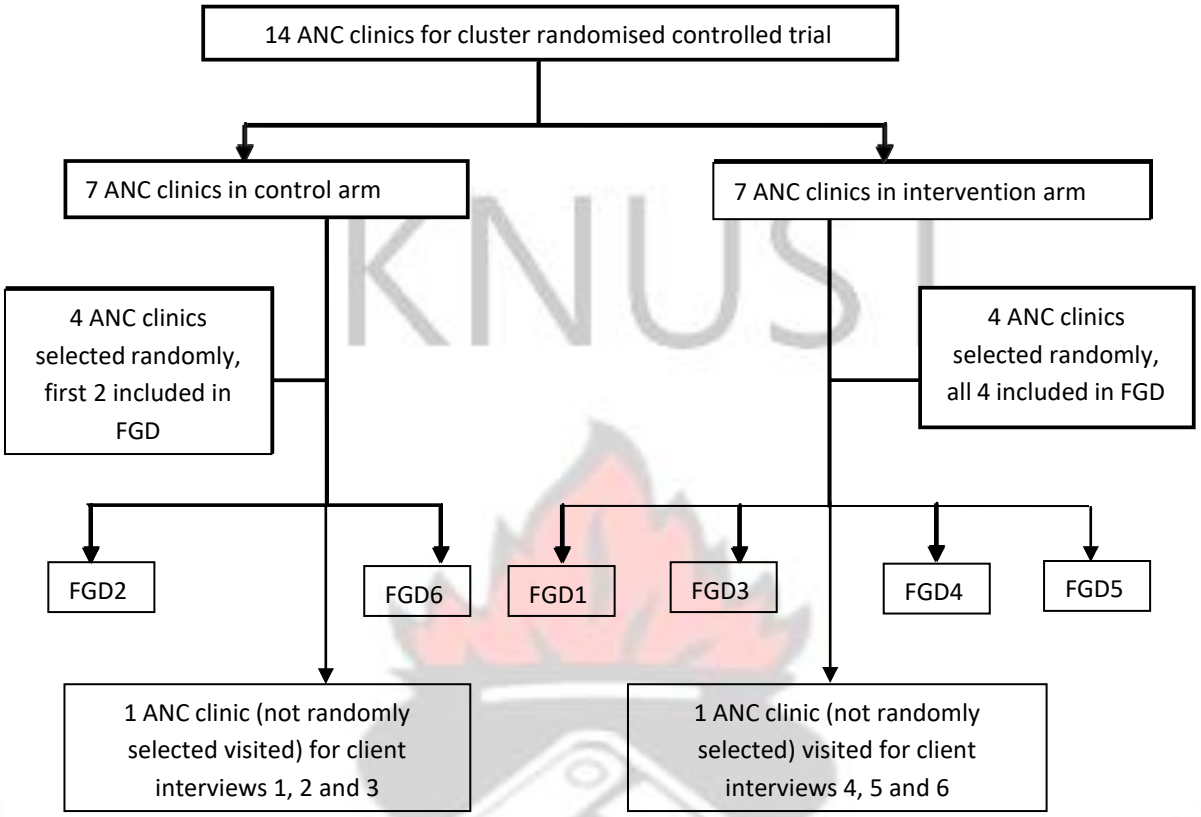


Figure 22: Diagram showing the selection of participants for the FGD and interviews by arm of the trial

7.2.2 Characteristics of participants

Table 25 below shows a summary of the sampling framework that was achieved at the end of conducting the study while Table 26 describes the socio-demographic characteristics of the women who participated in the FGDs and interviews. The total number of participants per FGD ranged from 6 to 11.The women that took part in this qualitative study were of diverse characteristics and locations as was hoped for when they were being selected. The majority (50.9 %) of the women were between 20 to 29 years followed by the 30 to 39 years age group (34.0%). Almost 8 in 10 women (79.4%) had had at least one delivery. Forty-five percent of the women first attended the ANC clinic in the first trimester while 49.1% first attended in the second trimester. Only 5.7%

first attended the clinic in their third trimester. Only 5.7 % had no formal education with the majority (67.9 %) reaching the Junior high school level.

Table 25: Sampling frame of participants

Discussion/ interview group	Location		Type of health facility			Affiliation of health facility		
	Rural	Semi-Urban	H	HC	MH	Mission	Gov't	Private
FGD1	X			X			X	
FGD2		X		X		X		
FGD3		X		X			X	
FGD4	X			X			X	
FGD5		X	X				X	
FGD6	X			X		X		
Interviews 1, 2, 3		X			X			X
Interviews 4, 5, 6		X			X			X

H-hospital, HC-health centre, MH-maternity home, Gov't-government

Table 26: Characteristics of participants of FGD and In-depth interviews

	FGD1	FGD2	FGD3	FGD4	FGD5	FGD6	Interviews
Characteristic							
Number of participants	8	8	11	6	8	6	6
Age (years)							
<20	1	1	1	1	2	1	0
20-29	2	3	7	4	3	3	5
30-39	4	4	3	1	3	2	1
>40	1	0	0	0	0	0	0
Average age (years)	29.25	29.5	26.45	26.5	27.35	24.33	27.67
Parity							
0	2	3	0	1	3	3	1
1	0	0	4	0	2	1	4
≥2	6	5	7	5	3	2	1
Average parity	3.00	2.63	2.09	2.67	1.38	1.83	1.67
Gestational age at first ANC visit (trimester)							
1	3	4	2	4	5	1	5
2	4	4	7	2	3	5	1
3	1	0	2	0	0	0	0
Marital status							
Married	5	4	7	3	3	2	3
Not married	3	4	4	3	5	4	3
Educational level							
None	0	0	2	0	1	0	0
Primary	1	1	1	1	1	1	0
Junior secondary	7	4	7	5	5	4	4
Senior secondary	0	3	1	0	1	1	1
Tertiary	0	0	0	0	0	0	1
Occupation							
None	1	1	2	0	2	2	0
Employed	7	7	9	5	6	4	6

7.2.3 Findings

FGD conducted lasted between 31 minutes and 47 minutes. All the audio-recordings were transcribed verbatim and then transported into NVIVO computer software to assist in analysis. A coding frame was used to summarise the transcripts. The content of the scripts was grouped into themes. Findings are described under the following headings: (1) ANC practices of the pregnant women and their motivation for receiving antenatal care (2) the women's perceptions and knowledge about malaria and anaemia in pregnancy (3) the women's experiences of the use of the RDT and HCS during their antenatal care.

7.2.3.1 ANC practices and motivation for receiving antenatal care

When the women were asked why they attended the ANC clinic during their current pregnancy, their aim was primarily to ensure that they and their babies stayed healthy during pregnancy and delivery. They reported that the ANC clinic was a very important place for every pregnant woman to go to receive the appropriate medical care that would ensure they and their babies stayed healthy. Some, for fear of death, either of themselves or of their unborn babies, attended the ANC clinic so that they could be taken care of if there were any problems. Others also thought it very dangerous to self medicate during pregnancy as this could also lead to the death of their babies.

I believe that as a woman, once you get pregnant, you have to come to the hospital for the doctor to assess your situation. This will help you. If you don't come, you might have a lot of negative effects so I believe that if you come, it would be good. (Client interview-1)

Sometimes, if you stay at home, you can die or your child too can die so that is why I came to the clinic. (Client interview-4)

Why we come is so that we will be healthy and not fall sick so that we will have peace for our children to be strong. (Woman C, FGD-2)

Most of the women said that they started attending the ANC clinic within the first three months of pregnancy with a majority starting at three months. These women started early because they wanted to be sure that they were indeed pregnant and that everything was alright with them and their babies. A few however admitted starting late, after the sixth month, because they felt very well and so did not need to go to the clinic until later.

I didn't start on time...about 7 months but from then, I continued till I delivered. Why I did not come is that I had made up my mind that I was not sick. (Woman D, FGD-2)

Re-attendance to the ANC clinic mostly depended on the schedules that the women were given by the ANC staff. They reported that they attended the clinic, quite regularly on a monthly basis, sometimes, up to 12 times during the pregnancy to receive appropriate medicines and vaccinations. They commented however that in the later stages of the pregnancy, they were asked to visit the clinic every two weeks or weekly until delivery. They also commented that in addition to their schedules, they could return to the ANC clinic any time to report illness or anything abnormal they had identified with themselves. On such occasions, the pregnant women said that the ANC staff received them well and took care of them and so they were not afraid to go to them if they had any problems. The women believed that the welcoming atmosphere of most of the ANC clinics and the positive staff attitude encouraged them to keep to their schedules of attending ANC clinic throughout their pregnancy.

They tell us too that it doesn't mean that because they tell us to come monthly, we should only come monthly. If you are not feeling well, you should come so that if they have to give you medicine, they do so. (Woman B, FGD-1)

We were very happy with what they did for us because it isn't at all 'doctors' that you will be pampered and then they will tell you to take the medicine they give you so that your child will be healthy so that is why we were always happy and we kept coming here. (Woman X, FGD-2)

Another reason for attending the ANC clinic was to receive refills for their medicines when their medicines got finished. They believed that the medicines they received gave them a healthy appetite to eat well so that they would get enough blood, receive strength to prepare them for a safe delivery and also make them and their babies healthy.

My reason for coming is to receive medicines for my wellbeing and that of my child so that when my time is due, I will deliver safely and my baby too will be fine. (Woman E, FGD-1)

The benefit we gained is that the medicines protect the child. When you're given the medicines and you take them, you get blood, you get strength, and your baby too. So when you come to deliver, you deliver safely. (Woman C, FGD-4)

The women also appreciated the health advice and education they got from the ANC staff very much and identified them as motivators for attending the ANC clinic. These, they said, helped them a lot to maintain healthy lifestyles for the sake of their babies and themselves. They said that the ANC staff advised them on how to lie down in order for the babies to be positioned well for deliver and on what to eat to get more blood. They also acknowledged that they were advised on how to prevent themselves from getting diseases and also to take their medicines regularly.

By God's grace [when] you get pregnant, you come here to receive information that will make you deliver safely. (Woman G, FGD-1)

Me too my opinion is that so that the child will be healthy and also that we the mothers too will be strong so that when the time is up we will be able to push for the

child to come out and also to get strength to take care of the children. And so we come to the clinic to listen to what they will teach us. (Woman B, FGD-2)

"Eat meat! If you cannot get meat, then beans, 'kontomire', 'koonsusuaa'. All these give blood. After that, when you have eaten and are full, you should get some fruits to eat." When we come they teach us that it makes the blood healthy. (Woman A, FGD-3)

The women reported that they went through routine procedures such as having their weight, blood pressure, temperature and abdomen measured any time they attended the clinic. None were able to give any reasons why the blood pressure and weight measurements were done routinely. However, the position of the baby, its movements and also ensuring that the heart of the baby was beating in the womb were perceived to be the reasons why their abdomen was measured during their ANC. They believed that if there was anything wrong, it would be identified and appropriate treatment prescribed by the ANC staff when they attended the clinic. They also reported that laboratory investigations were conducted on them to detect any sicknesses that they might be harbouring so that they would be given medicines. The pregnant women mentioned blood tests including checking their blood levels, HIV, malaria and Hepatitis B tests more frequently. Urine and stool tests were also mentioned however they did not mention any specific medical conditions that they were investigated for. They in addition mentioned ultrasound scans being done on their abdomen initially to confirm their pregnancy and then later to tell whether the baby was lying in a good position or not for delivery.

7.2.3.2. Perceptions and knowledge about malaria and anaemia in pregnancy

The discussions and interviews held also centred on what the women knew about the causes, signs and symptoms and the effects of malaria and anaemia during pregnancy and how they prevented themselves from getting malaria and anaemia.

(i) Perceptions and knowledge about malaria in pregnancy

Most of the women knew that it was the bite of the mosquito that caused malaria. They linked the breeding of mosquitoes in their environment with stagnant water in gutters and bushes behind their homes. They also identified dirty environments where there were rubbish dumps with empty containers as potential breeding grounds for mosquitoes. They recollected that uncovered collections of clean water meant for household chores or for drinking also served as potential breeding grounds for mosquitoes and all these could increase one's chances of getting malaria. Some of the women however mentioned the eating of certain foods like food cooked with a lot of vegetable oil, foods containing a lot of fatty meat, cold food and uncovered foods as causing malaria. A few of the women also mentioned houseflies and dirt as causes of malaria.

You can get malaria if you eat certain foods, like fatty meats, so it's not only mosquitoes. (Woman H, FGD-1)

When you finish cooking food, you have to keep it well, cover it, before you eat, so you don't get malaria. (Woman C, FGD-4)

It's from dirt. If you eat and you don't wash the bowls and flies from rubbish dumps come to settle in the bowls, and you just rinse the bowls with water and then eat from them, it's not good. You have to clean the bowls with soap and sponge. (Woman E, FGD-6)

A majority of the women were aware of the symptoms and signs of malaria. They mentioned headaches, body pains, body weakness, having no appetite for food, bitter taste of mouth, not being able to sleep well, having yellowish urine, becoming dizzy and restless, vomiting, feeling cold and sweating as the common ones. Some were also aware that malaria could cause miscarriages and anaemia, and that anaemia could lead to swollen feet. With this knowledge they did not hesitate to report immediately to the

ANC clinic as soon as they had any of these symptoms and signs. They believed that if they reported early enough to the clinic and took the medicines they were given, their babies' lives would be saved. They were also aware that other times too, the pregnant woman could show no symptoms and signs of malaria when infected and it was the nurse who could tell if she had malaria hence they had to report frequently to the ANC clinic during pregnancy.

I used to have headaches, I'll be feeling weak, I won't be able to eat. So when she said I had malaria, I believed her. (Woman A, FGD-4)

You have a bitter taste in your mouth; you won't even be able to eat well. You will feel weak. Sometimes you can bleed. (Woman B, FGD-1)

That is why they tell us all the time to come to the clinic because when you come to the clinic, the nurses themselves will know whether you have malaria. (Woman A, FGD-6)

The women also described other effects of malaria during pregnancy as giving birth to a small, weak and sick baby which is referred to as 'asram' in the local dialect or that the baby will be born prematurely. Children labelled as having 'asram' generally fail to thrive and the condition is associated with evil spirits. They also said that sometimes, the baby could be born with malaria or have the tendency to get malaria often during its lifetime. This they believed was possible because the child in the womb depended on the mother to survive so anything affecting the mother could also affect the child. Only a few of the women associated malaria in pregnancy with directly causing the death of the mother or bleeding heavily after delivery which could also lead to the death of the mother.

When you give birth, your baby will not be strong. People will say it is 'asram' but it will rather be malaria. (Woman F, FGD-3)

It will make the child small and thin. We sometimes attribute this to 'asram' and say a witch is responsible but all this is from malaria so we have to watch it. (Woman B, FGD-1)

Malaria can kill the pregnant woman; she can die. The baby in the womb can also die. If the baby is born, he will not be strong; he will also often get malaria. (Client interview-3)

Sleeping under the mosquito net was mentioned the most as the means of preventing malaria at home by the women. They mentioned the time at which they went under the net to sleep as crucial in preventing malaria. If the pregnant woman stayed outside her net and got bitten by the mosquitoes long before she went to sleep under the net, she would then get malaria although she slept under the net. Other means of prevention mentioned, although much less frequently, were the use of insecticide sprays and coils, wearing of protective clothing when outside the room and not leaving the door of their rooms ajar for mosquitoes to enter. A few also made mention of keeping the environment clean, having good eating habits like eating healthy and covered food as a means of preventing malaria. Some unorthodox means of driving mosquitoes away were mentioned like the use of smoke when outside the room or the use of the electric fan when inside the room.

Yes. I had a mosquito net that I was not sleeping in. I was sleeping with the fan and was thinking it was driving away the mosquitoes so I would not get bitten, not knowing that they were biting me. So we should not put that in our minds, we should sleep in mosquito nets. (Woman X, FGD-1)

Some of the women identified 'medicine given at the clinic' as medicine to prevent them from getting malaria. They admitted having to take the medicine in the clinic, up to three times during the pregnancy. One woman however said that she was given the medicine twice because she was said to have delivered five times and so had enough of

the medicine in her system.

As for me, I was given it twice. They say that when you give birth five times, that's how they do it... By the time you give birth up to five children, there will be a lot of the medicine in you, so they give you just twice. (Woman A, FGD-1)

(ii) Perceptions and knowledge about anaemia in pregnancy

When asked how a pregnant woman would know she was anaemic, a majority of the women were able to mention signs and symptoms such as dizziness, tiredness, weakness and pallor. Some also identified headaches and not being able to sleep well at night as symptoms of anaemia. A few also mentioned swelling of the feet as a sign of anaemia and debunked the myth that the swelling of the feet in pregnancy meant that the baby in the womb was a boy or a twin gestation.

Your legs will become swollen; when your legs become swollen, people might tell you it means you will give birth to twins or you will give birth to a boy, sometimes it's not like that. (Woman B, FGD-4)

A few did not know how a pregnant woman presented with anaemia but were quick to say that they would get to know when the nurse told them at the ANC clinic.

Most of the women associated anaemia in pregnancy with poor eating habits. They identified not being able to eat well, not eating the right foods and not eating on time as causes of anaemia. The right foods mostly mentioned included indigenous green leafy vegetables like 'nkontomire', the leaves of the coco yam plant; 'abeduro', the fruit of a shrub in the garden egg familiy and 'kwaunsusua', green berry-like fruits that grow in the wild. Some also mentioned foods like plantain, palm-oil, ground nuts, beans, dried fish and fruits as helping to prevent anaemia. Some myths existed concerning the eating of fruits during pregnancy. An example was fruits make the pregnant woman have a 'loose waist' such that delivery is difficult but the women debunked these in the

discussions and encouraged themselves to eat fruits for more blood during pregnancy. A few said that eating foods made with vegetable oil was highly prohibited during pregnancy as such foods caused anaemia.

When you are pregnant, you should often eat 'nkontomire' and 'abeduro' and palm oil and stop eating oily food as [vegetable] oil can cause it [anaemia]. (Woman C, FGD-1)

*Some pregnant women think that when they are told to eat well, when they eat fried rice, they have eaten well but that is not it. You have to eat the foods our mothers have been eating – leafy foods like 'nkontomire', 'kwaunsusua', yam, plantain, 'fufu' with palm nut soup or 'nkontomire' soup. If you eat well and consistently take the medicines given you, you will not have anaemia. (*Client interview-3)

They reported that the child in the womb also adds to the mother getting anaemia by drawing on the blood of the mother for its wellbeing thus making the situation worse.

If you can't eat! Me, for instance, when I'm pregnant, I vomit and spit a lot. So if you can't eat, you vomit and you spit, it doesn't give the baby strength so he draws the little blood you have and makes yours go even lower. (Woman A, FGD-4)

Whilst some women mentioned not adhering to the haematinics given them at the ANC as a cause of anaemia, most of them believed however that not taking the haematinics led to anaemia because the medicines were to give them a healthy appetite to eat well. They did not perceive the haematinics as blood forming on their own.

After eating in the morning, you have to take the medicines given you because when you take them, they can make you feel hungry to eat and that will help you eat well. (Woman B, FGD-1)

The medicines you are given when you come to the hospital. They help you to eat well, because when you are pregnant, you get low appetite for food, it helps you eat well. (Client interview-2)

Only a few of the women mentioned malaria as a cause of anaemia during pregnancy and thought preventing malaria could also prevent anaemia. Worrying or thinking a lot was also mentioned sparingly as a cause of anaemia during pregnancy.

When asked what anaemia could do to the pregnant women, a majority linked it to not having enough strength to be able to push during the delivery process. This could end them in the operating room or even having to receive blood transfusions before they are able to deliver. They were not comfortable with having to be transfused and so kept on saying that they needed to eat well to have enough blood so that they could avoid that. A few of them also mentioned that during delivery, the mother could bleed to death and the child too could die.

If you do not have enough blood, you do not have enough energy to push and so you can end up with an operation because you do not have enough blood to deliver (Woman A, FGD-2).

If it happens like that, you can bleed during delivery. If you do not have enough blood, when you deliver, you lose a lot of blood (Woman G, FGD-2).

7.2.3.3 Experiences of the use of the RDT and HCS during ANC

Six key themes were identified from the women's experiences that influenced their acceptability of the use of the RDT and HCS during their ANC. These were (i) the opportunity that the women had to see the tests being conducted, (ii) their ability to interpret the test results correctly, (iii) the ability of seen test results to influence their behaviour, (iv) ANC staff conducting the tests (v) time and cost saving and (vi) their general perceptions of the continued use of the tests during ANC.

(i) Opportunity to see tests being conducted

The women were happy that they could now see their blood tests being done for them. They believed that this reflected the truth about what was happening in their blood as

the results showing were for them and not for any other person. They expressed concern about the possibility of receiving wrong results from the laboratory since they did not see what went on inside there after their blood had been drawn. To them, it was possible that the blood samples could be swapped or the labels could fall off and thus re-labelling could be done wrongly. Hence they could not trust that the results they were being given from the laboratory really belonged to them.

It makes me know that the results are the truth. You may tell me the wrong results and this may be worrying. But if I see with my own eyes, there is no controversy about it. (Client interview-4)

... because if it goes to the lab, you realise that they collect a lot of different samples and line them up and they may forget whose it is. They may mix them up. (Client interview-5)

It was only one woman who thought that seeing the test being done would rather create a negative impression of fear and thus preferred not to see it. She thought it was better that the tests were done without her seeing them till she sent the results to the doctor. Her trust in the doctor to see the results and prescribe appropriate medicines for her was shown in her response.

It makes you scared. As a pregnant woman, you don't have to be worried and be thinking a lot so if the doctor sees it and he writes the medicine for you, it is better. (Client interview-1)

Because they could see what their blood was being used for, they did not have any fears or superstitious beliefs about the drawing of their blood.

(ii) Ability to interpret results correctly

A majority of the women were able to narrate how the tests were done on them. They were able to mention that the RDT was used to test for malaria and the HCS for their blood strength. A few however mentioned that the RDT was also used for HIV test.

They reported that the ANC staff took a finger prick of their blood and put it on the RDT, added some liquid to it and then later told them they either had malaria or not. Most of the time, they saw the results too and knew that if there were two lines in the test kit, then they had malaria but if it was only one line, then they did not have malaria. They said that the test results were not difficult to understand and it showed them right away whether they had malaria or not.

They prick your finger tip and then take some blood and drop it here then they put some liquid or medicine on it so if it marks two lines, then it means that there is malaria or a disease in the blood. If they are not two marks, then there is no disease in it. (Client interview-5)

She makes you understand that it's a malaria test she's doing for you. She tells you that when the lines are two, you have malaria, when it's only one, you don't have malaria. When I looked, the lines were two. (Woman E, FGD-1)

For the HCS, they reported they were happy to see their own blood being used in the test. The majority were able to describe how the test was done and said it was used to tell whether their blood level was good or bad. They said their blood was put on a piece of paper and moved up and down in a book till their blood matched a colour in the book. If the matched colour was down in the book, then it meant that their blood was low however if it was up then their blood was good.

