Factors Influencing Utilization of Iron and Folic Acid Supplementation Services among Women Attending Antenatal Clinic at Nyeri Provincial Hospital Kenya

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DECLARATION

This thesis is my originaI work and has not been presented for a degree in any other University.

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DEDICATION

I dedicate this work to my husband John Mwai, my son Mark Mwai, my mum Mary Wangui, my dad Joseph Gathigi, my cousin Lucy Nyandia and Miss Wakini Kariuki, former headmistress Naromoru Girls Secondary School.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF PLATES

LIST OF APPENDICES

LIST OF ABBREVIATION AND ACRONYMS

ACC/SCN	Administrative Committee on Coordination/Subcommittee on Nutrition
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal clinic
CDC	Centre for Disease Control and Prevention
CLSI	Clinical Laboratory Standards Institute
DNA	Deoxyribonucleic acid
ELISA	Enzyme-linked immunosorbent assay
FAO	Food Agricultural Organization
FDA	Food and Drug Administration
FNBIM	Food and Nutrition Board, Institute of Medicine
GOK	Government of Kenya
Hb	Haemoglobin
HIV	Human Immune deficiency Virus
ID	Iron Deficiency
INACG	International Anaemia Consultative Group
IOM	Institute of Medicine
MOPHS	Ministry of Public Health and Sanitation
MRC	Medical Research Council
OR	Odds ratio
PGH	Provincial General Hospital
RNA	Ribonucleic acid

sTFR	Soluble Transferrin Receptor
UNICEF	United Nations Children's Fund
USA	United States of America
WHO	World Health Organization

OPERATIONAL TERMS

Anaemia: Haemoglobin concentration below established cut-off levels depending on age, sex and physiological status. Anaemia will be defined as Hb concentration <110 g/L among pregnant women.

Iron deficiency: A state of insufficient iron to maintain normal physiological functions of tissues.

Iron deficiency anaemia: An advanced stage of iron depletion defined as iron deficiency and low haemoglobin resulting in the condition of anaemia.

Supplementation Provision of specified dose of nutrient preparation which may be in the form of tablet, capsule, oil solution or modified food for either treating an identified deficiency or prevention of the occurrence of such a deficiency in an individual

Receipt of supplements: The act of a pregnant woman being dispensed to or handed out the recommended supplements such as iron and folic acid supplements

Use of supplements: The act of a pregnant woman ingesting supplements such as folic acid and iron supplements

Utilization: Coverage of iron and folic acid supplementation services (receipt and use of supplements)

ABSTRACT

Iron deficiency is the most common nutritional cause of anaemia and has been associated with poor pregnancy outcome. On the other hand, lack of adequate folate intake prior to conception and during the early weeks of pregnancy increases the risk of the development of neural tube defects. In Kenya all pregnant women are targeted for free folic acid and iron supplementation. However, information about whether folic acid and iron supplements are actually used by the women is not available, and there is concern that women would not take them because of perceived side effects, particularly of iron supplements. This study aimed at determining factors associated with utilization of iron and folic acid supplementation services and the prevalence of anaemia among pregnant women attending antenatal clinic at Nyeri Provincial General Hospital. A cross sectional study was conducted among pregnant women selected through systematic random sampling. A semi-structured questionnaire was administered to collect information on receipt and use of supplements where high compliance to supplementation was defined as using each of the supplements for more than four days in a week. After administration of the questionnaire, haemoglobin level was determined directly from capillary blood via finger pricks and measured using a portable HemoCue B-Hb photometer. Of the 381 women interviewed, 51.2% and 69.3% reported being given iron and folic acid supplements respectively. Less than half 44.6 % and 58% reported receiving information on iron and folic acid respectively. Of the women who received supplements, 67.7% reported being initiated on iron supplements after 16 weeks gestation while 80.7% reported being initiated on folic acid supplements after 12 weeks. The most frequently

cited reason by the women for not taking the supplements was not receiving supplies of iron (89.4%) and folic acid (81.3%) supplements during ANC visits. Among those who reported receiving iron and folic acid supplements, 80.5% and 82.2% reported high compliance respectively.The prevalence of anaemia was 7.8%. The mean haemoglobin level was 12.6±1.2 g/dl. In multivariate analysis the only factor that was significantly associated with compliance to iron supplements (p=0.05) was to protect oneself from anaemia (OR=12.20). While factors significantly associated with compliance to folic acid supplementation (P=0.05) were: in order to improve general health (OR=20.82), because the health worker advised to take folic acid supplements (OR=56.02) and to protect oneself from anaemia (OR=14.10). Improvement in supplies of the supplements, sensitization and training of health workers to give information while delivering supplementation services and sensitization of community members on the importance of early supplementation during pregnancy is required.

CHAPTER ONE: INTRODUCTION

1.1 Background

Iron and folate are micronutrients as they are required in minute amounts for normal functioning, growth and development. Iron has several functions in the body which include: (i) It is a constituent of haemoglobin in the red blood cells which is responsible for transportation of oxygen from lungs to the cells; (ii) It is a constituent of myoglobin which serves as an important reservoir of oxygen to the muscles; (iii) It is essential in the synthesis of hormones and neurotransmitter; (iv) It is a component of many enzymes that are required for metabolism of glucose and fatty acids for energy and it is also essential in the body's immune function. The recommended dietary allowance for iron among non pregnant women is 18 mg per day (Wardlaw *et al.*, 2004). However, during pregnancy physiologic demand for iron increase from 0.8 to 7.5 mg absorbed iron per day and the recommended allowance increases to 30 mg per day (Barrett *et al.*, 1994).

Iron deficiency (ID) is a state of insufficient iron to maintain normal physiological functions of tissues. Iron deficiency leads to anaemia. While there are multiple causes of anaemia, it is generally estimated that approximately one half of the cases result from iron deficiency (WHO, 1992). At least one half of anaemia cases occurring during pregnancy are due to nutritional iron deficiency (Jane *et al.*, 2007). It is most prevalent and severe in young children and women of reproductive age. Global estimates show that 42% of women are anaemic. In Kenya 55% of women are estimated to be anaemic

and moderate to severe anaemia is higher among pregnant women than among non-pregnant women (Mwaniki *et al*., 1999).

On the other hand folate is an essential micronutrient in the human body. Its function include the following: (i) It is important for normal cell division as it is required in the synthesis of DNA; (ii) It is important in the formation and maturation of red blood cells; (iii) It works closely with Vitamin B12 in the enhancement of some enzymatic reactions such as in the formation of essential amino acids and derivatives. The recommended dietary allowance for folic acid among non-pregnant women is 170 µg. However, during pregnancy the recommended dietary allowance rises to 400 µg (Wardlaw *et al*., 2004). Deficiency of folate can result from factors such as insufficient dietary intake and high consumption of alcohol. The global prevalence as well as the prevalence of folate deficiency in Kenya has not been established (MOPHS, 2008). However, folate deficiency leads to adverse effects; a maternal deficiency of folate has been linked to the development of neural defects in the infants (Zhu *et al.*, 2009). Deficiency may also lead to megaloblastic anaemia (Wardlaw *et al*., 2004).

In Kenya, a number of interventions have been designed to prevent or correct iron deficiency anaemia and folate deficiency (MOPHS, 2008). These include: food fortification, dietary diversification and modification, malaria control, helminthes control and supplementation of folic acid and iron. Supplementation has the advantage of being capable of supplying an optimal amount of a specific nutrient or nutrients, in a highly

absorbable form, and is often the fastest way to control deficiency in individuals or population groups that have been identified as being deficient (WHO, 2006). According to the Kenya national guidelines (2008), all pregnant women are to receive free iron and folic acid supplements through the essential drug kit of the Ministry of Public Health and Sanitation. National recommendations are for women to begin supplementation during the first month of pregnancy or at the time of their first antenatal clinic (ANC) with 60 mg of iron sulphate and 400 µg of folic acid daily (MOPHS, 2008). Some industries have begun voluntarily fortifying foods such as maize, flour, sugar and fats and oils. In addition, current government work plans include community-based programmes to promote improved iron status through dietary change while deworming is done as part of a school health project. There is also routine collection of Hb concentration data at the antenatal clinics. However, there has been no adequate monitoring of the interventions and there has also been no feedback on the effectiveness of the programmes.

1.2 Problem Statement

Iron deficiency is the leading single nutrient deficiency in the world affecting the lives of more than 2 billion people. Pregnant women are particularly at high risk of iron and folate deficiency due to increased nutrient requirement. In developing countries infections such HIV/AIDS, malaria, and TB also lead to increased demand for micronutrients. Worldwide anaemia prevalence data suggest that normal dietary intake of iron is insufficient to meet daily requirement for a significant proportion of pregnant women (WHO and CDC, 2008). On the other hand folic acid deficiency can lead to

adverse consequences such as haematological consequences, pregnancy complications and congenital malformations (Black, 2001).

As an intervention supplementation programmes for iron and folic acid have been put in place. In Kenya all pregnant women are targeted for free supplementation of folic acid and iron supplements. The daily dose is 60 mg of iron sulphate and 400 µg of folic acid from the first month of pregnancy or on first contact (MOPHS, 2008). Despite the presence of these programmes there is still high prevalence of anaemia with 54% of women of reproductive age and 69% of pregnant women estimated to be anaemic (Mwaniki *et al.,* 1999). There is little feedback about the effectiveness of these programmes countrywide and there is concern that women would not take the supplements due to perceived side effects, particularly of iron supplements. There is therefore need to obtain evidence about implementation of these programmes and the factors influencing utilization of the supplements.

1.3 Justification

Micronutrient deficiencies have many adverse effects. Among others these include: impaired cognitive development, neurological dysfunction, poor work performance, impaired immunity, increased susceptibility to infections and poor maternal nutrition and pregnancy outcomes (Hunt, 2002, INACG, 2002b, WHO, 2001). In places where deficiency is prevalent effective control programmes may yield benefits to human health. Benefits include improved physical performance and cognitive development in young

children. Amongst pregnant women, there is decreased maternal mortality, obstetrical complications and improved pregnancy outcomes, while on infants it reduces prenatal and infant mortality (WHO, 2006).

In Kenya, one of the current programmes to prevent anaemia is routine supplementation through the antenatal clinics (MOPHS, 2008). However, receipt rates of the supplements at health facilities are not clearly documented. It is also not clear whether women actually use (ingest) the supplements. The factors associated with utilization of the iron and folic acid supplementation services have also not been documented. This study aimed at gathering this information at Nyeri Provincial General Hospital. The study was conducted at this hospital as it is the main referral hospital with a large catchment area in the Central Province of Kenya and would be more representative of the region than the other health facilities located in the region which have a smaller catchment area. The hospital also offers routine supplementation services to women through the antenatal clinic. The information gathered from this study will help health authorities understand the prevailing situation and address any observed gaps.

1.6 Objectives

1.6.1 General objective

To determine the factors associated with utilization of iron and folic acid supplementation services and the prevalence of anaemia among pregnant women attending ANC at Nyeri Provincial General Hospital, 2010.

1.6.2 Specific objectives

- To determine the prevalence of anaemia among pregnant women attending ANC at Nyeri PGH.
- To determine the level of receipt and use of iron and folic acid supplementation services among pregnant women attending ANC at Nyeri PGH.
- To determine factors associated with use of iron and folic acid supplementation services among pregnant women attending ANC at Nyeri PGH.

1.5 Conceptual frame work

Research questions	Independent variables	Dependent variables
What is the prevalence of anaemia?	Haemoglobin measurements	Anaemia or no anaemia
What is the level of receipt and use of the supplements	Access to supplementation services Number of days a women consumes supplements in a week	Receipt or non receipt of supplements Frequency of use of supplements
Are there factors that are associated with use of the supplements	Mothers health status: anaemic/non anaemic Awareness of importance and benefits of the programme Social support; support from friends and spouse Side effects Number of clinic visits Health worker advise; number of counselling sessions attended Religious and cultural practices	High or low compliance to supplementation

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview of micronutrients and micronutrient deficiencies

Micronutrients are vitamins and minerals required in minute amounts for normal functioning, growth and development. More than 2 billion people in the world today suffer from micronutrient deficiencies caused largely by a dietary deficiency of vitamins and minerals (WHO and CDC, 2008). The public health importance of these deficiencies lies upon their magnitude and their health consequences especially in pregnant women and young children, as they affect fetal and child growth, cognitive development and resistance to infection. Women in low-income countries often consume inadequate levels of micronutrients due to limited intake of animal products, fruits, vegetables, and fortified foods (Huffman *et al*., 1998). The resulting micronutrient deficiencies are exacerbated in pregnancy leading to potentially adverse effects on the mother such as anaemia, hypertension and complications during labor (Ramakrishnan *et al.*, 1999).