When the nurse checks your blood, she puts it beside the paper, when it goes down, she will tell you your blood is low, when it goes up, she says your blood level is good. (Woman X, FGD-4)

The midwives prick us, put the blood on paper and show us a book with some writings on it. They tell us to compare our blood colour on the paper to see which number it corresponds to in the book, maybe 8 or 10. (Woman D, FGD-1)

(iii) Ability of seen test results to influence behaviour

The women claimed they were able to identify with the messages that the results of the tests relayed to them in relation to their health status. They were able to tell whether they had malaria or not or whether their blood level was high or low. They thus became determined to act upon these messages so that they improved upon the state of their blood by their next antenatal visit. They then took the advice given them by the ANC staff seriously and acted upon it because they had seen the results for themselves and believed them. Activities they talked about included eating well; identifying foods that caused their blood not to be optimum so that they did not continue eating them but rather eat foods that will help improve their haemoglobin levels, acquiring a mosquito net, sleeping under the mosquito nets regularly, and getting indoors early enough to avoid being bitten by mosquitoes. Some also said that they had to take all the medicines they are given at the ANC clinic in order for their blood to be optimum.

Seeing with my own eyes, for me, it is good because I see that this is how my blood is. So when I go home, I am serious with what I need to eat to make my blood better and also stop thinking unnecessarily. (Client interview-4)

It has made us know that we need to eat well and then sleep under the mosquito net to prevent ourselves from being bitten so that anytime we come to the ANC clinic and our blood is checked, it will remain high. (Woman A, FGD-4)

... we do not see the tests. So if they tell you to eat this or that... maybe, I am argumentative [and] I will not follow because I did not see it for myself. But when I see it, I know that it is true that I do not have blood or I do. So if she gives me the advice, I will follow it. If I do not see it, I will think, "But I did not see it, what are you talking about"? (Woman A, FGD-2)

... if you see the kit shows you have malaria and you're given medicine, you will be careful to take the medicines so that the malaria will completely go.... (Woman B, FGD-6)

Seeing the test results also triggered in them the desire to follow up to see whether they had made any improvements at all from their previous results. Seeing no improvements would encourage them to adopt healthier lifestyles while seeing an improvement would inform them to continue along the path they had been on that lead to the positive results.

Let's say my blood level is good. The next time I come to the clinic, I would have the nurse check for me to see if it is still good. (Woman B, FGD-5)

Anytime you come, your blood level will be checked and if it's high, you would know what foods you ate that month for it to go up so you continue, or on the other hand if it's low then the foods you ate are not good so you should stop and eat something else. (Client interview-3)

Having repeated tests during their follow up meant they would have repeated finger pricks to collect blood for the tests. Although the women admitted that the pricks were painful, they thought the tests were done for their own good and so endured the pricks for the benefits they would derive. They said the pain of being pricked could not be equated to labour pains during delivery but they went through and delivered because it was necessary at that time. Similarly, they had the tests done in spite of the anticipated pain because they believed they were necessary during their pregnancy. They were not worried about the amount of blood being drawn either. They commented that the amount of blood drawn for the test was very minimal and therefore could not be harmful to their health.

It was painful but she is helping you so even if it's painful, you have to endure it. (Woman E, FGD-4)

Just ignore those who say it is painful and roll it out… even labour is painful but when you need to deliver you go through it so this is a small thing. (Client Interview-2)

(iv) ANC staff conducting the tests

A majority of the women preferred that the ANC staff performed their laboratory tests for them compared to the laboratory staff. Most believed that the ANC staff had better education about pregnancy and thus were more competent to deal with them. They said that the ANC staff understood them better and related to them well thus they felt closer to them (ANC staff). What they liked most was that the ANC staff members were patient with them and explained the test procedures and the results to them (pregnant women) unlike the laboratory staff who were interested in only taking their blood and handing results to them on a sheet of paper. Some lamented that they could not read and so it was not fair to just give them results on a sheet of paper without talking to them about what the results meant. If they had to bring the results back to the staff for them to explain the test results to them, why then did they not just do the tests for them and then afterwards explain the results to them?

If you go to the laboratory, may be you may not be educated and so you cannot read... they just hand over the results sheet to you. They do not tell you what is going on. But if the midwife does the test with you, even if you are uneducated, she explains the test results for you to understand it so I think that that is more helpful (Woman C, FGD-3)

Please, for the lab, if it is sent there, we will not see the tests. So if it is given to the nurses to do, while measuring your stomach, this is by the side, so as soon as your tummy is done, then she does it with you. It is better than sending to the lab for it to be done (Woman A, FGD-2)

When you go there [laboratory], they draw your blood and let you sit outside. When they finish, you just go for the results. Over here too, she will talk with you for a while before she tells you to go home. (Woman A, FGD-4)

Some women felt that doing the RDT and HCS increased the workload of the ANC staff durig the consultation process. Because they did not want to miss having the tests done with them, they suggested another ANC staff be assigned the task of conducting the tests whilst they waited to have their turn in the consulting room.

There is someone who checks our BP for us before we go and see the nurse. So, if we get someone like that who will do the tests with us, different from the nurse, so that before you go to the nurse, you would have done the tests. (Woman B, FGD-2)

A few of the women felt it was the duty of the ANC staff to perform the tests for them and so did not show any empathy with perceived increasing work load. These women felt that they had been placed in their care and so the staff should take responsibility of everything concerning them including performing any laboratory tests that pertained to them and their pregnancy.

It is because it is their work that is why we the pregnant women have been placed in their care so we don't have to join those at the lab. (Woman F, FGD-5)

A minority among the women however were not comfortable with the ANC staff carrying out the tests for them. They believed that the laboratory personnel had been trained better to conduct laboratory tests and so should be the ones to do the tests for them. Every health staff they believed had their specific roles to play and thus should be allowed to do so.

(v) Time and Cost saving

ANC staff conducting the tests meant that the tests were carried out at the point-of -care of the pregnant women. A majority of the comments that were given suggested that carrying out the tests at the ANC clinic during consultation was preferable to going to

the laboratories for the tests to be conducted. This is because they appreciated the fact that the results of the tests were known immediately both by the ANC staff and themselves for prompt action to be initiated. They did not enjoy joining long queues at the laboratories such that sometimes they returned late to the clinic and thus did not receive their medicines or any further care.

When they tested me and saw I had malaria, they immediately admitted me and put a drip on me. If the test had not been done here, how would I have known that I have malaria? (Woman X, FGD-1)

When you go to the laboratory, there are usually a lot of people so you can be there for a long time, sometimes they can't do the tests for you, but here, they are able to do it. (Woman B, FGD-4)

A majority complained about the extra cost of transportation to have their tests done at the laboratories outside of their ANC clinics. Although most of the ANC clinics had laboratories in the health facility, these were not accessible all the days of the week thus pregnant women reporting for ANC on days that the laboratories were not functional had to travel outside the facility to get their laboratory tests done. The anticipated extra cost for travelling coupled with the discomforts they experienced during travelling and the time spent both travelling and at the laboratory, sometimes deterred them from having their laboratory tests done at all. They thus could not receive appropriate care at the appropriate time which could sometimes end up in some complications.

We might not have money to go to Effiduase so if the madam can do it for us here, that would be really helpful. The lorry fare is expensive, when you go too, you'll drink water. (Woman C, FGD-4)

That time that you are pregnant, you get tired easily, you walk a little and you are tired. Coming here [ANC clinic], you would not have to travel. All you have to do is

to come here for them to attend to you, when they are done, you go home. (Woman H, FGD-1)

Contrary to what the majority said, there were a few who thought that doing the tests at the ANC was time consuming causing them to stay at the ANC for long hours while awaiting their turn. They would rather prefer to visit the laboratories at different times and then have their ANC with the results at another time.

(vi) General perception of the continued use of the HCS and RDT during ANC

When asked finally whether conducting the HCS and RDT during their ANC should come to stay, they showed their acceptability by an overwhelming majority resounding yes. They believed that they had benefited a lot from the tests being conducted with them at the clinic and would want to have it done again during their next pregnancy. Those who had already delivered expressed joy at the outcome. Some also pleaded for their siblings who were now getting pregnant to come and benefit from the tests. They dwelt on the fact that now they could see their own test results and understand what they meant so that it informed them to adopt healthier behaviours. Some even associated the regular testing of their blood to having received good quality care and others also commented that it would attract pregnant women to the ANC clinics.

It should stay here. It makes us see how our blood is. If the test is not here we will not see it [our blood]. (Woman B, FGD-3)

It would be good, that would be very good. If they check my blood and do all that for me, I would say that they have really attended to me at the hospital; that every month when I go, they really attend to me very well. (Client interview-3)

The benefits are lying on our laps right now! She really helped us, if your blood is low, she'll tell you. (Woman D, FGD-4)

One woman had this question to ask at the end of the FGD. She had found the use of the tests during her ANC beneficial and inquired for it to be extended beyond the ANC

clinic to the general outpatients' department, especially where there were no laboratories.

Please, why is it that it is only the pregnant women who have these tests being done for them and not at the hospital? If I come to the hospital, let's say with a headache, but this test is not there, how would I know that my blood is low? (Woman H, FGD-3)

7.3 ANC staff acceptability of the enhanced antenatal care package

7.3.1 Introduction

In this section, the responses given during in-depth interviews held with ANC clinic heads who participated in the randomised controlled trial are described. The aim of the interviews was to describe their ANC practices, explore their knowledge and perceptions of malaria and anaemia in pregnancy and also to describe their experiences of the use of the RDT and HCS as tools to facilitate the pregnant women's participation in their ANC.

7.3.2 Characteristics of respondents

Table 27 below shows the characteristics of the ANC staff interviewed. A total of 7 ANC clinic heads were interviewed. They had been providing antenatal care between 1 to 40 years of their lives. Six were trained midwives and the last a physician assistant with basic knowledge in midwifery. Although only 4 of them belonged to the intervention arm of the trial, all of them conducted point of care tests for the pregnant women including the urine dipstick for confirmation of pregnancy, urine proteins and sugar, the HIV and the syphilis tests. They practised in either health centres or maternity homes; none practised in hospitals. All except two in rural locations had laboratories in their health facilities.

Table 27: Characteristics of ANC clinic heads interviewed

	Interviewees						
	1	2	3	4	5	6	7
Characteristic							
Age (years)	52	51	56	57	29	25	65
Rank	Midwife officer	Senior Midwifery Officer	Senior Midwifery Officer	Senior Midwifery Officer	Physician Assistant	Staff Midwife	Senior Midwifery Officer
Number of years in ANC	9	9	13	32	1	3	40
Number of years in current ANC clinic	4	4	6	13	1	2	25
Type of health facility	Health Centre	Health Centre	Health Centre	Maternity Home	Health Centre	Health Centre	Maternity Home
Location of health facility	Rural	Semi-Urban	Semi-Urban	Semi-Urban	Rural	Rural	Semi-Urban
Laboratory present	No	Yes	Yes	Yes	No	Yes	Yes
Conduct point-of-care tests	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Implemented intervention	Yes	No	Yes	Yes	Yes	No	No
Do deliveries	Yes	Yes	Yes	Yes	Yes	Yes	Yes

7.3.3 Findings

In-depth interviews with the staff of the ANC clinics lasted between 15 minutes to 47 minutes. Audio recordings of the interviews were transcribed verbatim and with the help of NVIVO QSR 10 coded and summarised under the following headings: (1) ANC staff practices of antenatal care (2) ANC staff perceptions and knowledge about malaria and anaemia in pregnancy (3) the ANC staff experiences and perceptions of the use of the RDT and HCS for pregnant women's participation during ANC sessions and (4) ANC staff perceptions about conducting the HCS and RDT themselves for the pregnant women.

7.3.3.1 ANC staff practices during antenatal care

Importance of ANC

Discussions with the ANC staff revealed that they believed it was very important for every pregnant woman to attend the clinic regularly in order to maintain good health for herself and her baby. Although the staff admitted that pregnancy was not a disease, they

were committed to detecting any abnormal pregnancy states through thorough assessment of the pregnant woman from head to toe and to help normalise the conditions so that pregnancy could progress to a successful end.

There is the need for her to be assessed at the beginning of the pregnancy, especially her haemoglobin level, because of the baby she is carrying, which feeds on her. (Staff interview-4)

Timing of ANC visits

The ANC staff also stressed the importance of pregnant women visiting the clinic at least four times during their pregnancy in order for them to receive all the recommended interventions necessary for maintaining their health and that of their babies.

For a pregnant woman, if she is not ill, because pregnancy is not an illness, she should attend the ANC not less than 4 times because there are medicines that we will give to her so the pregnant woman should visit the ANC at least four times. (Staff interview-1)

Although the ANC staff recommended at least four visits for the pregnant women, they commonly scheduled the healthy pregnant women to return to the ANC clinic on a monthly basis during their first 7 months of pregnancy, then at two weekly intervals till she was 9 months and then weekly till she delivered.

Oh, when they come for the registration, I schedule them for one month and when they get to 30 weeks too, I do it two weeks, two weeks for them. (Staff interview-6)

Physical examination of pregnant women

In addition to measuring the blood pressure, temperature, weight and height of the pregnant women, the staff mentioned that they palpated the abdomen of the pregnant women as part of routine care any time they attended the ANC clinic. They were very much concerned with the position of the baby in the womb and taught the women different exercises and positions to lie in anytime they detected an abnormal position of

the baby. They also routinely measured the height of the uterus to estimate the growth of the foetus and listened to the heart beats of the baby for inconsistencies in the heart rate. During early pregnancy, they ordered for an ultrasound scan to confirm pregnancy and also to estimate the gestational age of the baby as most of the women were not sure of date of their last menstrual period. Ultrasound machines were only available in bigger clinics and so most of the women had to be referred outside their own ANC clinics to have this done. Only one staff reported that she had the machine and scanned the women herself during their visits. During the last trimester, the staff usually ordered for another ultrasound scan to confirm the lie of the baby in preparation towards delivery. It is interesting that one staff commented on the eagerness of the pregnant women to have the ultrasound scans done when they are referred out compared to going out to do laboratory tests.

If you refer them outside to do the scan, they are in a hurry to go and do it but not so with the labs, they do not find them necessary. (Staff interview-4)

None of the staff readily mentioned checking for conjunctival or palmar pallor as a routine physical examination procedure. It was only mentioned later on in the interview when discussing management of the pregnant woman with anaemia. When they suspected the pregnant woman to have anaemia, they would then check for pallor before referring for a laboratory test.

Laboratory tests conducted by ANC staff

All of the ANC staff interviewed admitted conducting the urine dipstick test to confirm pregnancy at the ANC clinic. They also conducted the urine dipstick test for sugar and proteins to check for signs of pregnancy induced hypertension, urinary tract infection or diabetes. Five of them also conducted the syphilis, Hepatitis B and the HIV tests at the clinic while the rest got them done at their laboratories. In addition to these, ANC staff at the intervention sites mentioned checking for malaria and anaemia at the ANC clinic.

The other staff however admitted sending the pregnant women to the laboratory to have their [Hb] and malaria parasitaemia status checked.

Now I do the malaria, ... we check Hb, that is how much blood you have; it should not go too low; and we check the protein in the urine and the sugar or glucose and PMTCT, that is HIV, prevention, to protect the mother and the baby. (Staff interview-1)

We do the RDT here, HIV both first and second response, we check the Hb, the urine for glucose and protein. They [pregnant women] go out to do blood grouping, sickling, G6PD and then stool and urine R/E. (Staff interview-5)

Treatments given during ANC

The staff said they wrote prescriptions for the pregnant women based on the results of the laboratory tests conducted. They also gave some medicines routinely. These routine medicines included iron and folic acid, multivitamins and SP for malaria prevention. They also gave the tetanus toxoid (TT) vaccination routinely.

For the routines we give the fersolate, folic acid and the multivitamins. That is the routine one and when they are due for SP too we give it and TT... we give it when they are due. (Staff interview-6)

Some of the staff noted that some of the pregnant women did not like to take their routine medicines as prescribed. They claimed that they preferred to keep some of the medicines till after delivery so that they would be able to eat well and look good.

When we go for home visits and ask about the medicines, they always say they are taking them but when you do the pill check, you realize that they have not been taking them. If you ask them, they will tell you that they are taking a few at a time so that they can have some to take after delivery. They are keeping them for the future. (Staff interview-5)

We give it to them but they just store them. They prefer to take them after delivery so, they appear beautiful. (Staff interview-6)

None of the ANC staff readily mentioned a de-wormer as given routinely. Only one of them said that she gave a de-wormer only when the pregnant women presented some complaints suggestive of worm infestation.

Sometimes too a de-wormer; when she comes she complains of rib pains, not being able to eat well. As soon as you give the de-wormer she becomes well. (Staff interview-1)

Health advice

In addition to the above activities, the ANC staff also reported giving educational talks and advice as part of routine services at the ANC clinic. Advice usually centred on the pregnant women's dietary requirements, the use of the bed net to prevent malaria and adherence to medicines they are given at the ANC clinic. They also taught them about danger signs to look out for during pregnancy and to report back immediately in case they noticed any. They also educated the women on how to prepare for delivery.

We advise them on their nutrition, what to eat and ask them to use the mosquito net. The malaria parasite alone can reduce your Hb level. In case you have malaria, we also advice that you complete the course of medicines issued to you, so your body does not develop resistance to the drug. (Staff interview-4)

7.3.3.2 ANC staff perceptions and knowledge about malaria and anaemia in pregnancy

(i) ANC staff perceptions and knowledge about malaria

Signs and symptoms of malaria

During the interviews about how pregnant women presented when they had malaria, the ANC staff mentioned quite rapidly a barrage of signs and symptoms including high body temperatures, chills, dizziness, lower abdominal pains, headaches, vomiting,

diarrhoea, anorexia, bitter taste in the mouth, insomnia and joint pains. They reported that the lower abdominal pains could be so severe the women could report to the clinic as if in labour.

They present with abdominal pains, LAP [lower abdominal pains] and in the advance stages, they present themselves as if they are in labour, but they may not be in labour. (Staff interview-4)

Complications of malaria in pregnancy

They all identified anaemia as a complication of malaria during pregnancy and mentioned the breakdown of red blood cells from the malaria infection resulting in the anaemia. Premature deliveries, still births and ante-partum haemorrhage were also mentioned as effects of malaria during pregnancy. They said the severe abdominal pain if left untreated could result in miscarriages or pre-term delivery or the baby dying in the womb before delivery.

...malaria, it can destroy the red blood cells and can end up in premature delivery and still birth and AP H [Ante-partum Haemorrhage] (Staff interview-3)

Where it [LAP] is not treated at the early stages it can lead to abortion... premature labour and have a preterm baby and some even get IUD [Intra Uterine Death] (Staff interview-4)

One staff linked malaria in the pregnant woman with stress on the baby in the womb leading to 'old' meconium stained liquor.

For those who get malaria, the babies get into crises, and they get meconium stained liquor. When they come to deliver and you rapture the membranes, you observe that the babies have old meconium stained liquor which was not brought on by the labour. (Staff interview-4)

Neonatal malaria was also described by one staff member. None of them talked about death of the mother as a direct effect of malaria in pregnancy.

With a lot of the infants, some of them are delivered fine. But they come back with high fever. Poor infant! High fever...that is coming from the mother. (Staff interview-2)

Treatment of malaria in pregnancy

With regards to treatment of malaria during pregnancy, all the staff reported the use of quinine tablets or injections for women in their first trimester of pregnancy and then ACT for those in the second and third trimesters. This was according to the national guidelines, they said. The hypoglycaemic side effect of quinine was well noted by the staff and so they asked the women to either eat very well before taking the tablets or prescribed anhydrous glucose for taking the tablets to counter the effect.

I give quinine in the first trimester, and you encourage the woman to eat well, because most of them do not eat well. To avoid any eventualities, I add glucose to the quinine. Above 16 weeks, depending on the drug available, AL [artemether-lumefantrine] or AA [artesunate-amodiaquine], then I issue it to them. (Staff interview-5)

The ANC staff said that mostly, they practiced diagnosis before treatment. However when sometimes, laboratory investigations were negative for malaria in spite of the women's suggestive complaints, they went ahead to treat for malaria. They believed that in that circumstance, the malaria parasites had not yet been released into the blood stream. They were however cautious about this and asked the women to report back in a few days' time to confirm that they had improved or otherwise.

...but sometimes they go and do the labs and it will be confirmed negative but I still go ahead and give the treatments so, I tell them to come back in three or four days, so if they come back and the symptoms are ok, then I know it was malaria. (Staff interview-6)

One staff member hinted on some of the pregnant women using herbal medicines for self medication before attending the ANC clinic if they did not improve.

Sometimes by the time they come in, the women themselves have gone to drink some kinds of herbal concoctions that make the situation worse by the time they come in. (Staff interview-7)

Prevention of malaria in pregnancy

The staff's knowledge of how to prevent malaria reflected in the advice they normally gave the pregnant women during their interactions with them, either on a group basis or on individual basis. They were particular about the pregnant women using of the ITN, keeping the environment and themselves clean and not leaving stagnant water around their dwelling places. They all mentioned the giving of SP to the pregnant women as a means of preventing malaria in the pregnant women. One staff interestingly reported that burning of rubbish in the environment helped to drive mosquitoes away.

They sometimes do not know that they need to keep neat and also have to treat the mosquito net. They should avoid keeping stagnant water in their compound, they should drain it away, burn any rubbish in their environment; when you burn it, this help to drive the mosquitoes away. (Staff interview-7)

(ii) ANC staff perceptions and knowledge about anaemia in pregnancy

Signs and symptoms of anaemia

When the ANC staff members were asked about anaemia in pregnancy, they all reported that they see quite a number of the pregnant women with anaemia in their clinics. The women did not often report symptoms and signs but the few who did reported with dizziness, weakness, pallor, palpitations and in extreme cases, pitting oedema of the legs and feet. Most of the time, the staff were the ones that identified pregnant women with anaemia during routine screening and clinical assessment.

There was a client with anaemia who developed serious oedema, pitting oedema and there are others you can see that have developed palmar pallor, and when you check their conjunctiva too... some of them too come with fainting symptoms like dizziness and the rest… (Staff interview-6)

Causes and prevention of anaemia in pregnancy

All of the staff attributed anaemia in pregnancy mainly to the poor dietary habits of the pregnant women. Although they mentioned malaria as a cause too, the emphasis was placed on diet. They reported that the pregnant women did not like to take fruits and vegetables but these foods helped to build the blood levels of the pregnant women in addition to eating other local foods. None of them mentioned haemo-dilution during the second trimester as a possible cause of anaemia during pregnancy; neither did they mention intestinal worms.

During their educational talk periods with the pregnant women, the ANC staff reported that they usually educated the women about healthy eating habits to maintain good blood levels and to prevent anaemia. Talks about prevention of malaria were also included because they also attribute anaemia to malaria infection. None of the staff mentioned explicitly the taking of the routine iron and folic acid supplements as a means of preventing anaemia but this was rather mentioned as a means of managing anaemia when it had occurred.

We ask them to vary their food intake:... some ground nut soup,' kontomire' stew, fish, beans; nature has given us a lot of fruits and they should eat these. (Staff interview-7)

Effects of anaemia in pregnancy

The ANC staff indicated that they knew about the effects of anaemia in pregnancy. During the discussions about the effects of anaemia on the pregnant women, all the staff

said that anaemia could result in the pregnant women giving birth prematurely or to small and underweight babies even at term. Anaemia during pregnancy, they said, could also lead to excessive bleeding during delivery which could take the mother's life.

When they become anaemic, they have preterm babies, small babies, underweight babies and sometimes miscarriage. Let's say when she is coming to deliver, PPH [post partum haemorrhage] ... and the mother can lose her life. (Staff interview-5)

Treatment of anaemia in pregnancy

When it came to how they managed the pregnant women with anaemia, they mentioned that the management plan depended on the severity of anaemia the women presented with. Immediate laboratory diagnosis of anaemia was difficult as most of the ANC's did not have laboratory services all the time except on their ANC clinic days. They would normally consider the symptoms that the woman complains of, do a clinical assessment of their conjunctiva and palms and then decide what to do. They usually prescribed local foods that they believed improved the haemoglobin level for women they assessed to have mild to moderate anaemia in addition to the routine haematenics. Their emphasis was more on nutritional advice than on routine haematinics. Haematenics that were accessible through the NHIS included fersolate tablets and folic acid tablets. One staff member felt that these tablets were not always effective in improving blood levels and so prescribed other types which the women needed to buy but could not always afford.

In case the Hb is a bit high, I let them go into the eating method, eating things like 'kontomire' and 'kwaunsusua' and the likes for a month or two. If it is still low, then I ask them to stop the folic acid and the fersolate medications and I put them on these capsules, Eleron….yes, the all in one. (Staff interview-6)

If she is anaemic, you prescribe the local foods for them; for the medicines, the routine drugs, most of the times they complain of not having money to buy them. So if you talk of 'kwaunsusua', 'abedru', they will eat it. (Staff interview-5)

For the women they suspected to be severely anaemic, the staff said they promptly referred them to bigger hospitals where they could be transfused with blood if needed and where they could be better monitored.

7.3.3.3 ANC staff experiences of the use of the RDT and HCS during ANC sessions.

(i) ANC staff experiences of the use of HCS during ANC sessions

The ANC staff experiences of the use of the HCS are described under the following headings: properties and ease of use of the HCS test kit, trust in the HCS results and the perceived influence of the HCS test results on the pregnant women.

a. Properties and ease of use of HCS test kit

Amongst the 7 staff interviewed, three of them had used the Tallquist haemoglobin scale before and compared the HCS to it. They preferred the HCS to the Tallquist scale because this new scale had the readings in g/dl, similar to the ones read by the laboratory machines instead of the percentages that the Tallquist scale measured. In their view, the HCS helped to better estimate the haemoglobin concentration of the pregnant women according to a language they understood better. The staff who used the HCS during ANC sessions thought the HCS was very simple to use and gave them results in no time. They also believed it was very easy for the pregnant women to appreciate the results of the test.

It is very clear and very simple to see; you just show them the two colours and compare. Ask her to tell you and she will point it out to you… (Staff interview-2)

The ANC staff however thought that the intervals of 2g/dl on the scale was too wide and did not really help them to make a very fair estimation of the haemoglobin

concentrations of the women. They would have been more comfortable with intervals of 1g/dl apart so that they could make estimates of 0.5g/dl in between readings.

b. Trust in the results of the HCS

There was a mixed reaction to the use of the HCS to diagnose anaemia in the pregnant women by the ANC staff. To the two ANC staff who had no access to laboratory services, they believed that the HCS was very helpful to them in their routine screening activities. They did not have to wait for days to weeks for laboratory results from the pregnant women before they could manage them. They were now able to regularly check the haemoglobin levels of the pregnant women during ANC instead of the recommended checks at registration and at term pregnancy. Thus they could monitor the pregnant women better and take the necessary actions when needed. They felt that the results the HCS gave them were reliable enough with minimal differences between that and what the laboratories gave.

Ooh! It is alright. Even when I find out that it is very low and I refer them to the lab, it is the same results, the difference is very minimal. (Staff interview-5)

For another ANC staff member too, the HCS helped her to confirm her suspicions of anaemia more than the laboratory tests. She believed that the laboratory results could sometimes be unreliable. She was thus happy she had the HCS to help her in assessing the Hb of the pregnant women. When she did the test herself using the HCS, she felt confident of the results she got and was able to manage the pregnant women accordingly.

Sometimes too, the colour scale results is very low but the lab results will be higher although the woman feels very weak so you can tell that it is because of the anaemia. (Staff interview-1)

For another staff however, the HCS could be used as a first step in their management of the pregnant women. It would just to give them a clue so as to take some action while

waiting for laboratory results. They could not rely solely on the HCS results because they felt it was not accurate enough compared to the laboratory machine.

It may not be 100% but it is the basic, it is a clue, if you are a medical person, at least to know what to do. (Staff interview-2)

For this, we do not have 11 but we use 11 [g/dl] as the borderline...so we can't base it on only this one because we do not have the 11. Sometimes it is more than 10 but not up to 11 so we need to confirm it. (Staff interview-4)

c. Perceived influence of HCS test results on the pregnant women

The ANC staff believed universally that it was a very good approach for the pregnant women to see their haemoglobin results for themselves using the HCS. The ANC staff commented that it made the women see how high or low their blood was instead of them using figures that did not usually register anything in them. It was very difficult for the women to appreciate what the figures meant. One staff member said sometimes she tried to use colours around in the consulting room to demonstrate how their blood looked like but was not successful in describing the situation to the women. The colour scale she said really brought the message home to them making them believe the results as theirs. Thus the women took the advice given them more seriously so that the next time they visited the ANC clinic, they would have improved upon their blood levels.

So when they see it, they exclaim: 'Ei, my blood is very low and I would love it if it is as high as the one in the book!' When they see the colour themselves, it helps them to be able to interpret their Hb levels themselves. (Staff interview-5)

It will make her cautious because she has seen her own test results. She will take your advice really serious this time rather than snubbing the advice we give. (Staff interview-4)

One of the staff also said that some of the women went to the extent of talking about the tests and their results to others with the aim of encouraging their fellow pregnant women to also attend the ANC clinic so they could also see their blood.

They do talk about its usefulness and they even tell others about the results. They tell them that they saw for themselves that their blood was low because the colour showed it when the madam showed the test to them. (Staff interview-5)

(ii) ANC staff experiences of the use of RDT during ANC sessions

The ANC staff experiences of the use of the RDT are described under the following headings: Accessibility and availability of the RDT, ease of use of the RDT, trust in the RDT results, ability of RDT to quantify parasitaemia, implications of use of RDT on IPT, perceived influence of performing RDT and interpreting results on pregnant women and perceived influence of RDT results on intentions and actions of pregnant women.

a. Accessibility and availability

All the ANC staff interviewed had seen and used the RDT before during antenatal procedures although not all of them belonged to the intervention arm of the study. Its use was however not a routine procedure in the non-intervention sites. The staff members in the intervention group were glad to have such a test by their side to use anytime the women came for ANC and wished this was normal practise while those in the non-intervention sites wished for the routine use of the RDT at each ANC visit. This, they said, would be very helpful in diagnosing malaria especially in asymptomatic women. According to them, the national guidelines on the use of the RDT for ANC indicated that it was to be used only on first time ANC attendees and when women presented with symptoms and signs suggestive of malaria to help diagnose malaria before initiation of treatment.

It will be very useful if it becomes part of the routine labs... I wish we could even do it at every visit, not only for the first visit or when the person complains of malaria symptoms. (Staff interview-5)

ANC staff in the non-intervention sites mentioned that they received their supplies of the RDT mainly through the Ghana Health Service central medical stores. However, unlike those in the intervention sites who enjoyed regular supply of the RDT, it was not always available at their sites and they sometimes had to resort to the open market to acquire them for use. Staff at the intervention sites wished the ANCs would continue to enjoy continuous supply of RDT even after the study was completed so they could continue identifying pregnant women with malaria parasitaemia for treatment.

When you go to the municipal you wouldn't get and so I go to the open market to buy (Staff interview-2)

b. Ease of use of RDT

The ANC staff did not find the RDT difficult to conduct. They thought that it was simple to conduct. They commended the fact that everything came packaged as one for each client such that they did not need to assemble the items necessary for a test to be done. They were able to easily integrate its use in their normal procedures at the clinic without it interrupting their work. The staff would normally conduct the test during the consultation process, especially when the woman's abdomen was being examined. If the woman was visiting for the first time, the ANC staff conducted the RDT in conjunction with other tests such as the HIV and Syphilis tests. Only one finger prick was thus used to draw blood needed for all the tests. They however commented on the need for the right lighting conditions for the test results to be read correctly.

This is very simple because everything comes in a pack...you prick her finger tip and then drop the blood and then you put it aside... By the time you are done with examining her, the test would have been ready for reading... (Staff interview-1)

When asked whether the pregnant women understood the results of the RDT, the ANC staff said that they believed that the RDT results were very easy for the pregnant women to understand. They mentioned that they explained the expected results to the women and they only had to see either one or two lines in the test kit to know whether they had malaria or not and to the staff, this was not a difficult task for the pregnant women to undertake at all.

They do understand. Before the test, we explain to them that if one line appears then you are negative but if the lines are two, it means you are positive. So, after the test you show the results to her and allow her to do the interpretation. Then she would say that 'Ei, Madam! This shows that I have been bitten by mosquitoes'. (Staff interview-5)

c. Trust in the RDT results

The ANC staff tended to trust the results of the RDT especially when it gave a positive indication of parasitaemia. It helped them to confirm malaria in those women in whom they suspected had the diseases because of their presenting complaints. They were especially happy with its ability to detect parasitaemia in women who did not show any symptoms and signs of malaria because they knew that pregnant women in areas of malaria endemicity would hardly show signs and symptoms. This would have gone unnoticed but for the use of the RDT during ANC sessions.

With the malaria test, if the outcome is positive, we immediately administer some drugs. We tell them that in some cases they have the parasites but they don't feel sick and that in pregnancy it can be very dangerous so we give them treatment and also advice them to use the mosquito net. (Staff interview-4)

They however had some concerns about the RDT not being able to detect parasitaemia in some of the pregnant women who presented with malaria-like symptoms. They however trusted in the RDT and continued to use them because of their ability to diagnose malaria in the majority of pregnant women. They admitted that it was only in

very few of the women that the RDT results were negative when malaria was suspected. They identified the limitation of laboratory tests and said that sometimes, this could even happen with malaria microscopy and so it was nothing to worry about. They also said that it could be that the parasites had not yet reached the blood for them to be detected or that the levels in the blood were too low to be detected by the test. One staff member also believed that if the woman had started taking some anti malaria medicine before presenting, then the results would be negative. Thus RDT negative results were not necessarily to be interpreted as the pregnant woman not having malaria when she had symptoms suggestive of malaria. Generally, they would go ahead to treat these women whom they suspected as having malaria, with caution though, insisting that they reported back immediately if they were not improving.

When RDT results are positive, we treat you for malaria, but when it is even negative but you complain of lower abdominal pain, headache, fever, etc, then I assume it is malaria then we will give you the treatment. (Staff interview-5)

One staff member was however emphatic in stating that she did not trust the results of the RDT so much, especially when the pregnant woman presented with malaria-like symptoms and the result was negative. She would ask the women to do a microscopy test which would come back positive most of the time. She believed that the RDT could detect only high parasitaemia levels and not scanty levels in the blood.

There are times when clients complain of malaria symptoms, when you use the rapid test kits, the results comes out negative but then when the microscopy is done it shows that there are mp's [malaria parasites]. This happened a lot of times, so I don't trust it so much. (Staff interview-6)

In spite of this observation she had made, she still thought the use of the RDT at the ANC clinic was a good idea provided they were of good quality and highly sensitive at detecting parasitaemia in the pregnant women.

d. Ability of RDT to quantify parasitaemia

Although the RDT was found to be a very useful diagnostic kit for malaria, a few of the staff members complained about it not being able to tell the parasite density when it was positive for malaria parasites. For them, the level of parasitaemia in the blood was an indication of the severity of the disease which would in turn determine their approach to managing the women. They had become used to the laboratory giving them an indication of the quantity of parasites in the blood of the women. Having a high parasite density of 3+ or more meant severe malaria to them and they would normally treat with quinine instead of the ACT.

RDT is very helpful, it gives you hints unlike the microscopy that helps you to know whether she has two pluses or one plus parasitaemia, the RDT just tells you either it is negative or positive. (Staff interview-5)

e. Implications of use of RDT for IPTp

For the ANC staff, the use of the RDT during ANC, especially at every visit, had implications for the coverage of SP for IPTp. Those pregnant women who tested positive with the RDT but did not have any symptoms or signs got treated for malaria instead of receiving the preventive medicine. Thus pregnant women who tested positive with the RDT during their ANC would not receive the recommended three doses of SP. The staff preferred to treat those who had positive parasitaemia instead of giving them the SP because of the adverse effects that they knew malaria had on the pregnancy. These women would otherwise have been missed if the RDT were not available. They gave SP for IPTp only when the women tested negative to the RDT and had no signs or symptoms suggestive of malaria.

So if we do it and it is negative and you do not have any complains then we will give you the monthly medicine that protects against malaria to take...if you look into our

books, someone had one episode of malaria and so took SP only twice... (Staff interview-1*)*

f. Perceived influence of performing RDT and interpreting results on pregnant women

When the ANC staff was asked what effect the pregnant women seeing the RDT results had on them, they reported that the women were happy about seeing their own blood being used for the test. The staff reported that some of the women were thrilled with the results appearing as was explained by the staff and re-echoed the results while being taken care of. The women also tended to believe the results because they saw their own blood being used for the test.

She is happy. Because she sees that it is her own blood that I put in the test kit and I do everything with her so she knows I did not use any other person's blood for the test. (Staff interview-1)

Pregnant women who had signs and symptoms of malaria but were RDT negative after the test was conducted sometimes asked why this was so, especially after they felt better with anti-malarial medicine. The ANC staff members said they tried to offer explanations to the pregnant women to their satisfaction and so were not worried that the RDT results sometimes appeared negative.

...she asked why we did not see it in her blood. So I told her that it had not reached the level for it to be detected in the blood that is why we did not see it so she understood it. (Staff interview-1)

g. Perceived influence of RDT results on intentions and actions of pregnant women

The ANC staff said that the pregnant women who were positive for malaria tried to find out when they could have been bitten by mosquitoes and discussed this with the staff. They then resolved to take better care of themselves so that the next time their blood was tested, it would be free from the parasites. Because of this, the staff believed that

the pregnant women took all the advice they were given very seriously, especially, taking anti-malarial medicines as prescribed and sleeping under mosquito net. One staff member said that some women wished they could carry the test kit home to show to their spouses that indeed they had malaria but she advised that they bring their spouses to the next ANC visit to witness the results of the test. She commented that this could increase the number of spouses who take interest in the ANC of their wives.

So far as they see the results, if you ask them to take the medicine, they will take it. For some of them, if they do not see any results, they will not believe it if you just tell them, especially if they do not feel sick. Why should she take the medicine? (Staff interview-4)

Some can even ask me to give to them to take home to show to their husbands but I say no because of the blood in it... (Staff interview-1)

7.3.3.4 ANC staff perceptions about conducting the HCS and RDT themselves for the pregnant women

The ANC staff perceptions of conducting the RDT and HCS themselves were summarised under five themes namely emotional satisfaction, prompt diagnosis and treatment, integration with work flow at the clinic, professionalism and confidence and staff-client interactions.

(i) Emotional satisfaction

When asked about how they felt about doing the HCS and RDT themselves for the pregnant women, all of the ANC staff expressed happiness at conducting the tests themselves. They said because it made the pregnant women happy, they were excited about that. They commented that when they did the tests themselves, it assured them of accurate results to help them manage the pregnant women better. They sometimes had doubts about the laboratory results they received and so were happy they could confirm malaria and anaemia in the pregnant women themselves.

It makes me happy, it gives me encouragement. When I do it, it makes me see the test results well because for some when we ask them to go and do the tests outside you see different results from the one you are expecting. (Staff interview-1)

At least, I see what goes on and I can say the results I get are accurate... if I do it myself then I can be sure of the values I'm getting. (Staff interview-5)

One staff member however reported that although doing the tests brought her satisfaction, she believed that laboratory technicians had been trained to carry out laboratory tests and so should be allowed to do their job. Taking up that responsibility would mean doing too much work and she could not accept that at all.

There are certain responsibilities, you can't assume on your own. Too much of everything is bad and we did not go to school to learn about these lab things. That is meant purposely for the lab technicians. So, he should do his work. (Staff interview-7)

(ii) Prompt diagnosis and treatment

Also, doing the tests themselves offered them the opportunity to identify women who had malaria or anaemia promptly when they visited the ANC clinic. When the women had to go out to do these laboratory tests, sometimes, they reported back after a long while with the laboratory results which may not have been indicative of their reporting health status. The staff claimed that the women complained of not having transportation fares or having to visit the laboratories on a number of occasions before receiving the test results. Some of the women, they also claimed, just did not feel like travelling and so did not have the tests done. They agreed that all these delays had been cut down since they started conducting the tests by themselves and have been able to manage the pregnant women promptly, especially for malaria, as they visited the ANC clinic.

It was very helpful and useful, because sometimes the results were not returned immediately. We need to do the Hb and MP's at registration but they would not come back with the results early enough. (Staff interview-5)

(iii) Integration with work flow at ANC clinic

Although the staff acknowledged some increase in workload and time consumption by doing these two tests, all they wanted was the well being of the pregnant women and their babies and so did not mind much about that. They had found a way around this. During consultation, the staff conducted the tests with the women before going on with the physical examinations. Doing this afforded the tests, especially the RDT, enough time to run for the results to be read accurately. They also started running the ANC clinic early enough to cater for the extra time so that all the pregnant women that reported could be seen within reasonable time. Some of the staff even thought that they doing the tests for them reduced the women's waiting time at the clinic by they not joining long queues at the laboratory.

It will increase, but who cares, all we want is the life of our patients. (Staff interview-2)

It is not about work load but rather that I will do everything on my own. It will reduce the patient waiting time because they go to queue to carry out their labs, and this keeps them waiting. (Staff interview-6)

Initially, when I started, it was a bit time consuming but now I have adopted a strategy of drawing the blood and dropping on all the tests that I need to do for each woman and then I do the Hb so it does not keep long at all. (Staff interview-3)

(iv) Professionalism and self-confidence

Some staff members, especially those at the ANC clinics that had no laboratories said they had become more confident in themselves and professional in referring the women to higher health facilities because they now had some diagnostic evidence to back their referrals. Initially, they referred the pregnant women based on clinical judgements alone and this they claimed was not received well by the staff at the higher institutions. The ANC staff also reported that pregnant women also tended to agree to the referrals

because they had seen the test results and as such believed what the staff was telling them. Doing the tests themselves also boosted their level of confidence in managing the pregnant women because they had conducted the tests themselves and seen the results for each pregnant woman. The fear of wrong test results being reported back to them had been removed and so they felt confident about their management plans.

So if you do the tests for the woman, you have the faith and confidence that what you have done is the correct results and so if she has to go and see the doctor, after explaining to her, she understands and then she goes promptly. (Staff interview-1)

(v) Staff-client interaction

Some of the staff also reported that doing the tests themselves with the pregnant women improved their interaction with the women. They were able to talk with the women some more and discussed the test results and their implications, giving ANC recommendations concurrently. They believed that they doing the tests for the pregnant women increased the trust of the women in the staff and made the women adhere to their recommendations. Conducting the tests one-on-one with the women, they also said, promoted confidentiality because the results of the tests remained between them and the pregnant women alone. These, they believed, made the pregnant women very happy and caused them to attend the ANC clinic as scheduled. They claimed that the pregnant women complained about the laboratory staff not telling them anything about their tests results and just handing them the results on a piece of paper and thus preferred having the tests conducted by the ANC staff.

It is very good, it gets the clients closer to you and its better for this confidentiality thing ...the result is between just the two of you [and] they prefer it that way rather. (Staff interview-6)

One ANC staff member interestingly identified a gender issue that could be a barrier to the pregnant women having their laboratory tests done at laboratories. She claimed that

the women were not comfortable with males carrying out tests for them at the laboratories and so preferred her to do the laboratory tests for them.

They've always had problems with the fact that it is men that carry out the tests on them but here because I'm also a woman they are able to express themselves and I also explain everything to them. (Staff interview-5)

CHAPTER 8 DISCUSSION AND CONCLUSIONS

8.1 Introduction

A cluster randomised controlled trial was conducted to determine the effect of an enhanced antenatal care package on malaria and anaemia control during pregnancy. It was conducted with antenatal clinics as the unit of randomisation to implement an intervention where antenatal care staff members were trained with a specifically designed desk guide to use the RDT and HCS (and a pictorial guide) as tools to facilitate the participation of pregnant women in their care. This was done during routine antenatal care sessions in addition to current care (the enhanced antenatal care package). The results of this study including results from the pre-intervention and post-intervention phases are summarised below under the following headings:

1. Malaria parasitaemia and anaemia among pregnant women in study area.
2. The feasibility of the enhanced antenatal care package.
3. The acceptability of the enhanced antenatal care package among pregnant women and antenatal care staff members.
4. The effect of the enhanced antenatal care package on malaria and anaemia during pregnancy.

This chapter is concluded by considering the implications of these results for policy and practice and research.

8.2 Asymptomatic malaria parasitaemia and anaemia among pregnant women in study area

The cross sectional study preceding the intervention trial showed that 15.5% of the pregnant women had asymptomatic malaria parasitaemia, significantly associated with parity, age and anaemia. The younger, nulliparous or primiparous women had

significantly increased risk of parasitaemia and anaemia compared to the multiparous women. Asymptomatic parasitaemia was also significantly associated with the level of adherence to health advice. However, ITN use, the number of SP doses received during pregnancy, knowledge about malaria and educational level had no significant associations with the risk of parasitaemia in the women. The prevalence of anaemia (Hb less than 11g/dl) was 42.6% among the pregnant women and asymptomatic malaria parasitaemia was the only variable significantly associated with anaemia in this study population.

Previously, asymptomatic malaria parasitaemia and anaemia of similar prevalence to those of the current study have been reported among pregnant women in Ghana. The prevalence of malaria parasitaemia reported was 12% and 15% while the prevalence of anaemia was 48% and 39% for studies conducted by Tagbor et al and Tutu et al respectively (Tagbor, Bruce et al. 2010, Tutu, Browne et al. 2011). The younger, nulliparous and primiparous mothers have had a greater risk of asymptomatic malaria parasitaemia compared to the older multiparous women and this has tended to decrease their Hb levels significantly (Tagbor 2005, Ofori, Ansah et al. 2009, Yatich, Yi et al. 2009). These associations were also found in this present study. This is not unusual because, generally, in areas of high or stable malaria transmission, where malaria in pregnancy is usually asymptomatic, women in the first or second malaria-exposed pregnancies tend to be most affected (W.H.O. 2004) because they may not have developed immunity to malaria infections during pregnancy yet. As the number of pregnancies increase, the woman's level of immunity against malaria also increases and hence she has a lower risk of malaria parasitaemia.

8.3 Feasibility of the enhanced antenatal care package

Feasibility in this study was assessed in terms of the integration of the use of the RDT and HCS into routine ANC sessions without disrupting work flow. The use of the RDT and the HCS as tools to facilitate pregnant women's participation in their ANC was found to be feasible. In all implementing ANC clinics, the ANC staff members were able to integrate the use of the RDT and HCS into routine ANC activities without disrupting the flow of work at the clinic. The staff adopted the strategy of adding these tests to already existing tests for HIV and syphilis such that they used one fingertip prick to draw the amount of blood needed for all these tests. Secondly, the tests were done with the pregnant women before their physical examination and/ or palpation of the abdomen during consultation. The tests (with the exception of the HCS which was read immediately and recorded) were left to run while the staff physically examined and/ or palpated the abdomen, inquired about any symptoms from the pregnant women and then recorded their findings into the MHRB or their ANC registers. Thus the anticipated increase in time spent during consultation was minimal while having the advantage of additional test results for Hb and malaria parasitaemia for prompt and appropriate management of the pregnant women.