Worldwide, the three most common forms of micronutrient malnutrition are iron, vitamin A and iodine deficiency. Vitamin A deficiency affects millions of women and children worldwide. Vitamin A deficiency in pregnancy is known to result in night blindness, to increase the risk of maternal mortality and is associated with premature birth, intrauterine growth retardation and low birth weight (Ladipo 2000). Approximately 100 million women of reproductive age suffer from iodine deficiency (Leslie, 1991). Severe iodine deficiency results in pregnancy loss, mental retardation and cretinism (Dunn, 1993). Iron deficiency results in anaemia, which may increase the risk

of death from haemorrhage after delivery. Improving maternal iron intake during pregnancy has been shown in Peru to improve the iron status of newborns (O'Brien *et al*., 2003). Deficiencies of other minerals such as magnesium, selenium, copper, and calcium have also been associated with complications of pregnancy, childbirth or fetal development (Black 2001). Magnesium deficiency especially has been linked with pre-eclampsia and preterm delivery (Chein *et al.,* 1996). Ramakrishnan *et al.,* 1999 stated that there is strong evidence primarily from high-income countries that zinc, calcium and magnesium supplementation could improve birth weight, prematurity and hypertension particularly in high-risk groups. When multiple supplements were provided to HIV-positive pregnant women in Tanzania, the risk of low birth weight decreased by 44% and by 39% for preterm births (Fawzi *et al.,* 1998). An estimated 82% of pregnant women worldwide have inadequate intakes of zinc to meet the needs of pregnancy (Caulfield *et al.,* 1998). Zinc deficiency has been associated in some studies with complications of pregnancy and delivery such as pre-eclampsia and premature rupture of membranes (Caulfield *et al.*, 1998) as well as with growth retardation, congenital abnormalities and retarded neurobehavioral and immunological development in the fetus (Black, 2001).

From a public health viewpoint, micronutrient deficiencies is a concern not just because such large numbers of people are affected, but also because micronutrient malnutrition, being a risk factor for many diseases, can contribute to high rates of morbidity and even mortality (WHO and FAO, 2006). It has been estimated that micronutrient deficiencies account for about 7.3% of the global burden of disease, with iron and vitamin A

deficiency ranking among the 15 leading causes of the global disease burden (WHO, 2002). According to WHO mortality data, around 0.8 million deaths (1.5% of the total) can be attributed to iron deficiency each year, and a similar number to vitamin A deficiency. Policy and programme responses to the deficiencies include food-based strategies such as: dietary diversification, food fortification, nutrition education, food safety measures, and supplementation (Jane *et al.,* 2001). Supplementation has the advantage of being capable of supplying an optimal amount of a specific nutrient or nutrients, in a highly absorbable form, and is often the fastest way to control deficiency in individuals or population groups that have been identified as being deficient. In developing countries, supplementation programmes have been widely used to provide iron and folic acid to pregnant women (WHO, 2006). However, a lack of supplies and poor compliance are consistently reported by many supplementation programme managers as the main barriers to success (Mora, 2002, Galloway and Mcguire, 1994).

2.2 Iron

2.2.1 Iron requirements, sources and iron deficiency during pregnancy

Iron is one of the most abundant minerals on earth of which the human body requires only small quantities (Hallberg, 2001). The best sources of iron in terms of amount and availability are red meats especially liver and kidneys. Other sources include: fish, poultry, eggyork, legumes and dark green leafy vegetables (Wardlaw *et al.,* 2004). Iron from plant sources is not readily bioavailable as they contain phytates, oxalates, and malic acid which inhibit absorption (MOPHS, 2008). Iron deficiency involves an

insufficient supply of iron to the cells following depletion of the body's reserves (Viteri, 1998) and its main causes are a diet poor in absorbable iron, an increased requirement for iron, a loss of iron due to parasitic infections, particularly hookworm, and other blood losses (Crompton and Nesheim, 2002).

Pregnancy is a time in which the risk for developing iron deficiency anaemia is highest, because iron requirements are substantially greater than average absorbable iron intakes (WHO, 2001). During pregnancy physiologic demands for iron increase from 0.8 to 7.5 mg absorbed iron per day, although there is considerable debate about the exact upper limits of this increased iron demand in the third trimester of pregnancy. The median need for iron in the second and third trimesters of pregnancy is calculated to be nearly 4.6 mg iron per day, whereas the 90th percentile is 6.7 mg iron per day (Viteri, 1997). These calculations are based on the estimation that the median iron need during pregnancy is 840 mg, with a 90th percentile of 1210 mg. If the iron needs for 6 months of lactation are considered, the median total iron requirement would be 1018 mg absorbed iron. This calculation translates into an additional median need of 426 mg iron during the nine months of pregnancy and 6 months of lactation. The decline in iron status that normally accompanies pregnancy results in an increase in the efficiency of absorption of dietary or supplemental iron (Barrett *et al*., 1994)

2.2.2 Causes and consequences of iron deficiency and anaemia

While iron deficiency is the most common cause of anaemia, other causes such as acute and chronic infections that cause inflammation; deficiencies of folate and of vitamins B2, B12, A, and C; and genetically inherited traits such as thalassaemia and drepanocytosis may be independent or superimposed causal factors (WHO, 2001). Iron nutritional status depends on long-term iron balance. It is favored by the ingestion of sufficient iron in food in a bioavailable form or through iron supplementation. Regulation of iron absorption is crucial in favoring absorption in iron deficiency and in avoiding iron excess. Mucosal turnover and skin desquamation; intestinal excretion; menstruation; the pregnancy-delivery-lactation cycle; and pathologic blood losses, mainly from excessive menstrual flow, hookworm and schistosomiasis, gastrointestinal bleeding from ulcerations, hemorrhoids, diarrhea, and other occult blood losses may lead to iron deficiency (Bothwell and Charlton, 1981).

The consequences of iron-deficiency anaemia are serious and can include diminished intellectual and productive capacity (Hunt, 2002) and possibly increased susceptibility to infections (Oppenheimer, 2001). During pregnancy, low haemoglobin levels, indicative of moderate (between 70 and 90 g/L) or severe (less than 70 g/L) anaemia, are associated with increased risk of maternal and child mortality and infectious diseases (INACG, 2002b). The lowest rates of low birth weight and premature birth mainly occur when maternal Hb levels are between 95 and 105 g/L during the second trimester of gestation (Steer 2000; Murphy *et al.*, 1986) and between 95 and 125 g of Hb/L at term (Hytten *et*

al, 1971). However, the results of several studies suggest that near term Hb levels below 95 g/L or even below 110 g/L may be associated with low birth weight, heavier placentas and increased frequency of premature births (Godfrey *et al.*, 1996).