According to national policy, all pregnant women visiting the ANC clinic for the first time should have their Hb and malaria parasitaemia status checked. The Hb should also be checked for all pregnant women at 36 weeks gestation. The national policy also requires that as much as possible any pregnant woman that reports to the ANC clinic with symptoms of malaria should have a laboratory test done either by microscopy or by RDT to confirm malaria before treating (M.O.H.a. 2010, M.O.H.b. 2010). Thus introducing these two POC tests into the ANC clinics was compatible with existing expectations of antenatal care services for the pregnant women with regards to malaria

and Hb laboratory investigations. RDT use during routine ANC sessions have been reported previously and found not to interrupt work flow at the ANC clinic (Tagbor 2005, Tagbor, Bruce et al. 2010) although in these previous studies, the RDT was conducted by research staff and not ANC staff. Antenatal care staff in those studies however felt they would be motivated and confident enough to use the RDT during ANC sessions for the good of the pregnant women provided they were appropriately trained, (Smith Paintain, Antwi et al. 2011). This perception was demonstrated by the staff in this current study when they managed to integrate the use of the RDT and HCS into their current practices at the clinics after they had been appropriately trained to do so.

8.4 Acceptability of the enhanced antenatal care package

In this context, acceptability was described as the attitudes, perceptions and beliefs that influenced the use of the RDT and HCS as tools to facilitate pregnant women's participation in their ANC during ANC sessions among staff members and pregnant women.

8.4.1 Acceptability of the enhanced antenatal care package among ANC staff

The use of the HCS as tools to facilitate pregnant women's participation in their ANC was found to be generally acceptable to the ANC staff due to characteristics of the tests themselves and also the perceived positive influence that doing the tests with the pregnant women had on the behaviour of the pregnant women.

The simplicity and ease of conducting and interpreting the tests and their results, their ability to give rapid results, their ability to confirm malaria and anaemia in suspected pregnant women and the perceived positive influence that these results had on pregnant women influenced their acceptability among the antenatal staff members. Having the

HCS and the RDT in the clinic enabled the staff to also monitor the Hb and malaria parasitaemia status of the pregnant women at each ANC visit instead of having to ask for laboratory tests only when these conditions were suspected. In this way, the ANC staff said that any change in the women was identified earlier and managed before any complications set in. The use of these tests during antenatal clinic sessions was also acceptable because the staff members perceived some emotional satisfaction, boost in their level of confidence, increase in their level of professionalism about their work and improvement in their interaction with the pregnant women. These they claimed had increased the trust of the pregnant women in them and in the antenatal care system.

However, the staff would have preferred to have the readings of the HCS divided into intervals of 1g/dl instead of 2g/dl so that in their view, they could estimate the Hb of the pregnant women more precisely, to 0.5g/dl instead of 1g/dl. Also they would have preferred the RDT to give a measure of the quantity of malaria parasites in positive women so as to aid in their management plan of the women. The ANC staff also showed some worry over the occurrence of RDT negative results in pregnant women they suspected of having malaria. However, this did not deter them from using the RDT during antenatal care sessions as they admitted that this occurred only occasionally. Perhaps, their clinical judgement was being challenged here and this attracted their disapproval. In the few pregnant women in whom this occurred, the staff usually prescribed anti malarials based on their knowledge and understanding of how malaria affects the pregnant woman. There was also some perceived increase in workload and time spent during antenatal sessions. Although these could have posed as potential barriers, the staff warmly accepted to use the tests to facilitate pregnant women's participation during antenatal care sessions because they also identified the potential of these tests to influence positively the behaviour of the pregnant women. They were

concerned about the welfare of the pregnant women and their babies more and thus welcomed any health intervention that would work towards achieving this goal. They perceived the pregnant women taking their recommendations and advice about malaria and anaemia more seriously because the women now saw the test results for themselves and were thus motivated to take action to improve their health status. Conducting the RDT and the HCS with the pregnant women's participation may have served as a decision aid to the pregnant women influencing their level of adherence to antenatal care recommendations with regards to malaria and anaemia.

Malaria RDT use among formal health workers and community health workers has been described elsewhere as acceptable although not in the context of patient participation in their care (Chandler, Whitty et al. 2010, Wijesinghe, Atkinson et al. 2011, Asiimwe, Kyabayinze et al. 2012, Baiden, Owusu-Agyei et al. 2012, Oryema-Lalobo 2013, Tine, Ndiaye et al. 2013) . Health workers in Ghana reported improved patients' perceptions about the health centres and the increased willingness of patients to report to health facilities (Chandler, Whitty et al. 2010), perceived improved quality of care because it offered improved communication between the health care worker and caregivers of children under five years which led to improved treatment outcomes (Baiden, Owusu-Agyei et al. 2012) and improved the diagnostic capabilities of the health workers attracting more community members to access their services (Tine, Ndiaye et al. 2013). The use of the RDT and HCS for pregnant women's participation in their care thus has the potential of improving perceptions of quality in ANC, pregnancy outcomes by positive behaviour change, diagnostic capabilities of ANC staff members and attendance at ANC clinics. These were observed in this current study.

Having RDT negative results in spite of malaria-like symptoms imposes a threat to the health worker's clinical judgement (Asiimwe, Kyabayinze et al. 2012). Health workers choose to rely on their clinical judgement to prescribe anti malarial medicines presumptively in such situations (Chandler, Whitty et al. 2010). The lack of clear guidelines on what to do in such circumstances, lack of training on alternative causes of symptoms, perceived mistrust of the patients in the health worker if no anti malarial is prescribed and perceived patient pressure for anti malarials may contribute to health workers behaviour of prescribing anti malarials in spite of negative RDT results (Chandler, Mwangi et al. 2008, Chandler, Whitty et al. 2010, Asiimwe, Kyabayinze et al. 2012). These, however, were not the reasons given in this present study for prescribing anti malarials presumptively. The ANC staff appeared knowledgeable about the life cycle of malaria parasite in the human being, its effect in pregnancy and some limitations of the RDT and these appeared to have guided their practice instead.

Although the potential that the HCS has in screening for anaemia among pregnant women especially in rural clinics with no laboratories has been documented (van den Broek, Ntonya et al. 1999, Critchley and Bates 2005) there are no known studies about its acceptability among ANC staff or pregnant women. This study thus has given an insight into probable issues that are likely to influence its acceptability during antenatal care sessions. In this study, only 7 ANC staff members were interviewed. Saturation may not have been reached and these views may not have reflected that of the wider population of ANC staff members who were part of the study. However 2 prior focus group discussions held among 15 ANC staff to discuss the implementation of the use of the HCS (and RDT) during ANC sessions reported similar findings to these interviews. Thus these results may be close to the general view of ANC staff who took part in the randomised controlled study.

8.4.3 Pregnant women's acceptability of the enhanced antenatal care package

Generally, the pregnant women also found the use of the HCS and RDT during their ANC sessions acceptable. They were happy with the opportunity that they had to see the tests being conducted and the results being interpreted correctly with the ANC staff. Other acceptable attributes included the positive influence of the seen test results on their behaviour, the fact that ANC staff conducted the tests instead of laboratory personnel and the time and cost saved from visiting laboratories elsewhere to have their tests done. No socio-cultural barriers to the use of the RDT and HCS were reported among the women and they seemed agreeable to the repeated finger pricks accompanying the tests during their antenatal care because the tests were perceived as helpful to themselves and their babies.

When health care providers conduct POC tests with their patients during consultation, there may be provided the added advantage of engaging their clients in the tests being done unlike in the laboratory where the clients are remote from the processes of testing. Most pregnant women in the intervention sites of this study were well informed about the RDT and the HCS through the participation process. They preferred the tests to be conducted by the ANC staff because they claimed that, unlike the laboratory personnel, the ANC staff explained the tests and the results to them. It was easier for the pregnant women to accept the test results because they had received prior information about them and what to expect and they had confirmed the results with their own eyes. They claimed that seeing the tests being conducted with their own blood and seeing the results for themselves made them believe in the implications of the results and felt motivated to take action to improve their health status. They were now ready to put into practice the recommendations they received from the staff members. The pregnant

women seeing the tests results guided them in their decision to act to improve their health status. Thus the concept of the pregnant women participating in their care through the use of visual, easy to use and interpret POC tests may have served as decision aids to influence their behaviour positively. POC tests act as decision aids that lead to improvement in adherence to treatment through increased patient motivation and satisfaction, thus minimising the occurrence of complications and reducing hospital stay (Price 2001a). POC tests also have the advantage of generating quick results for appropriate treatment to be initiated promptly. This provides economic benefits to both the patient and the health system and improvement in clinical outcomes (Price 2001b). The pregnant women recognised the economic benefits that doing the RDT and HCS during their care brought to them in addition to the positive influence that the tests had on their health behaviours. They preferred to have all their laboratory investigations done at the ANC clinic, at their point of care and by the ANC staff. Not only did they believe they got prompt diagnosis and treatment but they claimed they were also spared the extra time and costs they would have spent going to the laboratories outside and joining long queues to have their tests done. They implied better adherence to treatments and recommendations given to them at the ANC clinic and better outcomes for their pregnancies.

The apparent improved ANC staff-pregnant women relationship while conducting the tests also increased the pregnant women's level of trust in the ANC staff and the tests themselves and hence their acceptability of the use of the tests during their care. Similarly, acceptability was also increased when caregivers of children under five years were engaged with conducting the RDT (Baiden, Owusu-Agyei et al. 2012).

No socio-cultural barriers to the use of the RDT were reported among the pregnant women in this study. However, it was only one ANC staff member who mentioned a perceived gender issue with laboratory testing among the pregnant women that may have hindered some of the women from having their laboratory tests done. The pregnant women were thus perceived to prefer the blood tests done by the ANC staff instead of laboratory personnel who were mostly males. In a study conducted in a rural setting of central Cote d'Ivoire, patients' perception of blood as a sacred body fluid negatively influenced the acceptability of the use of the RDT (Comoe, Ouattara et al. 2012). For fear of the use of their blood for HIV testing and for witchcraft, community members in the Iganga district of Uganda showed unwillingness to have their blood tested using the RDT (Mukanga, Tibenderana et al. 2010). Testing for HIV among pregnant women is done as a routine at the ANC clinic, hence the pregnant women may have come to accept it as part of their ANC and not entertain any fears. Perhaps, also, conducting these tests in the ANC clinic instead of in the community could have allayed the pregnant women's fears in this regard hence their not reporting any perceived barriers.

Repeated finger pricks for repeated blood tests at each ANC clinic attendance did not also seem to worry the pregnant women in this study. They perceived the repeated testing of their blood as helpful to them and their unborn babies and so endured any discomfort. A similar finding has been reported previously (Smith, Jones et al. 2010). Pregnant women may have been used to the idea that they would have blood tests conducted when they visited the ANC clinic and thus may have conditioned their minds for that. Comparing the needle pricks to labour pains made it easier for the women to bear the pricks for the sake of the health of themselves and their babies Moreover, this present study was conducted among only women who had consented to be part of the

trial and thus may have excluded women who were against repeated blood tests or with any socio-cultural concerns.

8.5 Effect of the enhanced antenatal care package on malaria and anaemia during pregnancy and pregnancy outcomes.

The risk of asymptomatic parasitaemia and anaemia generally decreased among all the pregnant women in this trial during their antenatal care as their pregnancy progressed. However, there were some differences in the risks of asymptomatic parasitaemia, anaemia, low birth weight and sub-optimal pregnancy outcomes between the women in the two arms of the study; the reduction in risks being higher in the intervention arm compared to the control arm. Also the proportion of pregnant women with adequate knowledge about malaria and anaemia and adequate levels of adherence to health advice was higher in the intervention group after the implementation of the intervention. These, thus showed some potential benefit of the enhanced ANC package for the control of malaria and anaemia during pregnancy although they did not reach statistical significance. Thus the use of the HCS and the RDT to encourage pregnant women to participate in their ANC demonstrated overall benefit although there was no clear biologic effect.

It is possible that our findings may have been influenced by a number of factors among which are:

1. The complexity of the client participation concept

When patients are encouraged to be involved in their own health care, their level of adherence to treatment recommendations and hence overall health outcomes improve (Greenfield, Kaplan et al. 1985, Greenfield, Kaplan et al. 1988, Kaplan, Greenfield et al. 1989, Kaplan, Greenfield et al. 1996, Liaw, Lawrence et al. 1996, Atkin, Stringer et al.

1998). However, the complexity of the patient participation concept that spans across various contributory factors affects the outcome of the concept. These include the fact that varied definitions exist for this same concept, varied components go into patient participation and a varied number of patient and health care worker factors exist that influence the patient's participation in his health care (Longtin, Sax et al. 2010). In this current study, antenatal care staff members were trained to use POC tests for malaria and anaemia to encourage pregnant women participating in their care. In other documented studies, doctors or nurses were trained on evidence and skills for patient participation or patients were given various information leaflets and encouraged to ask questions during their consultation process (Kinmonth, Woodcock et al. 1998, Pill, Stott et al. 1998). Sanders et al in their recent review have revealed non-conclusive results for patients participating in their care as no overall effect of patient participation could be demonstrated on disease-related outcomes. In their review, some studies showed deterioration in health outcomes while others showed that the control patients had better outcomes than the patient participation group (Sanders, van Weeghel et al. 2013). In addition to varied definitions for patient participation that existed in the studies and the existence of only a few controlled studies, the inability to fully blind health providers during the conduct of the trials and the lack of actual behavioural differences between the intervention and control groups were given as possible explanations for the in-conclusive results (Pill, Stott et al. 1998).

This trial tested the hypothesis that the use of the RDT and HCS as tools to facilitate the pregnant women's participation in their ANC would promote better adherence to ANC recommendations and treatment among the pregnant women with regards to malaria and anaemia and thus improve maternal health and pregnancy outcomes. Thus the pregnant women's adherence to the ANC recommendations and treatments after they have been

involved with the conduct of the tests is also an important factor in measuring the effectiveness of the enhanced ANC package. Adherence as a health behaviour is affected by a complex interplay of factors such as the patient's health literacy rate, attitudes, beliefs and group norms; culture; psychological state and the patients involvement and participatory decision making level (Martin, Williams et al. 2005). Also other factors such as the disease characteristics and type of treatment, factors related to the health care system and the delivery of the health service, social and economic factors affect adherence (Jin, Sklar et al. 2008). It is only when the patient perceives he/she is susceptible to the disease, perceives it as severe, feels threatened by it, weighs the perceived benefits of adhering to recommendations and treatments against the perceived barriers to take action and perceives that he/she can successfully adhere to produce a better health outcome, that he/she changes his/her behaviour and improves adherence (Glanz, K. et al. 2008). Pregnant women may not perceive pregnancy and its associated ill health as a severe disease to feel threatened by compared to patient's of chronic disease where even in such patients, only 50% adhere to their medications (WHO 2003a). The scale of measurement of adherence in this study showed less than 40% of the pregnant women self-reporting adequate adherence in both arms of the trial (35.9% in intervention group versus 34.2% in control group). There was only a marginal increase in adherence after implementation of the intervention although the ANC staff perceived an improvement in adherence after the use of the tests during ANC sessions. Although self-reporting of adherence has the disadvantage of recall bias, it has been shown to give quite an accurate assessment of the patient's level of adherence (Vik, Maxwell et al. 2004). Hence the results shown in this current study are more likely to be a true reflection of the pregnant women's level of adherence. Pregnant women are expected to adhere to treatment recommendations for a maximum of only 9 months compared to chronic disease patients who are on lifelong medications but their

adherence cannot be guaranteed because of their probable beliefs, perceptions and knowledge about pregnancy itself and malaria and anaemia during pregnancy. Some women perceived medicines given at the ANC clinic to boost their appetite and cause them to eat well, a perception that may have had some negative implications. In some studies this perception has caused pregnant women to discontinue taking their antenatal medicines for fear of having big babies and hence difficult deliveries. Also, some, for fear of not having enough money to buy food to match their increased appetite have shunned taking the medicines (Galloway, Dusch et al. 2002). Although these observations were not reported by the pregnant women themselves in this present study, a couple of the ANC staff mentioned that the pregnant women tended to store away the antenatal routine medicines for after pregnancy so that the women could eat well and look good. Thus the pregnant women's behaviour with regards to iron and folic acid supplementation may not have changed after the intervention as was conceptualised based on their beliefs about the effect of the antenatal medicines. Also, pregnant women in the intervention arm of this present study appeared more knowledgeable about malaria and anaemia in pregnancy than previously reported in studies elsewhere (Nuwaha 2002, Mubyazi, Bloch et al. 2005, Mbonye, Neema et al. 2006, Menaca, Pell et al. 2013). However this did not translate into an overall effect of the intervention.

In this present study, adherence to iron and folic acid supplementation was used as a proxy measure for the overall level of adherence to health advice. This may not have been appropriate. The women may have adhered to other forms of health advice better compared to that for iron and folic acid supplementation as reflected in their responses in the use of the ITN to prevent malaria and changing eating habits to improve their blood levels during the focus group discussions and interviews. However, their level of adherence to these behaviours was not measured in this current study. Also, the scale

that was used for measuring adherence, the VAS, although validated in other chronic conditions (Walsh, Mandalia et al. 2002, Giordano, Guzman et al. 2004, Oyugi, Byakika-Tusiime et al. 2004) has not yet been validated among pregnant women. But it proved a useful tool to demonstrate adherence to iron and folic acid supplementation during pregnancy.

2. Discrepancies between information given by antenatal staff and use by pregnant women.

The hypothesis that this intervention tested to promote better adherence to ANC recommendations was based on the assumption that the recommendations given by the ANC staff members to pregnant women were appropriate for the control of malaria and anaemia in pregnancy and that the pregnant women understood and accepted them. This assumption may have been undermined because of the possibility of discrepancy of information exchange. For example, pregnant women were expected to know that routine medicines including iron tablets are to help them build on their blood haemoglobin levels and hence should be taken during pregnancy. However, some pregnant women in this present study tended to store iron tablets and other routine medicines given them during pregnancy for after delivery. Also, pregnant women were to receive three doses of IPTp during their pregnancy yet one of them reported that she received two because she was told by the ANC staff that she had had five pregnancies during which she had received IPTp and hence did not need all three doses during her current pregnancy. Such information discrepancies coupled with the fact that there appeared to be no difference in maternal and pregnancy outcomes between the intervention and control arms of the study suggests that there could have been a problem with the information given and/ or received during ANC with respect to malaria and anaemia in pregnancy. If information needed for behavioural change is

presented and/or received poorly, it is unlikely to influence informed decisions that will promote healthy behaviour change.

3. Methodological issues

This study assumed a reduction of 30% in the prevalence of malaria and anaemia by the intervention for the determination of the sample size. It is possible that the true effect is less than this and 30% may have been too ambitious to detect a statistically significant result. However, reducing the intervention effect would have meant a larger number of ANC clinics and possibly a larger number of pregnant women in both arms of the study which could not have been adequately managed logistically with the available resources. Secondly, the intra-cluster correlation co-efficient (ICC) was assumed to be 0.15 since no previous estimates were known. From the study results, the ICC is larger (0.41 from the baseline data) and so again implied a larger number of ANC clinics to minimise the effect that clustering could have had on the results of the study. Thus the sample size may have been inadequate to detect the true effect of the enhanced package.

The substantial loss to follow up that was recorded could have also contributed to the results of the study. More than 30% of the women could not be reached for the outcome measure at each time point. This was more than what was accounted for during the estimation of the sample size of the study. Akl et al have reported that when plausible assumptions are made concerning the outcome measures of patients that are lost to follow up, this could reduce the significance of results of randomised controlled trials (Akl, Briel et al. 2012). About 58% of the results of the trials they studied were no longer significant if the worst case scenario (all patients lost to follow up in the intervention group and none in the control group had the outcome of interest) was assumed concerning the patients lost to follow up. Hence it is possible that the loss to follow up in this study largely affected the significance of the study results. This study

was set up and allowed to run within the routine antenatal care system with minimum interference. The pregnant women were only followed up when they attended the antenatal clinics. As part of antenatal care, the next visits of the pregnant women are scheduled by the staff. It was anticipated that the introduction of the participation process would improve upon the pregnant women's adherence to scheduled visits. This was seen at the 4-8weeks follow up where 64.1% compared to 56.7% in the intervention versus the control arms were followed up but this gain fizzled out by 36-40 weeks of gestation and at delivery when similar number of women were followed up in both arms. This observed phenomenon could be a true reflection of what happens during routine antenatal care hence the reduced effectiveness of interventions that have been observed.

4. Implementation issues

The success or failure of any intervention during a clinical trial depends on the inherent nature of the intervention or the implementation of it. If the intervention itself is a problem, it leads to intervention failure but if implementation of the intervention is the problem, then it leads to implementation failure (Rychetnik, Frommer et al. 2002, Oakley, Strange et al. 2006). The results of the trial showed that the enhanced package had a potential benefit. Hence, the intervention could not have been inherently faulty but may have had some implementation problems.

For a new intervention to be adopted and implemented, there is usually an interplay of factors resulting from the characteristics of the intervention, the individuals expected to implement it and the context or setting within which the intervention is implemented (Glanz, K. et al. 2008). This enhanced ANC package was a complex intervention of many components including conducting the HCS and RDT tests, allowing the pregnant

women to see the test results, interpreting the results with the pregnant women and giving recommendations appropriate to the test results. The trial was multisite involving 7 different ANC clinics and in reality it could have been difficult for the same processes to have been followed at each site within their context (Oakley, Strange et al. 2006). The use of the HCS and RDT for pregnant women's participation in their ANC was generally acceptable to both the pregnant women and the ANC staff. However, the intervention was accepted and implemented differently at each site with some components missing as illustrated by the monitoring of implementation fidelity in section 6.3. None of the ANC clinics implemented the intervention to 100%, the range being from a low percentage of agreement of 20% to a high of 80%. Within the system of operation of some of the implementing health facilities, laboratory investigations for the pregnant women had to be conducted in their laboratories and hence the ANC staff here tended to refer the pregnant women instead of carrying out the tests with them. The women thus lost the component of seeing the test results and the interpretation of them because the RDT and HCS were carried out at the laboratories instead of at the point-of-care. Even for the staff that carried out the tests themselves, the results showed that most of them fell short in interpreting the results with the women. The individual characteristics of the ANC staff also had a part to play. Their own beliefs, as well as their perceptions and knowledge of the intervention affect their acceptability and compliance to implementation (Mubyazi, Magnussen et al. 2008). They could be either innovators, early adopters, early majority adopters, late majority adopters or laggards depending on their degree of willingness to adopt and implement the enhanced package (Rogers 2003) and this would have had an impact on the effect of the intervention. Health provider behaviour is not easy to change with respect to patient participation and this could also have contributed to the lack of effect. In a similar study, although health providers adopted the client participation concept with enthusiasm at the beginning of

the trial, this was not sustained throughout the period of the trial leading to insignificant differences (Pill, Stott et al. 1998).

It can be argued that the monitoring of the intervention was done only once at each site and hence not fair to conclude that there were implementation problems. But the observations made at the ANC clinics correlated with the responses of the pregnant women who were interviewed at each of the sites. Thus the loss of implementation of some of the components of the intervention at the implementation sites may have impacted on the results of the trial.

5. Health system issues

During the period of the trial, RDT were deployed to all ANC clinics by the GHS as part of a policy direction to make diagnosis of malaria accessible before treatment was made. Thus their presence in the control ANC clinics could have meant that RDT could have been conducted as POC tests with the pregnant women participating in their care and thus may have had the same effect on the women as it did in the intervention group. This was confirmed during the qualitative part of this study when all the ANC staff in the control sites reported using the RDT in their clinics by themselves or other ANC staff and some of the women interviewed reporting that they had seen the RDT before. This could have lead to a diluting out of the effect of the enhanced ANC package. It is also, however, possible that the RDT were conducted in the control ANC clinics without the pregnant women participating in them and hence may not have affected the overall study results at all. Secondly, in ANC clinics that had laboratories, the ANC staff tended to refer the pregnant women to these laboratories for their blood tests without the component of the pregnant women participating in the conduct of the tests. This occurred in a couple of the intervention sites as was observed and also mentioned by the ANC staff members of these clinics. The ANC clinics possibly had regulations of

conducting all laboratory tests at the laboratories and hence made it difficult for the ANC staff members to conduct POC tests. Thus some pregnant women who were expected to have benefited from the intervention were prevented from receiving them because of the policy and practices of the ANC clinic. This may have also contributed to a diluting out of the effect of the intervention.

8.5 Implications for research

This study has shown that 15% of pregnant women have asymptomatic malaria parasitaemia at term pregnancy while 42% of them are anaemic. Involving the pregnant women with their ANC through the use of the HCS and RDT is feasible and acceptable to both the pregnant women and the ANC staff. Although this approach appeared to have potential benefits to the health of the mother and baby, the true effect could not be measured probably due to complexity of intervention; discrepancies in health information flow; methodological, implementation and health system issues. Probably, a stronger and significant effect would have been observed if the intervention was tested in a larger number of ANC clinics, in ANC clinics that did not have laboratories and rigorous follow up done to reduce loss to follow up to the barest minimum.

Assuming improved adherence by the pregnant women to the recommendations given by the ANC staff without measuring the appropriateness of the information given and how the pregnant women understood and accepted them may have contributed to the lack of understanding of the concept being tested. A few studies have researched into components of information given and received during ANC and the time spent on these components (Anya, Hydara et al. 2008, Magoma, Requejo et al. 2011) but there do not appear to be any studies about the actual content of the information, how it is provided by the ANC staff to the pregnant women and how it is perceived and used by pregnant

women. Since in this current study the content of the recommendations that was given to the pregnant women was not studied, it would be beneficial to find answers to the following questions:

1. What is content of information pregnant women are given at the ANC clinic with respect to the prevention and treatment of malaria and anaemia in pregnancy compared to 'best practice' recommendations?
2. What is the pregnant women's understanding of information received in relation to the prevention and treatment of malaria and anaemia in pregnancy?
3. What are the intentions or actions of the pregnant women with respect to the prevention and treatment of malaria and anaemia in pregnancy and the reasons behind these intentions and actions?

Answers to these questions may be found by conducting a qualitative study using non-participatory observations of provider-pregnant women interactions at the ANC clinics; conducting interviews and focus group discussions among ANC staff, pregnant women and mothers up to six weeks post partum attending post natal clinics.

Gaining more understanding about this communication gap between the providers and recipients of ANC during ANC sessions is essential to be able to design more effective ways of engaging women in their ANC towards improving pregnancy outcomes for the women and their children. A key outcome of this research will therefore be recommendations about how to improve upon information dissemination and uptake for ANC interventions.

The use of the RDT has previously been found to be more cost-effective compared to microscopy (Matangila, Lufuluabo et al. 2014) and clinical diagnosis (Ansah, Epokor et al. 2013). However, there appears to be no known studies documenting the cost-

effectiveness of the use of the HCS. It would thus be prudent to find out how cost effective the use of the HCS is in diagnosing anaemia during pregnancy.

The operational accuracy and safety of the use of the RDT for diagnosing malaria has been tested in a number of field studies among differing populations and mostly by research staff (Tagbor 2005, Kyabayinze, Tibenderana et al. 2008, Tagbor, Bruce et al. 2008, d'Acremont, Malila et al. 2010, Abba, Deeks et al. 2011, Mubi, Janson et al. 2011, Hamer, Brooks et al. 2012, Senn, Rarau et al. 2012). No known studies however exist where the operational accuracy and safety of the use of the RDT has been tested using ANC staff members. Secondly, the operational accuracy of the use of the HCS by ANC staff among pregnant women is not known. It would be beneficial, to policy and practice, to prove the operational accuracy and safety of the use of the RDT and HCS by ANC staff members among pregnant women during antenatal care sessions.

8.6 Implications for policy and practice

The current recommendation by the GHS is to have all pregnant women screened for malaria and anaemia at their first ANC visit; to diagnose malaria in all pregnant women who report with malaria-like symptoms before treatment is initiated and to have the Hb of all pregnant women checked at 36 weeks gestation (M.O.H.b. 2010). However, screening and treating malaria and anaemia during pregnancy is not always possible because of the absence of diagnostic tools, especially at the peripheral clinics. The RDT and HCS present such diagnostic opportunities to have all pregnant women reporting to the ANC clinics screened and managed promptly and appropriately. RDTs are currently being deployed by the NMCP/GHS/MOH nationwide to all ANC clinics to facilitate prompt diagnosis and treatment of malaria during pregnancy. The HCS has already been documented to have the potential of screening for anaemia in rural ANC clinics where there are no laboratories (Critchley and Bates 2005) and this present study has also

shown that it is feasible and acceptable among ANC staff and pregnant women to use these POC tools during ANC sessions. Their use to facilitate pregnant women's participation in their ANC may also have a potential benefit in improved health outcomes. The HCS could thus be introduced alongside the RDT into ANC clinics, especially those without laboratories, to help with the screening and management of anaemia in pregnancy. To improve upon the effect of using these tools during ANC sessions, pregnant women should be involved with the conduct of the tests. The ANC staff should allow the women to see the test results and encourage discussions amidst giving recommendations as this has the potential of motivating the pregnant women to take action to improve upon their health status.

As alternatives to laboratory testing, the availability of the HCS and the RDT during ANC sessions may have granted the pregnant women the opportunity of having earlier and prompt assessments of their malaria parasitaemia and anaemia status, especially when they were not yet registered with the NHIS. However, ensuring an uninterrupted supply of high quality RDT and HCS is necessary if the use of these tools is to contribute to the effective control of malaria and anaemia during pregnancy. The GHS/MOH would need to ensure constant supplies of the RDT and HCS and cool chains for the storage and transportation of the RDT to the ANC clinics so as to minimise false results and solidify the trust in their use among ANC staff and pregnant women.

8.7 Conclusions

This present study has shown that asymptomatic malaria parasitaemia and maternal anaemia are prevalent among pregnant women in spite of on-going ANC interventions for the control of malaria and anaemia in pregnancy. The use of the RDT and HCS as

POC tests to engage pregnant women in their ANC for the screening of malaria parasitaemia and anaemia during routine ANC sessions is feasible and acceptable to both pregnant women and ANC staff. The use of the RDT and the HCS as tools to facilitate pregnant women's participation in their ANC was not effective in reducing the risk of malaria parasitaemia and anaemia during pregnancy, however it was demonstrated to be of potential benefit. They offered the pregnant women the opportunity to see their test results for themselves with the potential of influencing their behaviour positively. Their use also appeared to impact ANC staff-pregnant women interaction positively. These, the pregnant women perceived as improved quality of care. The use of the HCS and RDT during pregnancy could improve upon the prompt diagnosis and management of malaria and anaemia during pregnancy, especially in ANC clinics with no laboratories and in pregnant women with no symptoms. Since the RDT is being deployed nationwide to all ANC clinics, the government of Ghana could consider introducing the HCS as an additional tool to help with the screening of anaemia within the context of the pregnant women participating in their ANC.

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APPENDICES

APPENDIX 1 CHECK LIST FOR ANTENATAL CARE SERVICE OBSERVATIONS

Name of Health Facility: [_____]

Observer ID: [_____] Date:_____/_____/_____

ANC clinic code_____ Checklist number [__[__[__]

This checklist should be filled with the help of the ANC clinic in charge or Representative

1. Type of Health facility: [____]Hospital [____]Health Centre [____]Clinic [____]Maternity home [____] Other,……
2. Affiliation of Health facility: [_____]Government [____]Mission [____]Private
3. Insecticide treated nets available for free for pregnant women? [___] Yes [___] No
4. Insecticide treated nets available for sale for pregnant women? [___] Yes [___] No
5. If Yes to Q.4, what is the cost? [GhȻ_____]
6. Are laboratory services available in this health facility? [___] Yes [___] No
7. If no to Q.6, how do the pregnant women get laboratory tests done?
   ……
   ……
8. If yes to Q.6, is it separate from the ANC clinic? [___] Yes [___] No

   [If yes, please complete the Laboratory services sheet, Page 4]

9. Are dispensary/pharmacy services available in this health facility?[___] Yes [___] No
10. If no to Q.9, how do the pregnant women get their medicines?
    ……
    ……
11. If Yes to Q.9, is it separate from the ANC clinic? [___] Yes [___] No

    [If yes, please complete the Pharmacy/Dispensary sheet, Page 5]

12. Category of staff working on duty at ANC clinic today *(day of observation)*
(*Please tick the appropriate response*)

	CATEGORY	YES	NO	Total number
a.	Doctor			
b.	Medical assistant			
c.	Midwife			
d.	Nurse			
e.	Ward assistant			
f.	Other-			
g.	Other-			

13. Type of obstetric (delivery) services offered in health facility

	TYPE	YES	NO
a.	**Basic essential obstetric care**		
	Administer antibiotics by intramuscular or intravenous route		
	Administer oxytocin by intramuscular or intravenous route		
	Administer IM/IV anticonvulsants for pre-eclampsia and eclampsia		
	Perform manual removal of placenta		
	Perform removal of retained products of conception		
	Perform assisted vaginal delivery, preferably with vacuum extractor		
b.	**Comprehensive essential obstetric care**		
	Perform Caesarian sections		
	Give anaesthesia for surgery		
	Administer safe blood transfusions		

14. Is there a functional baby weighing scale? [___] Yes [___] No

15. How many different stations do the pregnant women have to sit at the ANC clinic for antenatal care to be completed? [_____]

16. List the stations:
    a. _____
    b. _____
    c. _____
    d. _____
    e. _____

17. ANC services provided in facility (*Please tick the appropriate response after observation*)

	ANC SERVICE	YES	NO	COMMENT
	I. Clinical assessment			
	Weight measurement			
	Height measurement			
	Temperature measurement			
	Blood pressure measurement			
	Conjunctival pallor assessment			
	Pedal oedema assessment			
	II. Obstetrical assessment			
	Symphysio-fundal height using tape measure			
	Ultra sonography			
	Foetal heart rate using fetoscope			
	Foetal heart rate using sonicaid			
	III. Health education/Counselling			
	Next ANC visit scheduling			
	Bed net use recommendation			
	Compliance to iron and folate supplementation			
	Post natal attendance			
	Danger signs			
	Nutrition			
	Birth preparedness			
	Family planning			
	IV. Point of care tests			
	Urine dip stick (protein and sugar)			
	Malaria rapid diagnostic test			
	HIV test			
	VDRL for syphilis			
	V. Treatments			
	Intermittent Preventive Treatment of malaria in pregnancy using SP			
	Presumptive de worming			
	Malaria treatment			
	Tetanus toxoid immunization			

18. Does the ANC clinic keep stock of sulphadoxine-pyrimethamine (SP)? [___] Yes [___] No

19. If yes to Q. 18, are stock cards kept to monitor the SP at the ANC?
[___] Yes (observed) [___] Yes, not observed [___] No

20. Number of stock outs of SP at the ANC in the last 6 months? [_____]

21. State the longest stock out period [_____] days

Laboratory services

This checklist should be filled with the help of the Head of Laboratory or Representative

1. On what days of the week are laboratory services available?

Day	Yes	No	Time of the day that laboratory is open
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

2. Types of tests conducted

	Types of tests conducted	Yes	No	Comment
a	Hb measurement using automated counter			
b	Hb measurement using colorimeter			
c	Urine Routine Examination (microscopy for deposits and pus cells)			
d	Urine dipstick test (protein and sugar)			
e	Stool Routine Examination (microscopy for intestinal parasites)			
f	Microscopy for malaria parasites			
g	Malaria Rapid Diagnostic Test			
h	Sickling test			
i	Hb electrophoresis			
j	Blood grouping			
k	VDRL for syphilis			
l	HIV test (spot test)			
m	CD4 count			
n	G-6-PD enzyme deficiency test			
o	Blood sugar using glucometer			
p	Other-			
q	Other-			

4. Are blood transfusion services available? [___] Yes [___] No

5. Do you have a blood bank? [___] Yes [___] No

6. If yes to Q5, is blood available always? [___] Yes [___] No

7. If no to Q6, number of stock outs in the last 6 months [_____]

8. Duration of longest stock out [_____] days

ANC clinic code_____ Checklist number [__[__[__]

Pharmacy/dispensary services

This checklist should be filled with the help of the Head of Pharmacy or Representative

1. Medicines for routine ANC stocked

	Medicine	Yes	No	Dosage (Frequency in a day X number of days served)	Stock outs in last 6 months		No. of stock outs In last 6 months + longest duration of stock out(days)
					Yes	No	
a.	Tab Fesolate						
b.	Tab Folic acid						
c.	Tab Iron III polymaltose						
d.	Tab Multivitamins						
e.	Tab Vitamin B Complex						
f.	Tab Calcium						
g.	Tab Calcium + Vit D						
h.	Tab Vitamin C						
i.	Syrup Iron III polymaltose						
j.	Syrup Ferric Ammonium Citrate						
k.	Tab Mebendazole/ albendazole						
l.	Other-						
m	Other-						
n.	Other-						
o.	Other-						

ANC clinic code_____ Checklist number [__[__[__]

Pharmacy/dispensary services

2. What anti-malarial medicines do you normally stock here?

	Medicine	YES	NO	Stock outs in last 6 months		No. of stock outs In last 6 months + longest duration of stock out
				Yes	No	
a.	Tab Artesunate-amodiaquine					
b.	Tab Artemether-Lumefantrine					
c.	Tab Di-hydro artemisinin piperaquine					
d.	Tab Sulphadoxine-Pyrimethamine					
e.	Tab Qunine					
f.	Tab sulphadoxine-pyrimethamine					
g.	Injection Quinine					
h.	Injection Artemether					
i.	Other-					
j.	Other-					

3. On what days of the week are pharmacy/dispensary services available?

Day	Yes	No	Time of the day that the pharmacy/dispensary is open
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

APPENDIX 2 CROSS SECTIONAL SURVEY: KNOWLEDGE AND ADHERENCE QUESTIONNAIRE

Questionnaire code no: [__]__]__] ANC clinic code: [__]__]__] Date:[____/_____/________]

- -

Name of Health Facility: [________________________] Interviewer code no: [___]___]___]

____

This questionnaire should be administered to pregnant women who are of 36 weeks gestation and above only at the ANC clinic.

Good day! My name is___________________and I am a member of a team of research assistants working with Dr. Gifty Antwi. She seeks to describe the prevalence of malaria and anaemia among pregnant women and their level of adherence to recommendations given by ANC staff in this district as part of her PhD project work. We would ask you about yourself as well as about some services you received at the ANC clinic. We would also want to test your blood for malaria and anaemia. The information that will be gathered will be treated with confidentiality and will not be linked to you in any way during reporting. The information gathered will assist us in improving upon antenatal care services in our district and help in shaping policy for the future.

This interview will last a maximum of 30 minutes. Permission has been sought from the health directorate of this district and the KNUST ethics committee.

If you agree to participate in this study, I would like you to show your consent by signing this form.

____

Name: ____

Community/Location:____

__________________________ __________________________

Signature Thumb print

If client is less than 18 years, please seek additional consent from a legal guardian.

Name of legal guardian:____

__________________________ __________________________

Signature Thumb print

With your permission, I would like to start the study.

Questionnaire code no: [__]__]__] ANC clinic code: [__]__]__] Date:[____/_____/_____]

A. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF CLIENT

1. Age: [_____years]
2. Parity: [_____]
3. Gravidity: [_____]
4. Gestational age of current pregnancy: [_____weeks] Don't know [___]
5. Marital status: [___] Married [___] Single [___]Not married but living with partner [___] Other, specify……..
6. Highest educational level: [___] None [___] Primary [___] Junior Secondary [___] Senior Secondary [___] Vocational/Technical [___] Tertiary
7. Occupation: [___] None [___] Salaried worker [___] Health worker [___] Trader
   [___] Farmer [___] Artisan [___] Other,……

B. KNOWLEDGE ABOUT MALARIA

(Please mention malaria in our local language to ensure the client is talking about the same disease)

1. What causes malaria? *(Multiple answers allowed)*
[____] Living in a dirty environment
[____] The bite of an infected mosquito
[____] Scorching sunshine
[____] Eating unwholesome food
[____] Don't know
[____] Other,
specify……..

2. What are some of the commonest symptoms of malaria you know? *(Multiple answers allowed)*
[___] Fever
[___] Headache
[___] Vomiting
[___] Abdominal pain
[___] Tiredness
[___] Loss of appetite
[___] Don't know
[___] Other,
specify……..

3. If a pregnant woman gets malaria, what effect can it have on her? *(Multiple answers allowed)*
[____] She can die
[____] She can become very weak
[____] She can become anaemic
[____] She can lose weight
[____] She can have a miscarriage
[____] Don't know
[____] Other, specify……

4. If a pregnant woman gets malaria, what effect can it have on her baby? *(Multiple answers allowed)*
[____] The baby can die in the womb
[____] A small baby will be born
[____] An unhealthy baby will be born
[____] The baby can be spontaneously aborted

[____] The baby can be born before nine months
[____] Don't know
[____] Other, specify……

5. How should a pregnant woman prevent herself from getting malaria? *(Multiple answers allowed)*
[____] She should sleep under a bed net
[____] She should wear protective clothing at night
[____] She should not stay out late
[____] She should go to the hospital for the medicine that is given to us to swallow
[____] She should weed around her house/keep her environment neat
[____] She should not eat oily food
[____] Use insecticides-sprays, repellents, coils
[____] Don't know
[____] Other, specify……

C. KNOWLEDGE ABOUT ANAEMIA

1. What causes anaemia in a pregnant woman? *(Multiple answers allowed)*
[____] Not eating good food
[____] The baby drains the mother's blood
[____] Malaria can cause anaemia
[____] Not taking her medicines regularly
[____] Don't know
[____] Other, specify……

2. What are some of the symptoms of anaemia in pregnancy? *(Multiple answers allowed)*
[____] Feeling weak
[____] Feeling tired
[_] Dizziness
[____] The heart beats faster/feels the heart beating stronger
[____] Having the feet swell up
[____] Pale conjunctiva
[____] Don't know
[____] Other, specify……

3. If a pregnant woman becomes anaemic, what effect can it have on her? *(Multiple answers allowed)*
[____] She can die
[____] She can become very weak
[____] She can lose weight
[____] She can have a miscarriage
[____] Don't know
[____] Other, specify……

4. If a pregnant woman becomes anaemic, what effect can it have on her baby? *(Multiple answers allowed)*
[____] The baby can die in the womb
[____] A small baby will be born
[____] An unhealthy baby will be born
[____] The baby can be spontaneously aborted
[____] The baby can be born before nine months
[____] Don't know

[____] Other, specify……

5. How can anaemia in pregnancy be prevented? *(Multiple answers allowed)*
   [____] By eating greens and meat
   [____] By eating well/eating well balanced diet
   [____] By taking fruits
   [____] By taking the medicines we are giving at the ANC
   [____] By preventing malaria
   [____] Don't know
   [____] Other,
   specify……

D. INSECTICIDE TREATED NET USE

1. Do you own a bed net? [____] Yes [____] No
2. Did you sleep under a bed net last night? [____] Yes [____] No
3. If yes to Q.2, is it an insecticide bed net? [____] Yes [____] No [____] N/A
   [____] Don't know

E. MALARIA EPISODES

1. Have you ever had a fever episode during this current pregnancy? [____] Yes [____] No
2. If yes, how many times? [____] [____] Can't remember [____] N/A
3. Have you had a fever in the last two weeks? [____] Yes [____] No
4. Have you taken an antimalarial medicine in the last two weeks? [____] Yes [____] No
5. How many times have you been diagnosed with/told you have malaria in this current pregnancy? [____] [____] Can't remember
6. Have you ever been given some medicine to take/swallow at the ANC clinic during this current pregnancy? [____] Yes [____] No
7. If Yes to Q.6, how many times were you given the tablets to swallow at the ANC clinic?
   [____] [____] N/A
8. Did you know what the tablets were for? [____] Yes [____] No [____] N/A
9. If yes to Q.8, what were the tablets for? *(Multiple answers allowed)*
   [____] To help me gain weight
   [____] To prevent me from getting malaria
   [____] To protect my baby in the womb from falling sick
   [____] To give me a lot of blood
   [____] Other,
   specify……

F.* ANC VISITS *(Please use the woman's maternal health record book (MHRB) also for the additional information)

1. How many times have you visited the ANC clinic in your current pregnancy (including this visit)?
   [____] Once [____] Twice [____]Thrice
   [____] ≥ 4 times [____] Can't remember
2. *(For the interviewe*r) How many visits are recorded in the MHRB (including current visit)?
   [____]

3. *[If less than four times (in the MHRB),]* Please what was your reason for attending this number of times? *(Multiple answers allowed)*

[____] Forgot
[____] Did not have money for transportation
[____] Other, specify ……

[____]N/A
[____] Travelled
[____] Felt well/Not sick

4. At what gestation did you first attend the ANC clinic?[_____] weeks [____] Don't know

5. *(For the interviewer)* What is the first visit gestation recorded in her MHRB? [_____] weeks

6. *[If in the third trimester (≥24 weeks) as per her MHRB]* Why did you first attend the ANC clinic at this time? *(Multiple answers allowed)*

[____] I did not find out I was pregnant early enough
[____] I wanted the pregnancy to be established before coming
[____] I did not have money for transportation to the ANC clinic
[_] I did not have money to register with the NHIS
[____] I was not sick
[____] I did not like my previous experience at the ANC clinic
[____] I was being attended to by a traditional birth attendant
[____] Other, specify……
[____] N/A

7. What was her Hb at booking as per the MHRB? [___]___].___g/dl] [___] Not done/recorded

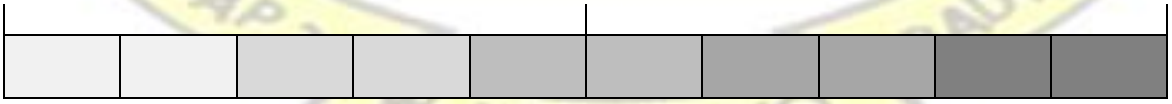
8. *(For the interviewer)* How many episodes of malaria are recorded in her MHRB? [____]

9. *(For the interviewer)* How many doses of SP have been recorded in the MHRB as given to her? [_]

G. MEASUREMENT OF ADHERENCE TO IRON AND FOLATE SUPPLEMENTATION (THE VISUAL ANALOGUE SCALE)

(Please ask the respondent to put an "X" in a coloured box below at the point showing her best guess about how much of her medicines she has taken in the last 2 weeks (0 means none of medicines taken; 50% means half of medicines taken; 100% means all of medicines taken).