Favorable pregnancy outcomes occur 30% to 45% less often in anaemic mothers, and probably their infants have less than one-half of normal iron reserves (Bothwell and Charlton, 1981). Iron deficiency adversely affects the cognitive performance and development and physical growth of infants (WHO, 2001). Moderate or severe iron deficiency during infancy has been shown to have irreversible cognitive effects (Gleason and Scrimshaw, 2007). Haemoglobin levels greater than 130 g/L at sea level have also been associated with negative pregnancy outcomes (Scholl *et al.*, 1997; Steer, 2000). During pregnancy, iron deficiency is associated with multiple adverse outcomes for both mother and infant (Jane *et al.*, 2007). It increases maternal mortality, prenatal and perinatal infant loss (WHO, 1992). Functional consequences of severe iron-deficiency anaemia during pregnancy include increased rates of premature delivery, perinatal complications in mother and newborn, low birth weight, and indications of iron deficiency and anaemia in the newborn or in later infancy. The finding that some of the negative effects on cognitive and affective function of iron deficiency in infancy may persist, even after iron deficiency and anaemia has been corrected is of great concern (Lozoff *et al*., 2006). Forty percent of all maternal perinatal deaths are linked to anaemia. Favorable pregnancy outcomes occur 30-45% less often in anaemic mothers, and their infants have less than one-half of normal iron reserves (Bothwell and charlton, 1981).

Such infants require more iron than is supplied by breast milk, at an earlier age, than do infants of normal birth weight (Llewellyn, 1965). Moreover, if pregnancy-induced iron deficiency is not corrected, women and their infants suffer all the consequences described above.

2.2.3 Occurrence and distribution of iron deficiency and anaemia

Anaemia is a widespread public health problem associated with an increased risk of morbidity and mortality, especially in pregnant women and young children. It is a disease with multiple causes, both nutritional (vitamin and mineral deficiencies) and non-nutritional (infection) that frequently co-occur. It is assumed that one of the most common contributing factors is iron deficiency. Anaemia resulting from iron deficiency is considered to be one of the top ten contributors to the global burden of disease (Jane *et al.,* 2007). Global prevalence of anaemia in pregnant women is 41.8%; in non-pregnant women is 30.2%. Globally 818 million women (both pregnant and non-pregnant) and young children suffer from anaemia and over half of these, approximately 520 million, live in Asia. The highest prevalence for all 3 groups is in Africa, but the greatest number of people affected is in Asia. In Asia 58% of preschool children, 56.1% of pregnant women and 68% of non-pregnant women are anaemic. More than half of the world's population of preschool aged children and pregnant women reside in countries where anaemia is a severe public health problem (Jane *et a.l,* 2007). Data analyzed from 1970 to 2000 showed a non significant trend in change in prevalence of anaemia among pregnant and non-pregnant women (β=-0.449, p=.15 and β=-0.463, p=.194) respectively.

Most regions were not found to be improving while regions like South Asia could have deteriorated (John *et al.*, 2001).

It is estimated that nearly all women are to some degree iron deficient, and that more than half of the pregnant women in developing countries suffer from anaemia. Even in industrialized countries, the iron stores of most pregnant women are considered to be deficient. Finally, as much as a 30% impairment of physical work capacity and performance is reported in iron-deficient men and women. In a normal population, 2.5% of the population would be expected to be iron deficient hence; iron deficiency anaemia would be considered a public health problem only when the prevalence of low haemoglobin concentration exceeds 5.0% of the population (WHO and CDC, 2008).

It is a challenge to assess global progress in the control of anaemia, since the methodology used for the estimates is so different in different studies. Previous global estimates indicated that approximately 30% of the world's population was anaemic (DeMaeyer and Adiels, 1985). These estimates seem to be based on an extrapolation of the prevalence in preschool-age children, school-age children, women, and men. These estimates which excluded China where 20% of the global population resides indicated that 43% of preschool-age children, 35% of all women, and 51% of pregnant women were anaemic. Current estimates, excluding China, are 52%, 34%, and 44%, respectively. Variations in the methods employed, and a larger proportion of nationally representative data, are more likely to account for the differences between these

estimates than a change in anaemia prevalence (WHO and CDC, 2008). Table 2.1 shows the prevalence of anaemia as estimated by WHO and the Micronutrient Initiative. In the WHO database there was no age range defined for the pregnant while for non pregnant women the range was 15 to 49.99 years. Different age range of 15 to 59 years was used in the Micronutrient Initiative report.

Table 2.1 Prevalence of anaemia among pregnant and non pregnant women

	WHO database prevalence estimate for 1993 to 2005		**Micronutrient initiative report prevalence in 1995**	
	Non pregnant women	Pregnant women	Non pregnant women	Pregnant women
Global estimate	30.7%	41.8%	42.0%	55.8%
Africa	44.4%	55.8%	36.6%	46.9%
Kenya	46.4%	55.1%	-	-

(John *et al*, 2001, WHO and CDC, 2008)

2.2.4 Diagnosis of iron deficiency

Iron-deficiency anaemia is defined as anaemia accompanied by depleted iron stores and signs of a compromised supply of iron to the tissues (IOM, 1993 and WHO, 2001). Iron deficiency in non-pregnant populations can be measured quite precisely using laboratory tests such as serum ferritin, transferrin, and transferrin saturation and transferrin receptors. However, these tests are often not readily available and their results may be of limited value in some settings and under some conditions, particularly among pregnant

women and where different infections for example malaria and HIV/AIDS, are prevalent. Furthermore, the results of those tests do not correlate loosely with one another because each reflects a different aspect of iron metabolism. Serum ferritin concentration is an indicator of iron reserves. During pregnancy, however, serum ferritin levels as well as levels of bone marrow iron fall even in women who ingest daily supplements with high amounts of iron, which casts doubts about their true significance in pregnancy and suggests the need to review cut off values (Puolakka *et al.,* 1980; Romslo *et a.l,* 1983). Currently, a serum ferritin concentration less than 12 μg/L in adults is accepted as an indication of depleted iron stores, even among pregnant women.