0 **50%** **100%**



H. HAEMOGLOBIN AND MALARIA PARASITAEMIA DETERMINATION

Please perform the HemoCue and the mRDT for the pregnant woman you have just interviewed.

HemoCue results: [____]____].____]g/dl

Malaria Rapid Diagnostic Test results: [____] Positive [____] Negative

(NB: Please show the results of the Hb and the mRDT to the ANC staff before dismissing the pregnant woman for appropriate management to be effected).

I. If self report of adherence to medication using the visual analogue scale is ≤ 50%, what is her reason for this? (*(Multiple answers allowed)*

[___] Forgetfulness
[___] Complexity of dose regimen of medicines deterred me
[___] Did not like the side effects of the medicines
[___] Did not want my baby to be too big to make delivery difficult for me
[___] Don't like taking medicines generally
[___] Did not think that the medicines would help me in any way
[___] Travelled often and left medicines
[___] Was busy
[___] N/A
[___] Other, specify……

APPENDIX 3 DESK GUIDE FOR IMPLEMENTATION OF CLIENT PARTICIPATION IN ANTENATAL CARE

APPENDIX 4 PICTORIAL GUIDE FOR MALARIA AND ANAEMIA IN PREGNANCY

APPENDIX 5 CHECKLIST FOR THE OBSERVATION OF 'CLIENT PARTICIPATION' CONCEPT

Name of Health Facility: _____

Health Facility code: [_____]

Date of visit:_____/_____/_____

Visit conducted by (Observer code no.): [_____]

Please observe the following activities in the antenatal clinic and tick appropriately

	Activity Observed	Yes	No
1.	Group education of pregnant women about malaria and anaemia using the pictorial guide		
2.	One on one education of pregnant women about malaria and anaemia using the pictorial guide		
3.	ANC staff using the rapid diagnostic test (RDT) to test for malaria in pregnant women		
4.	ANC staff using the Haemoglobin colour scale (HCS) to test for anaemia in pregnant women		
5.	ANC staff engaging pregnant women in the interpretation of results of the RDT		
6.	ANC staff engaging pregnant women in the interpretation of results of the HCS		
7.	ANC staff giving recommendations to pregnant women based on the results of RDT		
8.	ANC staff giving recommendations to pregnant women based on the results of HCS		
9.	ANC staff giving the pregnant women the opportunity to ask questions about antenatal consultation		
10.	ANC staff recording results of the HCS and RDT in note book		

APPENDIX 6 MONITORING OF IMPLEMENTATION: EXIT INTERVIEW GUIDES

Introduction: My name is ..... I am from KNUST. I am here to find out about the research work that is going on in this facility. I hear you have been asked to participate in this research. I will be grateful if you would spare me not more than 15 minutes to answer some few questions. If you agree to answer the questions, I would like to record what you say. This information is very confidential and will not be linked to you in anyway. If you agree to be part, please say I do agree. Thank you.

Do you agree to be interviewed? Thank you.

---

1. How many times have you been to this antenatal clinic with this current pregnancy?

2. Can you please tell me all that happened when you met the nurses at the clinic today?

Prompts

-BP check

-Urine test

-Weight measurement

-Measured my stomach, checked baby in my stomach

-Blood test for blood level

-Blood test to check for malaria parasites

-Wrote medicines to go for at the dispensary

Show the RDT to the pregnant woman

3. Have you seen this before?

4. Has it been used on you in this clinic before?

5. What was it for? Please describe how it was used.

Show the HCS to the pregnant woman

6. Have you seen this before?

7. Has it been used on you in this clinic before?

8. What was it for? Please describe how it was used.

9. Were you given any recommendations based on the results of these tests?

10. How did you find the tests?

Show the pictorial guide to the pregnant woman

11. Have you seen this before?

12. What was it for? Please describe how it was used.

13. How did you find this guide?

14. How have you found your antenatal care experience so far?

Thank you.

APPENDIX 7 DISCUSSION GUIDE FOR IMPLEMENTERS OF 'CLIENT PARTICIPATION' CONCEPT

Good day! My name is ..... I work at the KNUST and my assistant is ..... who some of you may have met before. We are here today to discuss the new ANC package that Dr. Gifty Antwi has introduced into your clinics. It has been about 9 months now since you started implementing it and we want to talk about how you have found it so far, how you have managed it within your routine ANC services, if you have any difficulties that need her attention, and if you have been able to resolve any difficulties that you encountered.

During this discussion, we will try as much as possible not to use your real names. I will assign numbers to you so that you mention it before you contribute to the discussion. What transpires here will not be linked to anyone in person. We want you to express yourselves very well and so don't mind if you speak Twi in addition to English. We will translate everything you say back into English. We would like to tape record the discussion to facilitate our capture of all the relevant information that you will share with me. The discussion will last about 45 minutes. If you agree to us having the discussion and also tape recording it, I would ask that you say a very big 'Yes' so that it is captured on to the recorder.

Do you agree to us having this discussion and also tape recording it?

Objective 1 To describe antenatal care services providers are currently offering after the introduction and implementation of a new antenatal care strategy for malaria and anaemia in pregnancy	*1.* Can you please describe what you do for a pregnant woman when she visits the antenatal clinic for the first time *(probe the following areas)* a. Education b. Registration c. Physical examination d. Palpation e. Laboratory investigations f. Consultation/recommendations g. medication 2. Can you please tell me what you do for the pregnant woman in her subsequent visits till she delivers? 3. In your opinion, are there any others that you could do but are not required of you to do?
Objective 2 To investigate the existence of barriers, if any, to the successful implementation of the new antenatal care strategy for malaria and anaemia in pregnancy	*1.* Can you please tell me the new procedures that you do for your clients after the introduction of the new programme for malaria and anaemia *(NB: These may have been mentioned above but need to explore further)* *2.* Can you please share some of your experiences in carrying out these new procedures? *(Allow for demonstrations)* 3. In your opinion, what are some of the difficulties that one is likely to face during the carrying out of these procedures? 4. Have you faced any of these difficulties during the past few months?
Objective 3 To explore possible means of improving upon implementation of the new antenatal strategy for malaria and anaemia in pregnancy	1. Can you please describe how have you been able to solve some of these difficulties that you encountered as you carried out the new programme *2.* What would you recommend as the best way of solving these difficulties? *(Encourage the participants to mention the difficulty first and then the solution)*
Objective 4 To explore the providers' perception of the new antenatal care strategy for malaria and anaemia in pregnancy	1. Describe how this new strategy for malaria and anaemia in pregnancy has influenced your work as a midwife 2. How do you think this new strategy has influenced the pregnant women? 3. Is there any aspect of the new strategy that in your opinion can be improved upon? 4. What do you think about the introduction of new strategies into antenatal care in general?

APPENDIX 8a PARTICIPANT INFORMATION LEAFLET: CONTROL ARM

Title of Research: The effect of an enhanced Antenatal Care service package on malaria and anaemia in pregnancy- A cluster randomized control trial.

Name(s) and affiliation(s) of researcher(s): This study is being conducted by Dr. Gifty Dufie Antwi of Department of Community Health, School of Medical Sciences, KNUST under the supervision of Dr. Harry Tagbor of the Department of Community Health, School of Medical Sciences, KNUST.

Background: In Ghana, malaria and anaemia in pregnancy contribute significantly to maternal and infant mortality. In spite of interventions that have been put in place through the antenatal care system, the problem continues to exist. About 70% of pregnant women are anaemic and 9.4% die from malaria. Some studies have shown that when health workers involve their clients in what is done for them at the hospitals, it results in better health outcomes. So in this study, we will encourage pregnant women to participate in the testing of their blood for malaria and anaemia using some simple tools whenever they come to the antenatal clinic and we will find out whether this will have any effect on them and their babies.

Purpose(s) of research: The purpose of this research is to find out what the effect of enhancing antenatal care services through the participation of pregnant women in the screening and treatment of malaria and anaemia in pregnancy using point of care diagnostic (POC) tests will have on malaria and anaemia prevalence during pregnancy and pregnancy outcomes.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:

After you have agreed to be a part of the study, a questionnaire will be administered to you to enquire about your socio-demographic status, medical and obstetric history as well your use of ITNs. The routine antenatal care will be given to you with routine laboratory tests done for you as pertains in this clinic. You will receive anti malarial treatment and SP for intermittent preventive treatment as is already being done in the clinic. In addition, your blood haemoglobin level will be tested using the HemoCue as you visit the ANC clinic by research assistants. Also, at these visits, drops of your blood will be put on a glass slide by the research assistants to look for malaria parasites later. You will receive your routine haematinics and any other medicines that are given routinely in this clinic. At delivery, your baby's weight will be recorded. During your pregnancy, if you feel unwell, you are expected to report back to the ANC clinic to be taken care of. If for any unfortunate reason, your pregnancy does not progress to full term, please notify the ANC staff immediately so that you can be taken care of and the event recorded.

This research will go on for two years and at the end, a total of about 1500 pregnant women are expected to participate. The study will be conducted in the Ejisu-Juaben and Sekyere-East districts of the Ashanti region in 14 health facilities.

Risk(s): The pricking of your finger to test your blood for malaria and anaemia will cause some pain or discomfort and may predispose to infection. However, the research assistants have been trained very well to test you and we will ensure that they always clean your finger tips very well with alcohol before the pricking is done.

Benefit(s): This research aims to introduce a new package of antenatal care service geared towards improving maternal haemoglobin levels and pregnancy outcomes. We hope that at the end of your pregnancy, your haemoglobin level would have been monitored and you and your baby will be very healthy. However, we cannot be certain about this as this is research.

Confidentiality: All information collected in this study will be given code numbers. No names or identifiers will be used in any publication or reports from this study and data collected will not be linked to you in any way. However, as part of our responsibility to conduct this research properly, we may allow officials from the KNUST ethics committee to have access to your records.

Voluntariness: Your participation in this study should be out of your own free will. You are not under any obligation to be a part. This research is purely on voluntary basis

Alternatives to participation: If you choose not to participate, this will not affect your antenatal care at the clinic in any way.

Withdrawal from the research: You may choose to withdraw from the research at anytime without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private. But we would wish that you stayed on till you delivered once you agree to participate.

Consequence of Withdrawal: There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study. Please note however, that some of the information that may have been obtained from you without identifiers before you chose to withdraw may be used in the analysis, reports and publications. These cannot be removed anymore. We however do promise to try to comply with your wishes as much as practicable.

Costs/Compensation: For your time and any inconvenience that we may cause during our interaction with you, you will be given a compensation package at the end of your participation in the study to show our appreciation.

Contacts: If you have any further question concerning this study, please do not hesitate to contact Dr. Gifty Antwi of the Community Health department of KNUST on 0244 596 229 or Dr. Harry Tagbor of KNUST, Community Health Department on 0244 417 701.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

The Office of the Chairman

Committee on Human Research and Publication Ethics

Kumasi

Tel: 03220 63248 or 020 54537

APPENDIX 8b PARTICIPANT INFORMATION LEAFLET: INTERVENTION ARM

Title of Research: The effect of an enhanced Antenatal Care service package on malaria and anaemia in pregnancy- A cluster randomized control trial.

Name(s) and affiliation(s) of researcher(s): This study is being conducted by Dr. Gifty Dufie Antwi of Department of Community Health, School of Medical Sciences, KNUST under the supervision of Dr. Harry Tagbor of the Department of Community Health, School of Medical Sciences, KNUST.

Background: In Ghana, malaria and anaemia in pregnancy contribute significantly to maternal and infant mortality. In spite of interventions that have been put in place through the antenatal care system, the problem continues to exist. About 70% of pregnant women are anaemic and 9.4% die from malaria. Some studies have shown that when health workers involve their clients in what is done for them at the hospitals, it results in better health outcomes. So in this study, we will involve pregnant women in the testing of their blood for malaria and anaemia using some simple tools whenever they come to the antenatal clinic and we will find out whether this will have any effect on them and their babies.

Purpose(s) of research: The purpose of this research is to find out what the effect of enhancing antenatal care services through the participation of pregnant women in the screening and treatment of malaria and anaemia in pregnancy using point of care diagnostic (POC) tests will have on malaria and anaemia prevalence during pregnancy and pregnancy outcomes.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:

After you have agreed to be a part of the study, a questionnaire will be administered to you to enquire about your socio-demographic status, medical and obstetric history as well your use of ITNs. Your blood haemoglobin level will be measured as you visit the ANC using a HemoCue which is a small machine and recorded by a research assistant. Also, at these visits, drops of your blood will be put on a glass slide to look for malaria parasites under the microscope later. The ANC staff will in addition to the routine antenatal care service encourage you to participate in the testing of your blood using the rapid diagnostic test for malaria and the haemoglobin colour scale for anaemia in the antenatal clinic during your antenatal visits whether or not you are sick. They will also use a pictorial guide to encourage you to participate in an educational session on malaria and anaemia. Anytime you are found to be positive with the malaria rapid diagnostic test, you will be given antimalarial treatment by the ANC staff. If you are found to be negative with the malaria rapid diagnostic test at your antenatal visits, you will receive sulphadoxine-pyrimethamine (SP) for intermittent preventive treatment of malaria as is done in Ghana now and you will be given a maximum of three doses during your pregnancy. However if in between scheduled visits you feel unwell, you will have to report to the ANC clinic so that you will be taken care of. You will be given routine haematinics that you will be expected to be taking during your pregnancy and any

other medicine that is given routinely in the facility. At delivery, your baby's weight will be recorded. If for any unfortunate reason, your pregnancy does not progress to full term, please notify the ANC staff immediately so that you can be taken care of and the event recorded. This research will go on for two years and at the end, a total of about 1500 pregnant women are expected to participate. The study will be conducted in the Ejisu-Juaben and Sekyere-East districts of the Ashanti region in a total of 14 health facilities.

Risk(s): The pricking of your finger to test your blood for malaria and anaemia will cause some pain or discomfort and may predispose to infection. However, the ANC staff and the research assistants have been trained very well to test you and we will ensure that they always clean your finger tips very well with alcohol before the pricking is done.

Benefit(s): This research aims to introduce a new package of antenatal care service geared towards improving maternal haemoglobin levels and pregnancy outcomes. We hope that at the end of your pregnancy, your haemoglobin level will be improved and you and your baby will be very healthy. However, we cannot be certain about this as this is research.

Confidentiality: All information collected in this study will be given code numbers. No names or identifiers will be used in any publication or reports from this study and data collected will not be linked to you in any way. However, as part of our responsibility to conduct this research properly, we may allow officials from the KNUST ethics committee to have access to your records.

Voluntariness: Your participation in this study should be out of your own free will. You are not under any obligation to be a part. This research is purely on voluntary basis.

Alternatives to participation: If you choose not to participate, this will not affect your antenatal care at the clinic in any way.

Withdrawal from the research: You may choose to withdraw from the research at anytime without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private. But we would wish that you stayed on till you delivered once you agree to participate.

Consequence of Withdrawal: There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study. Please note however, that some of the information that may have been obtained from you without identifiers before you chose to withdraw may be used in the analysis, reports and publications. These cannot be removed anymore. We however do promise to try to comply with your wishes as much as practicable.

Costs/Compensation: For your time and any inconvenience that we may cause during our interaction with you, you will be given a compensation package at the end of your participation to show our appreciation.

Contacts: If you have any further question concerning this study, please do not hesitate to contact Dr. Gifty Antwi of the Community Health department of KNUST on 0244 596 229 or Dr. Harry Tagbor of KNUST, Community Health Department on 0244 417 701.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

The Office of the Chairman

Committee on Human Research and Publication Ethics

Kumasi Tel: 03220 63248 or 020 5453785

APPENDIX 9 SCREENING FORM

Screening ID		
Date		
Interviewer code		
Woman's name		
Initials		
Age(years)		
Community of residence		
Health facility		
	Yes	**No**
1. She is attending the ANC for the first time for this current pregnancy?	☐	☐
2. Her pregnancy is of gestation ≤ 30 weeks (by palpation or ultrasound)?	☐	☐
3. She stays within the catchment area of the health facility?	☐	☐
4. She is willing to attend all ANC clinics in this health facility?	☐	☐
5. She is willing to participate and complete the study?	☐	☐
6. She has a known history of sickle cell disease, HIV/AIDS, thalassaemia, G-6-P-D deficiency, tuberculosis?	☐	☐
7. She has a significant illness that requires hospitalisation (including severe malaria and anaemia)?	☐	☐
8. Her haemoglobin concentration is < 7g/dl	☐	☐
If responses to questions 1-5 are all YES and responses to questions 6-8 are all NO, the research assistant **should invite the pregnant woman to enter the study**. Otherwise, the **pregnant woman should go through her antenatal care as given by the health facility.**		
9. Haemoglobin assessment using the HemoCue (g/dl)	☐	☐
10. Woman eligible?	☐	☐
11. Woman enrolled?	☐	☐
12. If eligible but not enrolled, provide reasons		
Declined consent	☐	☐
Not convinced	☐	☐
Needs to consult family	☐	☐
Other		
STUDY ID NUMBER		

APPENDIX 10 INFORMED CONSENT FORM

Statement of person obtaining informed consent:

I have fully explained this research to_____and have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant make an informed decision to or not to participate.

DATE:_____ NAME: _____

Statement of person giving consent/accent:

I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction.

I understand that my participation is voluntary (not compulsory).

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it.

I understand that I may freely stop being part of this study at any time without having to explain myself.

I have received a copy of this information leaflet and consent form to keep for myself.

NAME:_____

DATE:_____ SIGNATURE/THUMB PRINT: _____

INFORMED CONSENT FORM

Statement of person witnessing consent (Process for Non-Literate Participants):

I_____ (Name of Witness) certify that information given to

_____ (Name of Participant), in the local language, is a true reflection of what l have read from the study Participant Information Leaflet, attached.

WITNESS' SIGNATURE (maintain if participant is non-literate): _____

Statement of person witnessing accent (Process for Participants under 18 years):

I_____ (Name of Witness) certify that information given to

_____ (Name of Participant) is a true reflection of what l have read or had translated to me from the study Participant Information Leaflet, attached.

LEGAL GUARDIAN' SIGNATURE: _____

LEGAL GUARDIAN'S NAME: _____

INFORMED CONSENT FORM

Statement of person witnessing accent (Process for Non-Literate Participants under 18 years):

I_____ (Name of Witness) certify that information given to

_____ (Name of Participant), in the local language, is a true reflection of what l have read from the study Participant Information Leaflet, attached.

WITNESS' SIGNATURE (maintain if participant is non-literate): _____

APPENDIX 11 ENROLMENT VISIT FORM

STUDY ID NUMBER		
Date		
Interviewer code		
Woman's name		
Initials		
Age(years)		
Community of residence		
Health facility		
Health facility code		
Woman's address		
Telephone number		
A. SOCIO-DEMOGRAPHICS		
1. Age		
2. Parity		
3. Gravidity		
4. Gestational age of current pregnancy (months)		
5. Highest educational level (None/primary/JHS/SHS/Technical or vocational/ tertiary)		
6. Marital status (Married/ Not married)		
7. Occupation (None/farming/petty trading/artisan/ salaried worker		
B. ITN USE		
	Yes	**No**
1. Do you own an ITN?	☐	☐
2. Did you sleep under this ITN last night?	☐	☐
C. MEDICAL HISTORY		
1. Have you had any illness during your current pregnancy?	☐	☐
2. Did you visit any health facility with the illness above?	☐	☐
3. Were you told you had malaria?	☐	☐
4. Was the malaria diagnosed within the last two weeks of this visit?	☐	☐
5. Have you taken any antimalarial drug within the last two weeks?	☐	☐
6. Do you have a history of hypertension?	☐	☐
7. Do you have a history of diabetes mellitus?	☐	☐
8. Do you have a past history of jaundice?	☐	☐

ENROLMENT VISIT FORM

STUDY ID NUMBER	
Date	
Initials	
D. OBSTETRIC HISTORY	
	Yes **No**
1. Do you have a history of previous still birth?	☐ ☐
2. Do you have a history of spontaneous abortions?	☐ ☐
3. Do you have a history of small baby (birth weight of a baby < 2500g)?	☐ ☐
4. Have you had blood transfusion during pregnancy/delivery?	☐ ☐
5. Have you had any home deliveries?	☐ ☐
E. SYMPTOMS ASSESSMENT	
1. Have you felt unwell during the past three days?	☐ ☐
Have you had the following symptoms within the last three days?	☐ ☐
2. Fever	☐ ☐
3. Headache	☐ ☐
4.Weakness/Fatigue	☐ ☐
5.Body pains	☐ ☐
6. Joint pains	☐ ☐
7. Unable to eat	☐ ☐
8. Feeling like vomiting	☐ ☐
9. Watery stools	☐ ☐
10. Generalised abdominal pain	☐ ☐
11. Lower abdominal pain	☐ ☐
12. Urinary frequency	☐ ☐
13. Pain or discomfort in urinating	☐ ☐
14. Vaginal discharge and/or itch	☐ ☐
15. Cough	☐ ☐
16. Catarrh/Runny nose	☐ ☐
17. Sore throat	☐ ☐
18. Body itching	☐ ☐
19. Swelling of the feet	☐ ☐
20. Feeling of the heart beating harder/faster	☐ ☐
21. Bleeding per vagina	☐ ☐
22. Other-	

ENROLMENT VISIT FORM

STUDY ID NUMBER		
Date		
Initials		
F. PHYSICAL EXAMINATION		
	Yes	**No**
Temperature (^{0}C)		
2. Pulse/minute	☐	☐
3. Blood pressure (mmHg)	☐	☐
4. Symphysio-fundal height(cm)	☐	☐
5. Foetal heart beat heard using sonicaid	☐	☐
G. HISTORY OF DEWORMING		
1. Have you taken a de-wormer in the past one month?	☐	☐
2. Since you got pregnant, have you taken any de-wormer?	☐	☐

APPENDIX 12 LABORATORY FORM

STUDY ID NUMBER		
Date		
Woman's Initials		
Interviewer code		
Visit number (Enrolment, 1,2,3,4,5)		
1. HemoCue results (g/dl)		
	Yes	**No**
2. Blood film for malaria parasites done	☐	☐
3. Stool sample submitted	☐	☐
Continue with 4 and 5 only if in **intervention arm**		
4. HCS results (g/dl)	☐	☐
5. RDT results (Positive/Negative)	☐	☐

APPENDIX 13a TREATMENT FORM-INTERVENTION ARM

STUDY ID NUMBER		
Date		
Woman's Initials		
Interviewer code		
Visit number (Enrolment, 1,2,3,4,5)	Yes	No
1. Has pregnant woman been treated for malaria today?	☐	☐
2. If m RDT result for pregnant woman today is positive, why was she not treated for malaria?		
Antimalarial medicine not available in health facility	☐	
Pregnant woman refused antimalarial medicine	☐	
Other, specify	☐	
Not applicable	☐	
3. Which antimalarial medicine was she given?		
Quinine	☐	
ASAQ	☐	
AL	☐	
DHAPQ	☐	
Not applicable	☐	
	Yes	No
4. Was IPTp served?	☐	☐
5. Was iron supplementation given?	☐	☐
6. Was folate given?	☐	☐
7. Was a de-wormer served?	☐	☐
8. List any other medicines that were served		