The lowest point of maternal serum ferritin occurs by week 28, before higher iron demands are believed to occur, a decrease only partially explained by the normal plasma volume expansion that occurs during pregnancy (Taylor *et al.,* 1982). Other indicators of iron status are also distorted during pregnancy, even among women who are administered supplements containing 200 mg of iron daily (Puolakka *et al.,* 1980). Recently it has been suggested that the ratio of serum transferrin receptors to serum ferritin, a seemingly good estimator of iron nutrition among non pregnant adults, could also be used to estimate the iron nutritional status of pregnant women. However, this ratio does not seem to differentiate clearly between an iron-deficient and an iron-sufficient population of pregnant women (Cook *et al,* 2003).

World Health Organization and CDC Technical Consultation on the assessment of iron status at the population level concluded that Hb and ferritin were the most efficient combination of indicators for monitoring change in the iron status of a population as a consequence of iron supplementation (WHO/CDC, 2005). The concentration of haemoglobin should be measured, even though not all anaemias are caused by iron deficiency. The prevalence of anaemia is an important health indicator and when it is used with other measurements of iron status the haemoglobin concentration can provide information about the severity of iron deficiency (WHO/CDC, 2005). The measurement of Hb is essential for the diagnosis of nutritional anaemia and is one of the most common, easiest and least expensive methods. Kits are available from several manufacturers and there are also small portable haemoglobin meters for use in the field. Unfortunately the Hb measurement is not very sensitive and specific for iron deficiency (only the third stage affects Hb synthesis). Thus, to determine if iron deficiency is responsible for anaemia, it is usually necessary to include other indicators. Ferritin is currently considered the most important indicator of the iron status as even in the first stage of iron deficiency, its concentration decreases. Therefore it is the most sensitive indicator and the cost of ferritin ELISA kits or other methods for the measurement of ferritin are relatively low. Ferritin is increased by many factors, including infection and inflammation, thus a high value does not necessarily indicate a good iron status. It is therefore also valuable to measure parameters for acute [C - reactive protein (CRP)] and chronic infection [alpha-1-glycoprotein (AGP)]. Soluble Transferrin Receptor (sTfR) is increasingly being used to determine iron deficiency in situations where infection is a

factor, as it is much less influenced by this condition. It is not as sensitive as ferritin, but is more sensitive than Hb. Until now there is no internationally certified standard available and each method/kit has its own cut off values. sTfR measurements are still much more expensive than ferritin measurements. The ratio of sTfR to ferritin is the most sensitive indicator for the iron status, since it allows the calculation of the iron stores in mg/kg body weight. It is therefore similar to the gold standard of bone marrow staining in defining iron deficiency.

Besides these indicators the following three are sometimes also of interest: Iron saturation of plasma transferrin and mean corpuscularvolume (MCV): They are well established indicators and relatively inexpensive to measure but only useful in clinical settings where the equipment to measure them is available (WHO, 2001). Hematocrit is very easy to measure but since it is even less sensitive than Hb for iron deficiency it is not very helpful in diagnosing nutritional anaemia. Zinc protoporphyrin (ZnPP) is a simple and robust measurement and useful in screening for iron deficiency but requires a special machine. It must be noted that lead even at normal environmental exposures can increase ZnPP. In most situations, though, it is not a problem (WHO, 2001).

2.2.5 Diagnosis of anaemia

Hemoglobin (Hb) assessments are the most reliable indicator widely used to screen individuals for anaemia, to draw inferences about the iron status of populations and to evaluate responses to nutritional interventions (Morris *et al.,* 1999). According to the

criteria of Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO), anaemia during pregnancy should be diagnosed if a woman's haemoglobin (Hb) concentration is lower than 110 g/L during the first or third trimester or lower than 105 g/L during the second trimester. The prevalence of anaemia in a population is best determined by using a reliable method of measuring haemoglobin concentration (CLSI, 1994). Compared with the cost and difficulty of biochemically assessing the prevalence of iodide deficiency and vitamin A deficiency, the determination of the prevalence of anaemia in a population is relatively simple and inexpensive.

Hemoglobin concentration is measured routinely using automated hematology analyzers. Although these counters are very accurate and reliable, they are expensive (Jahr *et al.,* 2002). In resource poor settings where automated hematology analyzers are not available, the Cyanmethemoglobin method is often used. Hb estimation by this method though cheaper than the automated method takes more time (Sari *et al.,* 2001). In blood donations, the semi-quantitative gravimetric copper sulfate method which is very easy and inexpensive may be used, but does not provide an acceptable degree of accuracy (Boulton *et al.,* 1994, James *et al.,* 2003). The HemoCue® Hb photometer has been widely used for these purposes in recent years because it is portable, requires only a small sample of capillary/venous blood, is relatively inexpensive and simple to use, does not require access to refrigeration or even electricity, and gives immediate, digitally displayed results (Jahr *et al.,* 2002). It requires very little staff training thus making it a

very useful tool in resource limited areas as well as at field conditions since it can easily be transported (Dacie and Lewis, 2001).

The methods generally recommended for use in surveys to determine the population prevalence of anaemia by haemoglobinometry are the cyanmethemoglobin method in the laboratory and the HemoCue system. The cyanmethemoglobin method for determining haemoglobin concentration is the best laboratory method for the quantitative determination of haemoglobin. It serves as a reference for comparison and standardization of other methods (CLSI, 1994). A fixed quantity of blood is diluted with a reagent (Drabkins solution) and haemoglobin concentration is determined after a fixed time interval in an accurate, well-calibrated photometer. The HemoCue system is a reliable quantitative method for determining haemoglobin concentrations in field surveys (Vanshenckh *et al*, 1986), based on the cyanmethemoglobin method. The HemoCue system consists of a portable, battery-operated photometer and a supply of treated disposable cuvettes in which blood is collected. The system is uniquely suited to rapid field surveys because the one-step blood collection and haemoglobin determination do not require the addition of liquid reagents. Survey field staffs without specialized laboratory training have been successfully trained to use this device (WHO, 2001). The HemoCue system gives satisfactory accuracy and precision when evaluated against standard laboratory methods (John and Lewis, 1989). Long-term field experience has also shown the instrument to be stable and durable. These features make it possible to

include haemoglobin determinations in multipurpose health and nutrition surveys (WHO, 2001).

2.2.6 Strategies for mitigating iron deficiency

Interventions to control iron deficiency and iron-deficiency anaemia include iron supplementation and iron fortification, health and nutrition education, control of parasitic infections, and improvement of sanitation (INACG, 1977). The results of some studies suggest that the amount of iron that can be absorbed from diet alone is insufficient to cover women's increased iron requirements during pregnancy except when women can draw enough iron from pre-pregnancy iron reserves (IOM, 2001). Since most women would need additional iron as well as sufficient iron stores to prevent iron deficiency (Bothwell, 2000), direct iron supplementation for pregnant women has been used extensively in most low- and middle income countries as an intervention to prevent and correct iron deficiency and anaemia during pregnancy. It has been recommended that iron supplements also contain folic acid, an essential B-vitamin, because of the increased requirements of pregnancy, due to the rapidly dividing cells in the fetus and elevated urinary losses.

Other micronutrients for which deficiencies are documented may justify their addition to the supplementation formula. Several studies have shown that iron supplementation, with or without folic acid during pregnancy, results in a substantial reduction in women's risk of having haemoglobin levels less than 100 g/L in late pregnancy, at

delivery and six weeks postpartum (Villar and Bergsjo, 1997). However, the overall impact of iron supplementation interventions under field conditions has been limited and the effectiveness of these interventions has been questioned (Beaton and McCabe, 1999). The limited success has been attributed to inadequate infrastructure and poor compliance (Mora, 2002) The effectiveness of iron supplementation for pregnant women has been evaluated mostly in terms of improvement in haemoglobin concentration, rather than improvements in maternal or infant health (Beaton, 2000).

International organizations have been advocating routine iron and folic acid supplementation for every pregnant woman in areas of high anaemia prevalence (Beard, 2000). While iron supplementation with or without folic acid has been used in a variety of doses and regimens, some current recommendations for pregnant women include the provision of a standard daily dose of 60 mg of iron and 400 ug of folic acid for six months or, if six months of treatment cannot be achieved during pregnancy, either continued supplementation during the postpartum period or increased dosage to 120 mg iron daily during pregnancy (WHO, 2006), or if iron deficiency prevalence in the country is high or the pregnant women are anaemic (INACG/WHO/CDC, 1998).

The first preventive measure against infant iron deficiency is assuring adequate body iron at birth by avoiding gestational iron deficiency and other conditions leading to low birth weight and premature delivery (Colomer *et al.*, 1990). Interventions to address iron deficiency are one of the most cost effective public health interventions. Objections to

the strategies for the control of iron deficiency have sometimes been raised by hematologists in developed countries. They cite the danger of possibly accelerating or inducing iron excess and overload conditions in some clinical conditions, as well as claims for its involvement in a variety of cancers and heart disease in their countries (Halliwell *et al.*, 1992). Nevertheless, in the face of the widespread iron deficiency and ferropenic anaemia in the great majority of populations in the developing world and in groups at risk for iron deficiency everywhere, this should not be an issue (ACC/SCN, 1997). As long as monitoring of interventions is done excessive administration of iron in therapeutic and chronic supplementation programmes poses no threat to these populations

2.2.7 Iron supplements and side effects

Gastrointestinal side effects have been identified as the critical adverse effect on which to base the tolerable upper intake level for iron, as gastrointestinal distress is observed commonly in women consuming high levels of supplemental iron on an empty stomach. High dose iron supplements are commonly associated with constipation and other gastrointestinal effects including nausea, vomiting and diarrhea, with frequency and severity varying according to the amount of elemental iron released in the stomach. The Institute of Medicine has established the tolerable upper limit for iron during pregnancy based on gastrointestinal side effects as 45 mg/day of iron, a daily dose much lower than international recommendations (IOM, 2001).

In most industrialized countries, the decision to prescribe or recommend antenatal iron with folic acid supplementation to women during pregnancy is left to the health care personnel, and is based on the individual maternal condition. In the United States, iron supplementation as a primary prevention intervention involves smaller daily iron doses (i.e. 30 mg/day) but higher doses, up to 120mg daily are recommended in the presence of anaemia (CDC, 1998). Less frequent regimens of iron supplementation, such as once weekly or twice weekly with iron alone or in conjunction with folic acid, have been evaluated in the last decade as a promising innovative regimen. The weekly iron administration is based on two lines of evidence: first daily iron supplementation, by maintaining an iron-rich environment in the gut lumen and in the intestinal mucosal cells, produces oxidative stress, reduces the long-term iron-absorption efficacy and is prone to increasing the severity and frequency of undesirable side effects (Srigiridhar *et al*, 2001). Secondly the concept that exposing intestinal cells to supplemental iron less frequently, every week based on the rate of mucosal turnover that occurs every five to six days in the human, may improve the efficiency of iron utilization.

Additionally, compliance could increase due to fewer side effects and the costs of supplementation may be favorable if provided outside of the medical context (Viteri *et al*, 1995). However, some authors have questioned this belief, indicating that the main reason for the poor compliance with programmes is the unavailability of iron supplements for the targeted women (Galloway and McGuire, 1994). Recently, lower birth weight and premature delivery have been associated with excess iron intake and

with higher levels of haemoglobin concentrations late during the second trimester and early into the third trimester but not at term (Casanueva and Viteri, 2003).

2.3 Folate

2.3.1 Sources of folate and requirements during pregnancy

Folate is a B vitamin needed for cell replication and growth. Folate helps form building blocks of DNA, the body's genetic information, and building blocks of RNA, needed for protein synthesis in all cells. Therefore, rapidly growing tissues, such as those of a fetus, and rapidly regenerating cells, like red blood cells and immune cells, have a high need for folate. The recommended daily allowance for adults is 400µg. This is based on the amount needed to maintain red blood cell folate, control blood homocysteine and maintain normal blood folate concentrations. Also considered is the intake necessary to prevent neural tube defects for women capable of becoming pregnant. (FNBIM, 1998)The recommended dietary allowances for folic acid among non pregnant and pregnant women are 170µg and 400µg respectively (Wardlaw *et al.,* 2004). The best sources of folate in terms of amount and availability are liver, fortified foods, legumes and green leafy vegetables. Other less rich sources include eggs, dried beans and oranges (Wardlaw *et al.,* 2004).