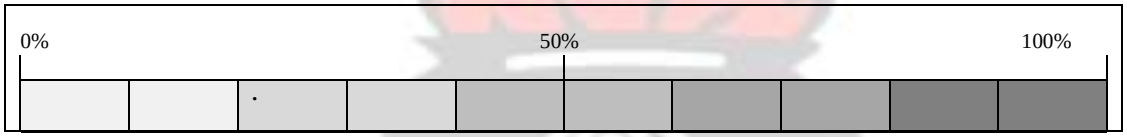
APPENDIX 13b TREATMENT FORM-CONTROL ARM

STUDY ID NUMBER		
Date		
Woman's Initials		
Interviewer code		
Visit number (Enrolment, 1,2,3,4,5)	Yes	No
1. Has pregnant woman been treated for malaria today?	☐	☐
2. How was the malaria diagnosed?		
After microscopy was done and it was positive	☐	
After an RDT was done and it was positive	☐	
Based only on clinical symptoms and signs	☐	
Other, specify	☐	
Not applicable	☐	
3. Which antimalarial medicine was she given?		
Quinine	☐	
ASAQ	☐	
AL	☐	
DHAPQ	☐	
Not applicable	☐	
	Yes	No
4. Was IPTp served?	☐	☐
5. Was iron supplementation given?	☐	☐
6. Was folate given?	☐	☐
7. Was a de-wormer served?	☐	☐
8. List any other medicines that were served		

APPENDIX 14 ADHERENCE AND KNOWLEDGE QUESTIONNAIRE

STUDY ID NUMBER	
Date	
Woman's Initials	
Interviewer code	
A. MEASUREMENT OF ADHERENCE TO IRON AND FOLATE SUPPLEMENTATION (THE VISUAL ANALOGUE SCALE)	

Please ask the respondent to put an "X" in a coloured box below at the point showing her best guess about how much of her medicines she has taken in the last 2 weeks (0 means none of medicines taken; 50% means half of medicines taken; 100% means all of medicines taken)



B. KNOWLEDGE ABOUT MALARIA AND ANAEMIA IN PREGNANCY		
	Mentioned	**Not mentioned**
1. How do people get malaria?		
a. From the bite of a (an infected) mosquito	☐	☐
b. By having collection of water in containers around house	☐	☐
c. By having chocked open gutters	☐	☐
d. By having weedy environments	☐	☐
e. By living in a dirty environment	☐	☐
f. By staying out late	☐	☐
2. Mention what "signs" will make a pregnant woman know that she has malaria		
a. Headache	☐	☐
b. Fever	☐	☐
c. Chills/feeling cold	☐	☐
d. Feeling like vomiting	☐	☐
e. Vomiting	☐	☐
f. Loss of appetite	☐	☐
g. Lower abdominal pains	☐	☐
h. Dizziness	☐	☐
i. Weakness/tiredness	☐	☐
j. Generalised abdominal pain	☐	☐
i. Other, specify	☐	☐

Adherence and Knowledge Questionnaire

STUDY ID NUMBER	
Date	
Initials	
	Mentioned Not mentioned
3. What effect can malaria have on the pregnant woman?	
a. She can develop anaemia	☐ ☐
b. She can die	☐ ☐
c. She can have any of the symptoms mentioned above	☐ ☐
d. She can fall sick	☐ ☐
e. Other, specify	☐ ☐
4. What effect can malaria have on the baby in the womb?	
a. The baby can die in the womb	☐ ☐
b. The baby can be aborted/miscarried	☐ ☐
c. The mother can have a miscarriage	☐ ☐
d. The mother can deliver a premature baby	☐ ☐
e. The baby born can be small for its age	☐ ☐
f. An unhealthy baby can be born	☐ ☐
g. Other, specify	☐ ☐
5. How can a pregnant woman prevent herself from getting malaria?	
a. By sleeping under an insecticide treated net	☐ ☐
b. By visiting the ANC clinic to receive the medicine (SP) given to prevent malaria	☐ ☐
c. By weeding her environment	☐ ☐
d. By keeping the environment clean	☐ ☐
e. By not allowing collection of water in pools or cans around the house	☐ ☐
f. By using insecticide spray, coils etc in the house	☐ ☐
g. By wearing protective clothing when out at night	☐ ☐
h. By screening doors and windows with net	☐ ☐
i. By not staying out late	☐ ☐
j. Other, specify	☐ ☐
6. How can a pregnant woman get anaemia?	
a. By getting malaria	☐ ☐
b. By not eating well nourished food	☐ ☐
c. By not taking the medicines given at the ANC clinic	☐ ☐
d. By not eating fruits	☐ ☐
e. By not eating green leafy vegetables	☐ ☐
f.Other, specify	☐ ☐

Adherence and Knowledge Questionnaire

STUDY ID NUMBER	
Date	
Initials	
	Mentioned Not mentioned
7. Mention what "signs" can make a pregnant woman know that she has anaemia	
a. Pallor (palms, soles of feet, beneath eyes, tongue)	☐ ☐
b. Dizziness	☐ ☐
c. Palpitations (Heart beating harder and faster)	☐ ☐
d. Swollen feet	☐ ☐
e. Weakness	☐ ☐
f. Tiredness	☐ ☐
g. Headaches	☐ ☐
h. Other, specify	☐ ☐
8. What effect can anaemia have of the pregnant woman?	
a. She can die	☐ ☐
b. She can have a miscarriage	☐ ☐
c. She can have any of the symptoms mentioned above	☐ ☐
d. She can bleed heavily after she delivers	☐ ☐
e. Other, specify	☐ ☐
9. What effect can anaemia have of the baby in the womb?	
a. The baby can die in the womb	☐ ☐
b. The baby can be born prematurely	☐ ☐
c. The baby can be aborted	☐ ☐
d. A small baby can be born	☐ ☐
e. Other, specify	☐ ☐
10. How can a pregnant woman prevent herself from getting anaemia?	
a. She should eat good nutritious food	☐ ☐
b. She should take the medicines she is given at the ANC clinic regularly	☐ ☐
c. She should eat green leafy vegetables	☐ ☐
d. She should eat fruits regularly	☐ ☐
e. She should visit the ANC regularly (on schedule) to receive her medicines	☐ ☐
f. Other, specify	☐ ☐

APPENDIX 15 DELIVERY FORM

STUDY ID NUMBER	
Date	
Woman's Initials	
Interviewer code	
1. Pregnancy outcome (Spontaneous abortion, Intra uterine foetal death, preterm delivery, term delivery, not known)	
2. Date of delivery/termination of pregnancy	
3.Place of delivery/termination of pregnancy	
4. Mode of delivery (Spontaneous vaginal delivery, caesarian section, assisted vaginal delivery, not applicable)	
5. Total number of babies born	
6. Foetal outcome	
Live birth/ Still birth	☐
Birth weight (kg)	☐☐.☐
Sex (male, female)	☐
7. Maternal outcome	
Alive, no complications	☐
Alive, with post partum haemorrhage, referred	☐
Alive, with post partum haemorrhage, not referred	☐
Maternal death	☐
Other, specify	
8. Cause of maternal death	
Post partum haemorrhage	☐
Eclampsia	☐
Post partum infection	☐
Other, specify	

APPENDIX 16 FOCUS GROUP DISCUSSION GUIDE FOR PREGNANT WOMEN ON 'CLIENT PARTICIPATION' CONCEPT

Introduction

My name is Afua Dufie. I am a student of KNUST. I am here today to have a discussion with you about certain aspects of your antenatal care. I would want to us to discuss why you come for antenatal care, what you know and understand about malaria and anaemia in pregnancy and what your experiences and perceptions are about some laboratory tests that were used during your antenatal care.

I will be visiting other ANC clinics in this district to have the same kind of conversation with some of the pregnant women like we will do today. I will not be referring to you by your real names but instead, I will give everybody a letter of the alphabet. No one will know about who participated. I am doing this because I do not want to associate names with the discussion we have. I want you to feel very free to express yourselves very well. Although I would want to record this conversation, the recording is so that I will be able to capture all the important things that you will tell me to enable me write a report out of it for my work. The discussion will be erased from the tape recorder as soon as I have written it out. This discussion is for academic purposes only and will remain as such.

I have .....here to assist me with the discussion. I believe you have already met him/her.

If you agree to take part, I would like to ask my assistant to put on the tape recorder and then you all answer 'yes, we agree' so that it is captured on the recorder.

Do you all agree to participate?

Objective 1 To describe pregnant women's general understanding of antenatal care	1. Why do/did you attend ANC clinic during your pregnancy? 2. Why do/did you attend ANC clinic repeatedly during your pregnancy? 3. What was done for you during your ANC? 4. How often are/were you expected to attend the ANC clinic? 5. What do/did you like about the ANC clinic? 6. What did you not like about the ANC clinic?
Objective 2 To explore pregnant women's knowledge and perceptions of malaria and anaemia in pregnancy	For malaria 1. Can you please tell me about malaria? 2. Are there any local names or descriptions for malaria? 3. What causes malaria? 4. What are some of the effects that malaria can have on the pregnant woman and baby in the womb? 5. How can malaria in pregnancy be prevented? For anaemia 6. Can you please tell me about anaemia? 7. Are there any local names or descriptions for anaemia? 8. What causes anaemia during pregnancy? 9. What are some of the effects that anaemia in pregnancy can have on the mother and baby in the womb? 10. How can anaemia in pregnancy be prevented?
Objective 3 To describe pregnant women's experiences and perceptions of the use of the RDT and HCS as tools to facilitate their participation in their antenatal care	1. Can you please tell me what is/was done for you when you attend(ed) ANC clinic? 2. Can you please describe what laboratory tests are/were done for you? 3. Who did the laboratory tests for you? 4. Where were the laboratory tests done for you (in the consulting room or laboratory)? 5. Do you know what the different tests were for? Please tell me what they were for. 6. Are/were the results of the laboratory tests explained to you? 7. What do/did you do with the explanations about the laboratory test results? How did the explanations you received affect your behaviour? 8. Did you have any questions about the laboratory tests or results? 9. Are/were you allowed to ask questions about the laboratory test results? 10. How satisfied were you with the answers you received? *(NB: If responses to Q6 &Q9 are in the negative, ask about how they would feel if the results were explained to them)* 11. Which would you prefer and why: laboratory tests done in the laboratory for you or done by the ANC staff during the consultation process? **For Rapid Diagnostic Test (Show an example)** 1. Have you seen this before? 2. What is it for? 3. Can you please describe how it is used?(Probe cleaning of fingers, pricking, drawing blood with pipette, dropping blood on cassette, adding buffer, waiting for results, reading and interpreting results) 4. Have you ever had this test before during ANC? 5. Who did the test for you? 6. Where was it done? During consultation with the midwife or in the laboratory? 7. What were the results of your test when it was done? 8. Did you understand the results of the test? How hard or easy to understand did you find the results of this test? 9. How did the results make you feel? 10. Did you receive any advice from the nurse or labman after the results of the test? 11. What advice did you receive? 12. Did you receive any medicines from the pharmacy after the results of the test? 13. What medicines did you receive?

	14. What effect did the results have on you? How did the results impact on your behaviour? Did the results make you change your behaviour in any way? 15. In what way did you change your behaviour?? *(For those who have not seen and experienced it before, demonstrate its use and show various results and interpretation. And ask the following questions)* 1. What do you think about the use of this test in antenatal care? Is this something you would like to be done for you? 2. Do you think you understand the results of the test? How hard or easy to understand did you find the results of this test? 3. Do you think the results of this test will have any effect on you? Will it make you change any behaviour of yours? In what way? 4. Who and where would you prefer to do the tests; by the midwives in the consulting room or by laboratory personnel in the laboratory? 5. Why would you prefer this to the other? (Depending on which route of administration is chosen in Q4) **For Haemoglobin Colour Scale (Please show an example)** 1. Have you seen this before? 2. What is it for? 3. Can you please describe how it is used?(Probe cleaning of fingers, pricking, drawing blood with filter paper, reading and interpreting results) 4. Have you ever had this test before during ANC? 5. Who did the test for you? 6. Where was it done? During consultation with the midwife or in the laboratory? 7. What were the results of your test when it was done? 8. Did you understand the results of the test? How hard or easy to understand did you find the results of this test? 9. How did the results make you feel? 10. Did you receive any advice from the nurse or labman after the results of the test? 11. What advice did you receive? 12. Did you receive any medicines after the test results? 13. What medicines did you receive? 14. What effect did the results have on you? How did the results impact on your behaviour? Did the results make you change your behaviour in any way? 15. In what way did you change your behaviour? *(For those who have not seen and experienced it before, demonstrate its use and show various results and interpretation. And ask the following questions)* 1. What do you think about the use of this test in antenatal care? Is this something you would like to be done for you? 2. Do you think you understand the results of the test? How hard or easy did you find the results of this test to understand? 3. Do you think the results of this test will have any effect on you? Will it make you change any behaviour of yours? In what way? 4. Who and where would you prefer to do the tests; by the midwives in the consulting room or by laboratory personnel in the laboratory? 5. Why would you prefer this to the other? (Depending on which route of administration is chosen in Q4)

APPENDIX 17 IN-DEPTH INTERVIEW GUIDE FOR PREGNANT WOMEN ON 'CLIENT PARTICIPATION' CONCEPT

Introduction

My name is Afua Dufie. I am a student of KNUST. I am here today to have a discussion with you about certain aspects of your antenatal care. I would want to us to discuss why you come for antenatal care, what you know and understand about malaria and anaemia in pregnancy and what your experiences and perceptions are about some laboratory tests that were used during your antenatal care.

I will be visiting other ANC clinics in this district to have the same kind of conversation with some of the women like we will do today. I will not be referring to you by your real name. I am doing this because I do not want to associate any name with the discussion we have. I will use a code identify you and show where you had you ANC. I want you to feel very free to express yourself very well. Although I would want to record this conversation, the recording is so that I will be able to capture all the important things that you will tell me to enable me write a report out of it for my work. The discussion will be erased from the tape recorder as soon as I have written it out. This discussion is for academic purposes only but may inform policy and practice later after I have written it out.

If you agree to take part, I would to put on the tape recorder and then you all answer 'yes, I agree' so that it is captured on the recorder.

Do you agree to participate?

Objective 1 To describe pregnant woman's general understanding of antenatal care	1. Why do/did you attend ANC clinic during your pregnancy? 2. Why do/did you attend ANC clinic repeatedly during your pregnancy? 3. What was done for you during your ANC? 4. How often are/were you expected to attend the ANC clinic? 5. What do/did you like about the ANC clinic? 6. What did you not like about the ANC clinic?
Objective 2 To explore pregnant woman's knowledge and perceptions of malaria and anaemia in pregnancy	For malaria 1. Can you please tell me about malaria during pregnancy? *Prompts*-Any local names or descriptions for malaria? -Causes of malaria -Effects of malaria on the pregnant woman and baby in the womb -Treatment and prevention of malaria in pregnancy For anaemia 2. Can you please tell me about anaemia? *Prompts*- Any local names or descriptions for anaemia? -Causes of anaemia during pregnancy -Effects of anaemia on the mother and baby in the womb - Prevention and treatment of anaemia in pregnancy
Objective 3 To describe pregnant women's experiences and perceptions of the use of the RDT and HCS as tools to facilitate their participation in their antenatal care	1. Can you please tell me what is/was done for you when you attend(ed) ANC clinic? 2. Can you please describe what laboratory tests are/were done for you? Prompts-Who did the laboratory tests for you? - Where the laboratory tests were done (in the consulting room or laboratory)? -Different tests done -Results explained? -What you did with the explanations about the laboratory test results? -How the explanations received affected behaviour? -Any questions about the laboratory tests or results? -Allowed to ask questions about the laboratory test results? –Satisfaction with the answers you received? *(NB: If responses to prompts about results explanations are in the negative, ask about how they would feel if the results were explained to them)* 3. Which would you prefer and why: laboratory tests done in the laboratory for you or done by the ANC staff during the consultation process? **For Rapid Diagnostic Test (Show an example)** 1. Have you seen this before? 2. What is it for? 3. Can you please describe how it is used?(Probe cleaning of fingers, pricking, drawing blood with pipette, dropping blood on cassette, adding buffer, waiting for results, reading and interpreting results) 4. Have you ever had this test before during ANC? 5. Who did the test for you? 6. Where was it done? During consultation with the midwife or in the laboratory? 7. What were the results of your test when it was done? 8. Did you understand the results of the test? How hard or easy to understand did you find the results of this test? 9. How did the results make you feel? 10. Did you receive any advice from the nurse or labman after the results of the test? 11. What advice did you receive? 12. Did you receive any medicines from the pharmacy after the results of the test?

	13. What medicines did you receive? 14. What effect did the results have on you? How did the results impact on your behaviour? Did the results make you change your behaviour in any way? 15. In what way did you change your behaviour?? 16. *(For those who have not seen and experienced it before, demonstrate its use and show various results and interpretation. And ask the following questions)* 17. What do you think about the use of this test in antenatal care? Is this something you would like to be done for you? 18. Do you think you understand the results of the test? How hard or easy to understand did you find the results of this test? 19. Do you think the results of this test will have any effect on you? Will it make you change any behaviour of yours? In what way? 20. Who and where would you prefer to do the tests; by the midwives in the consulting room or by laboratory personnel in the laboratory? 21. Why would you prefer this to the other? (Depending on which route of administration is chosen in Q4) **For Haemoglobin Colour Scale (Please show an example)** 1. Have you seen this before? 2. What is it for? 3. Can you please describe how it is used?(Probe cleaning of fingers, pricking, drawing blood with filter paper, reading and interpreting results) 4. Have you ever had this test before during ANC? 5. Who did the test for you? 6. Where was it done? During consultation with the midwife or in the laboratory? 7. What were the results of your test when it was done? 8. Did you understand the results of the test? How hard or easy to understand did you find the results of this test? 9. How did the results make you feel? 10. Did you receive any advice from the nurse or labman after the results of the test? 11. What advice did you receive? 12. Did you receive any medicines after the test results? 13. What medicines did you receive? 14. What effect did the results have on you? How did the results impact on your behaviour? Did the results make you change your behaviour in any way? 15. In what way did you change your behaviour? 16. *(For those who have not seen and experienced it before, demonstrate its use and show various results and interpretation. And ask the following questions)* 17. What do you think about the use of this test in antenatal care? Is this something you would like to be done for you? 18. Do you think you understand the results of the test? How hard or easy did you find the results of this test to understand? 19. Do you think the results of this test will have any effect on you? Will it make you change any behaviour of yours? In what way? 20. Who and where would you prefer to do the tests; by the midwives in the consulting room or by laboratory personnel in the laboratory? 21. Why would you prefer this to the other? (Depending on which route of administration is chosen in Q4)

APPENDIX 18 IN-DEPTH INTERVIEW GUIDE FOR ANC STAFF ON 'CLIENT PARTICIPATION' CONCEPT

Introduction

Good day! My name is Gifty Antwi. I am a PhD student of KNUST conducting a research project in your ANC clinic. I am here today to have a discussion with you about certain aspects of ANC. I would want to us to discuss malaria and anaemia in pregnancy and what your experiences and perceptions are about some laboratory tests that are being used during antenatal care; the RDT and HCS.

I will be visiting other ANC clinics in this district to have the same kind of conversation with other ANC staff like we will do today. I will not be referring to you by your real. I am doing this because I do not want to associate names with the discussion we have. I want you to feel very free to express yourself very well and to share your opinion with me. I would want to record this conversation but with your permission, so that I will be able to capture all the important things that you will tell me to enable me write a report out of it for my work. The discussion will be erased from the tape recorder as soon as I have written it out. This discussion is for academic purposes only but may be used to inform policy and practice after it has been published. I promise not to take more than 40 minutes of your time.

If you agree to take part, I would like to put on the tape recorder and then you answer 'yes, I agree' so that it is captured on the recorder.

Do you agree to participate in this interview?

Objective 1 To describe ANC staff understanding of antenatal care	1. Why should a pregnant woman attend ANC clinic? 2. How many times should a pregnant woman visit the ANC clinic? 3. Why should the pregnant woman attend this number of times? 4. What do you do for a pregnant woman when she attends ANC? Could you please describe the processes the woman goes through before ending her ANC? 5. Why do you take the pregnant women through all these processes?
Objective 2 To explore ANC staff knowledge and perceptions of malaria and anaemia in pregnancy	For malaria 11. What are some of the common symptoms and signs that a pregnant woman who has malaria will present with? 12. What are some of the effects that malaria can have on the pregnant woman and baby in the womb? 13. How can you confirm that a pregnant woman has malaria?? 14. How is malaria in pregnancy treated? 15. How can a pregnant woman prevent herself from getting malaria? For anaemia 16. What are some of the common symptoms and signs that a pregnant woman who has anaemia will present with? 17. How can you confirm that a pregnant woman has anaemia? 18. How is anaemia in pregnancy treated? 19. What are some of the effects that anaemia in pregnancy can have on the mother and baby in the womb? 20. How can a pregnant woman prevent herself from getting anaemic?
Objective 3 To describe ANC staff experiences in the use of the RDT and HCS as tools to encourage pregnant women's participation in antenatal care	*1.* Can you please describe what you do for a pregnant woman when she visits the antenatal clinic for the first time? *(probe the following areas:* • *Health Education* • *Physical examination and palpation* • *Laboratory investigations* • *Consultation/recommendations* • *Medication* *2.* What laboratory tests do you do for the pregnant woman? *3.* Which ones do you refer to the laboratory to be done? 4. How do you feel about doing some tests yourself for the pregnant woman? Can you please share some of your experiences with me? 5. If you could do all the laboratory tests required for the pregnant woman yourself during the consultation period how would you feel about it? 6. Which would you prefer and why: laboratory tests for pregnant women done in the laboratory or done by the ANC staff during the consultation process? For Rapid Diagnostic Test (Show an example) 16. Have you seen this before? 17. What is it for? *18.* Can you please describe how it is used? *(Probe cleaning of fingers, pricking, drawing blood with pipette, dropping blood on cassette, adding buffer, waiting for results, reading and interpreting results)* 19. Have you ever used it during your consultations before? 20. How did you find its use? (*Probe with respect to workload and time*) 21. How hard or easy is it to read and interpret the results? 22. What do you think about the results that it gives? In your opinion are they reliable? Do you believe in the results of this test? *23.* What do you do with the results after you have performed the test? What advice or medicines do you give? *(probe what is done with the*

	pregnant woman too) 24. What effect do you think the doing of the test and the interpretation of the results has on the pregnant woman? In your opinion could it lead to any behaviour change in the pregnant woman? In what way? *(For those who have not seen and experienced it before, demonstrate its use and show various results and interpretation. And ask the following questions)* 6. What do you think about the use of this test in routine antenatal care? Is this something you would like to do for the pregnant women? 7. How hard or easy is it to read and interpret the results? 8. What do you think about the results that it gives? In your opinion are they reliable? Do you believe in the results of this test? 9. How do you compare this test to doing microscopy for malaria? 10. What do you do with the results after you have performed the test on a pregnant woman? What advice or medicines would you give? (probe what will be done with the pregnant woman too) 11. What effect do you think the doing of the test and the interpretation of the results will have on the pregnant woman? In your opinion could it lead to any behaviour change in the pregnant woman? In what way? For Haemoglobin Colour Scale (Please show an example) 1. Have you seen this before? 2. What is it for? 3. Can you please describe how it is used? (Probe cleaning of fingers, pricking, drawing blood with the filter paper, reading and interpreting results) 4. Have you ever used it during your consultations before? 5. How did you find its use with respect to workload? And time consumption? 6. How hard or easy is it to read and interpret the results? 7. What do you think about the results that it gives? In your opinion are they reliable? Do you believe in the results of this test? 8. How do you compare the results that it gives to the results from the laboratory? 9. What do you do with the results after you have performed the test? What advice or medicines do you give? (probe what is done with the pregnant woman too) 10. What effect do you think the doing of the test and the interpretation of the results has on the pregnant woman? In your opinion could it lead to any behaviour change in the pregnant woman? In what way? *(For those who have not seen and experienced it before, demonstrate its use and show various results and interpretation. And ask the following questions)* 1. What do you think about the use of this test in antenatal care? Is this something you would like to do for the pregnant women? 2. How hard or easy is it to read and interpret the results? 3. What do you think about the results that it gives? In your opinion are they reliable? Do you believe in the results of this test? 4. What would you do with the results after you have performed the test on a pregnant woman? What advice or medicines would you give? (probe what will be done with the pregnant woman too) 5. What effect do you think the doing of the test and the interpretation of the results will have on the pregnant woman? In your opinion could it

	lead to any behaviour change in the pregnant woman? In what way? 1. Can you please tell me how you think the pregnant woman's seeing of the tests (HCS and RDT) being done for her and the results and interpretation of them affects her behaviour? 2. Do you think it is necessary to engage them in their antenatal care in this way? Why? 3. Did /do you think the pregnant women got/will get any benefits from engaging them in doing the tests with you? Mention some of the benefits 4. Were there/do you anticipate any negative feelings from the pregnant women about the use of the RDT and HCS test during their antenatal care? Can you please mention them to me? 5. In your opinion, what can be done better during antenatal care to engage pregnant women in their care?