2.3.2 Causes, consequences and occurrence of folate deficiency

Folate deficiency can result from a low intake ; inadequate absorption, which often is associated with alcoholism; increased requirement, most commonly occurring in

pregnancy; compromised utilization , typically associated with vitamin B12 deficiency; use of certain chemotherapy medications and excessive excretion linked to long standing diarrhoea.(Wardlaw *et al,* 2004). Deficiencies of folate first affect the cell types that are actively synthesising DNA. Such cells have a short life span and rapid turnover rate. Thus one of the major folate deficiency signs is in the early phases of red blood cells synthesis. Without folate the precursor cells in the bone marrow cannot divide normally to become mature blood cells because they cannot form new DNA. The cells grow larger because there is formation of RNA, leading to increased synthesis of protein and other cell components to make new cells. Haemoglobin synthesis also intensifies. However when it is time for the cells to divide they lack sufficient DNA for normal division. The cells therefore remain in the bone marrow known as megaloblasts. Unlike normal mature red blood cells megaloblasts retain their nuclei. Once the cells enter the blood stream they are called macrocytes. This result in a form of anaemia called megaloblastic (or macrocytic) anaemia (Wardlaw *et al,* 2004).

Large immature cells also appear along the entire length of the gastrointestinal tract during chronic folate deficiency this occurs because these cells are replaced very frequently which means that DNA for the new cells has to be produced rapidly. In a folate deficiency, cell division in the gastro intestinal tract is impaired. This change contributes to decreased absorptive capacity of the GI tract and persistent diarrhoea. White blood cells synthesis is also disrupted by a folate deficiency because these cells are made in rapid bursts during infections. Thus immune function can be diminished

during a folate deficiency. This effect likely can occur with milder folate deficiency than is needed to produce anaemia (FNBIM, 1998). A maternal deficiency of folate and a generic predisposition have been linked to the development of neural tube defects in the infants. These defects include spina bifida and anencephaly (Wardlaw *et al.,* 2004). Plates 2.1 and 2.2 show new born babies with spina bifida and anencephaly respectively. It is widely recognized that the interplay between genetic and environmental factors contributes to the etiology of structural birth defects (Zhu *et al*., 2009). Folic acid exerts a pivotal role in promoting normal embryonic development: folic acid supplementation is critically important in protecting against neural tube defects (Molloy *et al*., 2009). Despite the consistent scientific evidence on the association between folate status and/or impaired folate metabolism with fetal birth defects, biological mechanisms involved in embryonic folate utilization are not yet well understood (Beaudin and Stover, 2007). Sub-optimal maternal folate status appears to impose biochemical stress to the embryo via inducing disturbances of the methionine one-carbon metabolism and resulting in abnormal closure of the neural tube (Zhang *et al*., 2008).

The risk reduction in neural tube defects (NTDs) amounts up to 70% with 4 mg/day dose of supplementation (MRC, 1991), whereas a near 100% reduction of NTDs in addition to significant reductions of congenital heart defects was achieved by periconceptional supplementation of a multi-vitamin product containing 0.8 mg of folic acid (Czeizel *et al*., 2004).The folic acid dose of 0.8 mg daily was demonstrated to be the optimal dosage for lowering homocysteine levels as well (Wald *et al*., 2001). Hyperhomocysteinemia

has been postulated as a mechanism involved in neural tube defects, because an abnormality in homocysteine metabolism was reported in women who gave birth to children with neural tube defects (Mills *et al*., 1995). These observations suggest that an increased total homocysteine level might be the actual causal factor in the etiology of neural tube defects (Beaudin & Stover, 2009). Homocysteinylation of placental folate receptor 1 seems to trigger an autoimmune response leading presumably to the block of folic acid transport (Taparia *et al*., 2007). This indicates that folate transport may be the critical step in ensuring normal embryonic development (Blom, 2009). The incidence of neural tube defects seems to correlate also with the level of vitamin B12 (Molloy *et al*., 2009). Women with low folate supply in combination with low blood vitamin B12 levels had a drastically increased risk of neural tube defects (Padmanabhan, 2006).

The global prevalence as well as the prevalence of folate deficiency in Kenya has not been established. Deficiency can arise from insufficient dietary intake, high alcohol consumption, drug interactions as well as malabsorption, resulting from gastrointestinal disorders and secondary deficiencies of B6 and B12 (MOPHS, 2008). Folate deficiency has significantly decreased in North America primarily due to folic acid fortification of the food supply but the need for adequate folate intake prior to conception and during the early weeks of pregnancy remains a significant concern to reduce the risk for the development of neural tube defects (Scholl and Johnson, 2000).

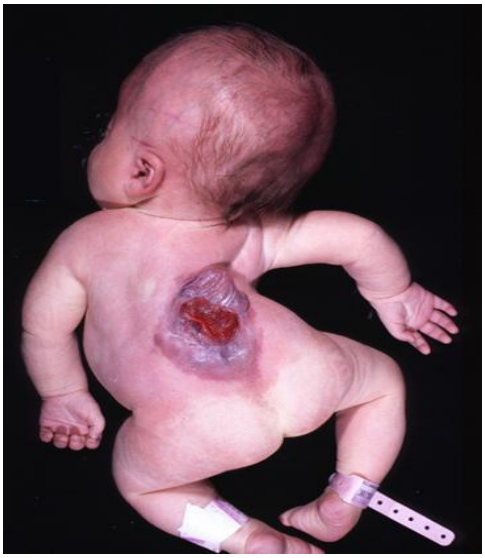

Plate 2.1: A new born baby with spina bifida

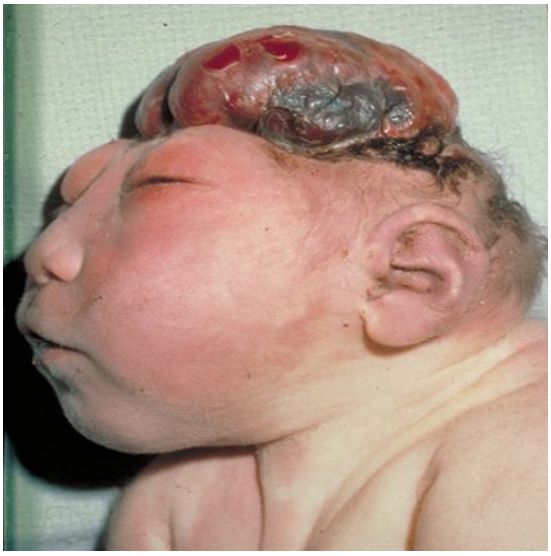

Plate 2.2: A new born baby with anencephaly

(Source: **GoldBamboo**TM. www.goldbamboo.com/pictures-t1570.html)