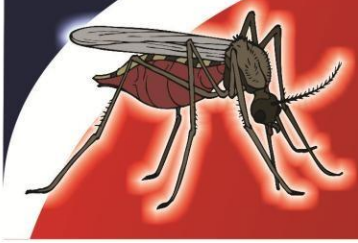
APPENDIX 3 DESK GUIDE FOR IMPLEMENTATION OF CLIENT PARTICIPATION IN ANTENATAL CARE

A DESK GUIDE

FOR

THE IMPLEMENTATION OF THE 'CLIENT PARTICIPATION CONCEPT'

FOR



MALARIA AND ANAEMIA

IN

PREGNANCY

This desk guide was developed by:

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Malaria Capacity Development Consortium

Department of Community Health

School of Medical Sciences

KNUST

as part of research work towards the award of a PhD in Community Health.

Illustrations by

Sela Adjei

Eric Andre

Purpose of this desk guide

This desk guide has been developed to provide a simple guide for antenatal care service providers to implement an enhanced antenatal care package for the management of malaria and anaemia in pregnancy.

It is also intended to be used by the antenatal care service providers as a reference manual for the implementation of the enhanced antenatal service package.

Acknowledgements

This work was supported by the Malaria Capacity Development Consortium (MCDC) which is funded by The Wellcome Trust (Grant number WT084289MA).

Supervised by

1. Imelda Bates (MD MA FRCP FRCPath) of the Liverpool School of Tropical Medicine
2. Harry Tagbor (MBCHB DrPH) of the Kwame Nkrumah University of Science and Technology

Contents

Introduction

This desk guide aims at guiding antenatal care service providers in the use of the malaria rapid diagnostic test (RDT) and the haemoglobin colour scale (HCS). It will also guide them to encourage pregnant women to participate in the diagnosis and management of malaria and anaemia with the help of a pictorial guide and the RDT and HCS tests. It will take antenatal care service providers through the following:

1. How to do the malaria Rapid Diagnostic Test and Haemoglobin Colour Scale test
2. How to read the malaria Rapid Diagnostic Test results
3. How to read the Haemoglobin Colour Scale test results
4. How to encourage the pregnant woman to participate in the diagnosis and management of malaria and anaemia

Guide 1. How to do the malaria Rapid Diagnostic Test and Haemoglobin Colour Scale test

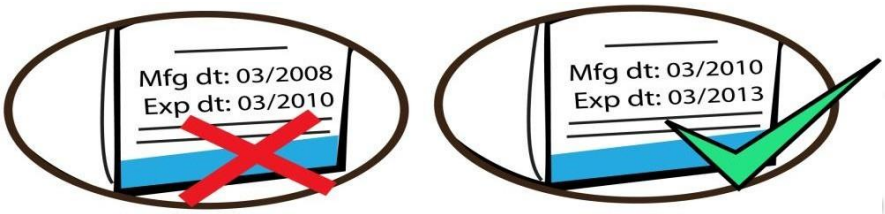
Specific steps

STEP 1. Assemble all you will need for the tests.

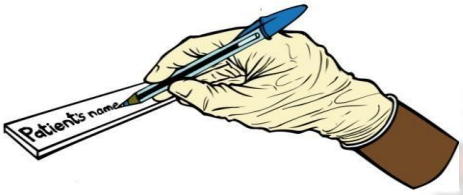
mRDT	HCS
A new unopened test packet	Approved only test-strips
Buffer	A corresponding Haemoglobin colour scale
A new pair of gloves , A new unopened alcohol swab, A new blood lancet, A timer,	
Sharps disposable container, non-sharps disposable container	

STEP 2: **Ensure a well lighted environment. Avoid direct sunlight and marked shade. Avoid your own shadow or any other shadow.**

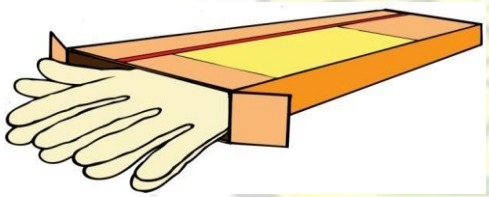
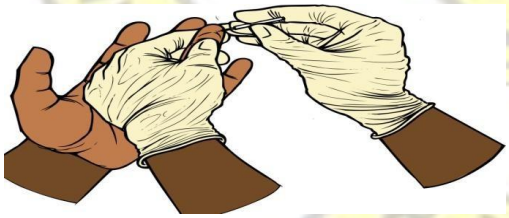
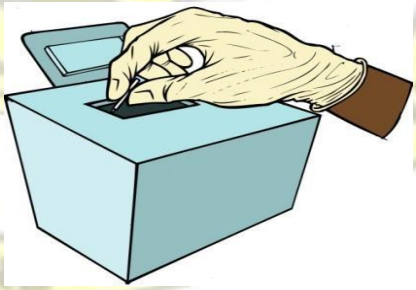
STEP 3: Check the expiry date on the test kit (Do not use if expired!)



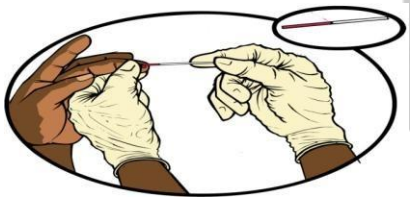
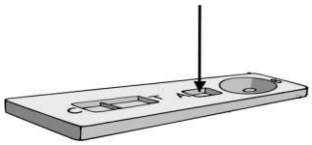
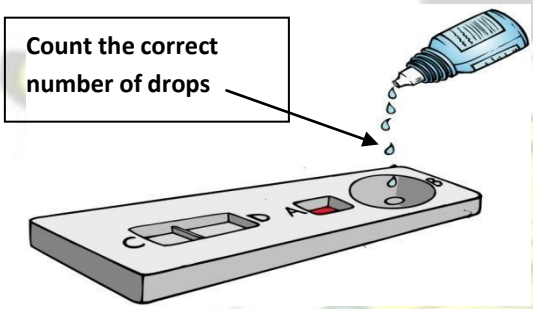
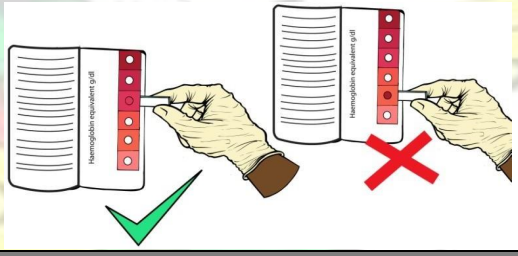
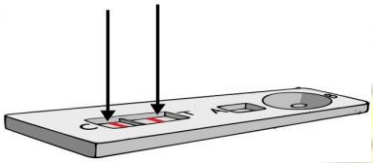
STEP 4. Label tests kits appropriately with the client name and date



STEP 5: Ensure sterile conditions to obtain blood sample

a. Put on a new pair of gloves 	**b. Open the alcohol swab; hold the fourth finger of patient's left hand. Clean with alcohol swab and allow drying.** 
c. Open the lancet; prick the patient's finger to get a drop of blood. 	**d. Put the used lancet immediately into the sharps disposable container.** 

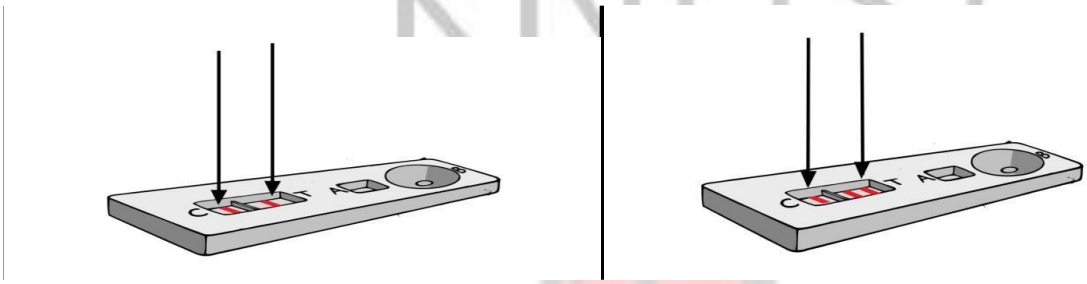
STEP 6: Perform the mRDT and HCS tests, one after the other.

mRDT	HCS
a. Use the capillary tube to collect the drop of blood. Make sure the blood does not exceed the mark in the capillary tube. 	a. Add a drop of blood to one end of the test-strip. This should be just enough to completely cover an aperture in the Colour Scale. 
b. Drop the blood into the test window (marked with an arrow) 	b. Wait for about 30 seconds 
c. Add buffer into the round hole 	c. Read immediately by comparing the blood stain with the Colour scale to find the best colour match. Keep the test-strip close to the back of the Colour Scale. 
d. Wait for time stipulated in the test kit pack to read the results 	
e. Read the test results. Do not read the test sooner than the time stipulated in the test kit packet after adding the buffer. It might give you wrong results!) 	

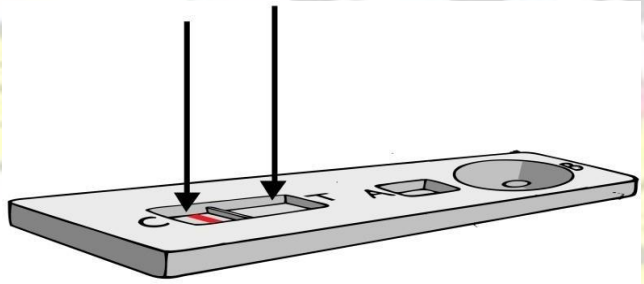
STEP 7: Dispose of all used test kits, capillary tubes, alcohol swabs, gloves appropriately into the sharps and non-sharps containers after recording the test results.

Guide 2. How to read the malaria Rapid Diagnostic Test results

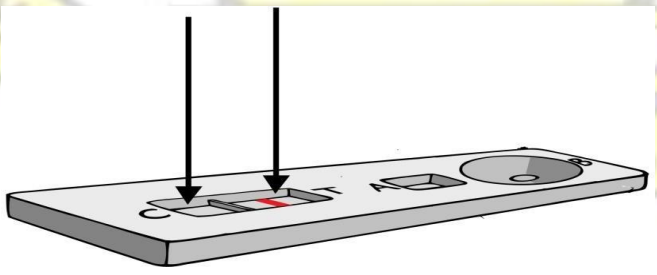
1. **POSITIVE RESULTS: A stained line near letter 'C'** followed by **one or two lines near letter 'T'** means patient is positive for malaria.



2. **NEGATIVE RESULTS: A line near letter 'C'** followed by **no lines near letter 'T'** means the patient does not have malaria.

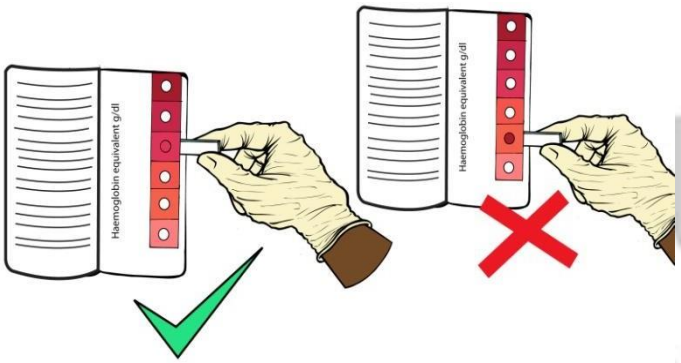


3. **INVALID RESULTS: No line near 'C'** and one or two lines or no line near 'T' means the test is invalid. The result **cannot be used**. **Repeat** the test using a **new unopened test packet** and a **new unopened lancet.**

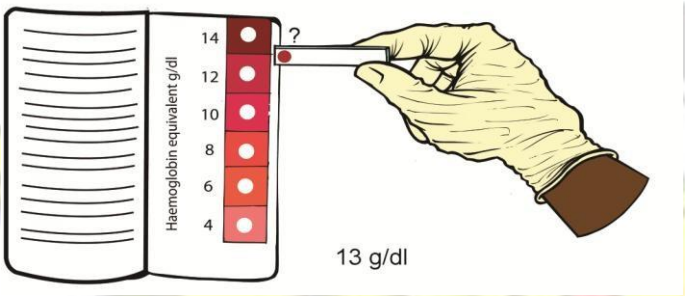


Guide 3. How to read the Haemoglobin Colour Scale results

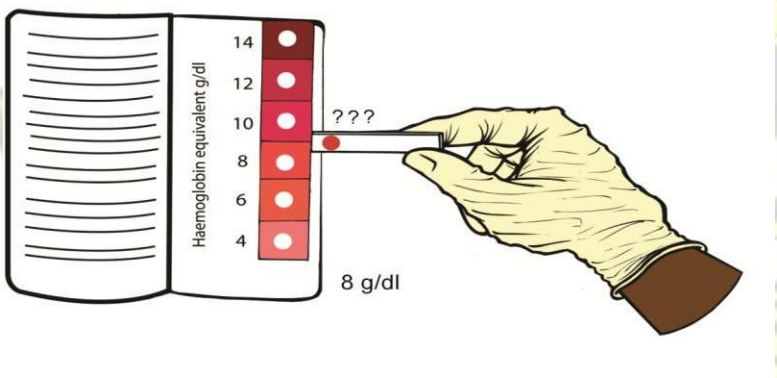
1. If the blood stain matches one of the shades of red exactly, record the haemoglobin value.



2. If the colour lies between two shades, record the mid-value.



3. If in doubt between two shades, record the lower value



Guide 4. How to encourage the pregnant woman to participate in the diagnosis and management of malaria and anaemia

The pictorial guide has been developed to aid in the client participation process between the pregnant women and the antenatal care provider. It is made up of a series of pictures to help educate the pregnant woman on malaria and anaemia in pregnancy before the mRDT and HCS tests are performed.

1. Seat the pregnant woman opposite the ANC provider.
2. Flip over the pictorial guide to show the pictures to the pregnant woman while asking her to interpret the pictures.
3. Correct any misinterpretations given by the pregnant woman whiles flipping through the guide until the whole guide has been used.
4. Perform the RDT and HCS tests whilst asking the pregnant woman to observe closely and ask any questions she may have.
5. Interpret the results with the pregnant woman.
6. Record the results of the tests in the corresponding columns of the checklist for the participatory consultation attached in the Maternal Health Record Book.
7. Ask the subsequent questions and tick appropriate columns.
8. Based on test results and answers to the questions asked, aid the pregnant woman to decide on what she intends to do to improve upon her health status.
9. Add on appropriate recommendations.
10. Schedule the pregnant woman for her next ANC clinic visit and record the date.

Some examples of recommendations given at the ANC clinic for malaria and anaemia in pregnancy

1. Encouraging the pregnant woman to use the insecticide treated bed net
2. Encouraging the pregnant woman to wear protective clothing in the night
3. Encouraging daily iron and folate supplementation intake
4. Encouraging the pregnant woman to report to the hospital as soon as she feels unwell, especially with symptoms of malaria
5. Encouraging the completion of antimalarial medicines given for treating malaria
6. Encouraging the pregnant woman to keep to her scheduled ANC visits. This will ensure she receives SP-IPTp and regular supply of iron and folate supplementation
7. Encouraging the pregnant woman to eat fruits and vegetables.
8. Encouraging pregnant woman to eat nutritious food.

Appendix 1: Check list for participatory consultation of pregnant women with ANC staff

(To be used by the ANC staff)

Date			
	Visit 1	Visit 2	Visit at 38 +/- 2 weeks
Haemoglobin colour scale results			
Rapid diagnostic test results			
Does she own an ITN?			
Did she sleep under an ITN last night?			
Did she finish taking all her routine medicines?			
Next ANC visit date			

APPENDIX 4 PICTORIAL GUIDE FOR MALARIA AND ANAEMIA IN PREGNANCY

A PICTORIAL GUIDE TO THE COMMON SYMPTOMS, EFFECTS AND PREVENTION OF MALARIA AND ANAEMIA IN PREGNANCY

A COMMUNICATION TOOL KIT

1

1. COMMON SYMPTOMS OF MALARIA

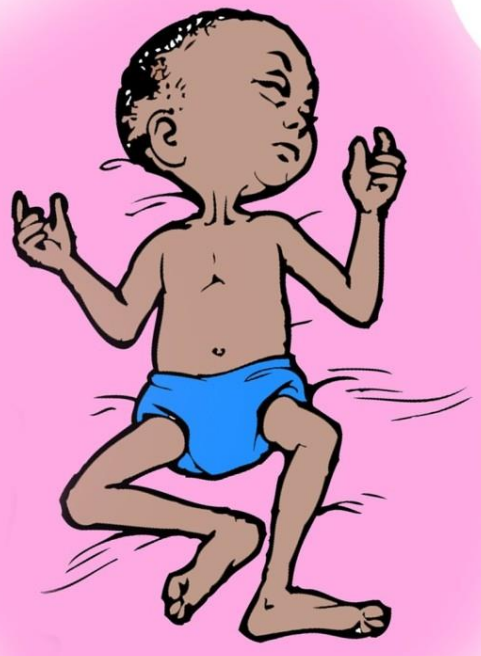
- HEADACHE
- FEVER
- JOINT PAINS
- LOSS OF APPETITE
- FEELING COLD/SHIVERING

2

2. COMMON SYMPTOMS OF MALARIA

- VOMITING
- DIZZINESS
- TIREDNESS/WEAKNESS
- LOWER ABDOMINAL PAIN

3



3. EFFECTS OF MALARIA ON PREGNANT WOMEN

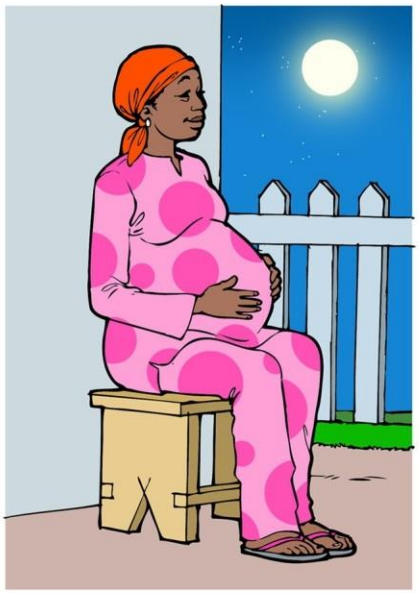
- ANAEMIA
- SPONTANEOUS ABORTION
- WEAK SICKLY BABY / SMALL FOR AGE BABY/ LOW BIRTH WEIGHT PRETERM

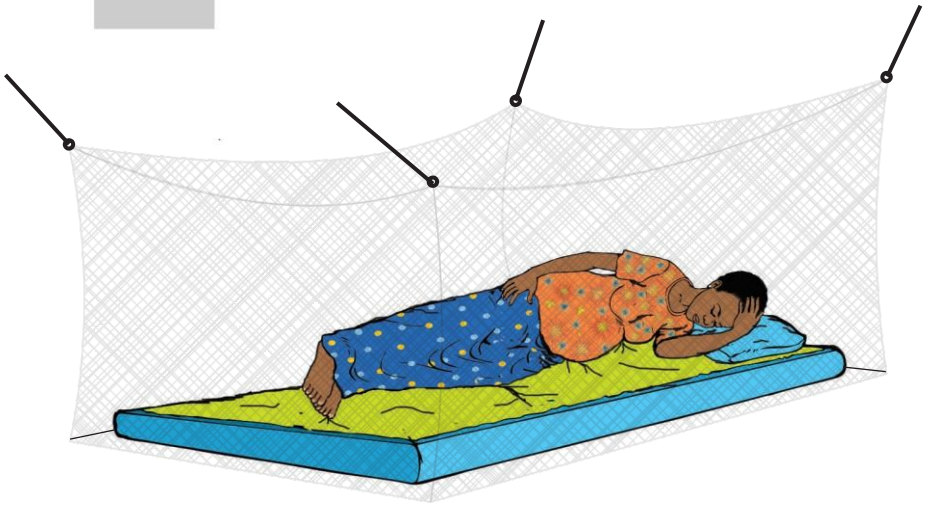
4

4. SYMPTONS/ EFFECTS OF ANAEMIA IN PREGNANCY

- SWELLING OF THE FEET
- PALPITATIONS
- DIZZINESS
- POST PARTUM HAEMORRHAGE

5





5. PREVENTION OF MALARIA DURING PREGNANCY

- SLEEPING UNDER INSECTICIDE TREATED BED NETS
- USE OF PROTECTIVE CLOTHING AT NIGHT WHEN OUTSIDE
- TAKING OF SP (FANSIDAR) THREE TIMES DURING PREGNANCY AT THE ANC CLINIC
- USE OF REPELLENTS
- REPORTING PROMPTLY TO THE ANC CLINIC WITH SYMPTOMS OF MALARIA FOR TREATMENT

6

6. PREVENTION OF ANAEMIA DURING PREGNANCY

- TAKING ROUTINE MEDICINES GIVEN AT ANC REGULARLY
- DEWORMING
- EATING FRUITS AND A NUTRITIOUS MEAL

7

VALUED OUTCOME

- HEALTHY HAPPY MOTHER AND BABY