2.3.3 Diagnosis of folate deficiency

The presence of megaloblastic changes in the marrow usually implies a diagnosis of cobalamin or folate deficiency. In patients with either cobalamin or folate deficiency, the mean corpuscular volume tends to increase before the hemoglobin level decreases significantly (Sant *et al.*, 1997, Lindenbaum and Allen, 1995). The presence of hypersegmented neutrophils has been said to be highly sensitive and specific for the diagnosis of megaloblastic anaemia (Lee, 1993, Thompson *et al*. 1989). The use of metabolite measurements for the diagnosis, confirmation, and differentiation of cobalamin and folate deficiencies has been made possible by the development of accurate assays for serum and urine methylmalonic acid and serum homocysteine. Elevations of both metabolite levels are anticipated in patients with cobalamin deficiency, whereas only homocysteine levels would be expected to increase in patients with folate deficiency. Also, an increase in the homocysteine level suggests tissue folate deficiency but the level is also affected by vitamin B12 and vitamin B6 levels, renal insufficiency, and genetic factors. A normal methylmalonic acid level may differentiate folate deficiency from vitamin B12 deficiency because methylmalonic acid level rises in vitamin B_{12} deficiency but not in folate deficiency (Green, 2008). Factors other than cobalamin or folate status can increase serum methylmalonic acid levels. Renal insufficiency causes serum levels of both metabolites to increase, although the elevations are typically modest compared with those caused by cobalamin deficiency (Savage *et al*., 1994).

If serum folate is < 3 μg/L (< 7 mmol/L), deficiency is likely. Serum folate reflects folate status unless intake has recently increased or decreased. If intake has changed, erythrocyte folate level better reflects tissue stores. A level of < 140 μg/L (< 305 mmol/L) indicates inadequate status. The accurate diagnosis of folate deficiency is a complex task. No easily performed test can reliably serve as a diagnostic gold standard. Consequently, the performance characteristics of the available laboratory tests are difficult to ascertain. In each case, the primary physician must integrate clinical information, laboratory test results, and response to specific treatment and keep in mind the relative risks and benefits of administering or withholding vitamin replacement therapy (Christopher, 1999).

2.3.4 Strategies for mitigating folate deficiency

Strategies to address deficiency include: supplementation, dietary diversification, and modification and information, education and communication. Scientific evidence indicates that the strategy with the greatest impact in reducing the prevalence of maternal anaemia and neural tube defects is supplementation. (Wharton and Booth, 2001) Folic acid supplementation was primarily indicated for the prevention and treatment of megaloblastic and maternal anaemia (Smail, 1981). Supplementation is also indicated in individuals with a genetic defect requiring greater amounts of folate than can be derived from the diet (Ashfield *et al*, 2002). Based on evidence that folic acid also prevents neural tube closure defects (MRC, 1991), supplementation in public health programmes was recommended, particularly since, unlike megaloblastic anaemia, sera concentrations

of folic acid in mothers of children with neural tube defects were normal. Supplements may be in the form of synthetic monoglutamate (folic acid), or food folate reduced polyglutamates. A supplementation of 400µg is recommended level for pregnant women, which is given with iron supplements (Mahomed, 1997).

2.3.5 Toxicity and side effects of folate

Food and Nutrition board limits the amount of folic acid in non prescription vitamin supplements for non pregnant women individuals to 400 µg when no age is listed on the supplement label. When age related doses are listed there should be no more than 100 µg for infants, 300 µg for children and 400 µg for adults. FDA regulates the potency of folic acid supplements because of the ability of excessive amounts of folic acid to mask a vitamin B-12 deficiency and the upper level of for synthetic folic acid is 1000 µg (1 mg) based on this observation (FNBIM, 1998). Although controversial, high folate status achieved through folate fortification or supplementation may increase the risk of certain chronic diseases among certain individuals, possibly by interfering with the homeostasis of one-carbon metabolism (Stolzenberg *et al*, 2006).

There are benefits of fortification, but various adverse effects exist, and for every pregnancy with neural tube defect prevented, hundreds of people may be exposed to high levels of folic acid intake (Hoey *et al.,* 2007). According to estimates by Bell & Oakley (2009), 27% of the world population has access to flour fortified with iron and/or folic acid. Fortification with folic acid reduced the frequency of neural tube defects in United

States (Boulet *et al.,* 2008) and Canada (Godwin *et al.,* 2008). Investigations carried out have suggested that excessive intake of synthetic folic acid can promote the progression of undiagnosed neoplastic lesions (Kim, 2007), and has been linked to recurrent early pregnancy loss (Nelen *et al.,* 2000) and vitamin B12 deficiency (Hirsch *et al.,* 2002). A cautious approach to implementing universal fortification policies have been recommended since 1995 (Wharton and Booth, 2001). Many countries have therefore opted against mandatory fortification, primarily because additional health benefits are not yet proven in clinical trials and due to the unknown risks (Eichholzer *et al,* 2006).

2.4 Gaps and challenges

In most countries, national policies have been implemented to provide iron supplements to pregnant women and to a lesser extent to young children as the primary strategy for preventing iron deficiency and anaemia (WHO, 2006). In Kenya, a number of interventions have been designed to prevent or correct iron deficiency anaemia and folate deficiency. These include: food fortification, dietary diversification and modification, malaria control, helminthes control and supplementation of folic acid and iron. According to the Kenya national guidelines, (MOPHS, 2008) all pregnant women are to receive iron and folic acid supplements. The official guidelines were not published until 2008; however it was already considered standard of practice for supplementation to be given or prescribed to pregnant women. National recommendations are for women to begin supplementation during the first month of pregnancy or at the time of their first antenatal clinic (ANC) with 60 mg of iron sulphate and 400 µg of folic acid daily.

Although these guidelines specify what women are supposed to be provided or prescribed, they do not indicate whose responsibility it is to ensure that these guidelines are followed or that supplies are available at the clinics. There is also general belief that even if women receive the supplements, they don't take the supplements because of concern about side effects, particularly with iron supplementation; however, whether this occurs has not been studied. On the other hand, some industries have begun voluntarily fortifying foods such as maize, flour, sugar and fats and oils. Current government work-plans include community-based programmes to promote improved iron status through dietary change while deworming is done as part of a school health project. There is also routine collection of Hb concentration data at the antenatal clinics. However, the available nutrition surveillance mechanisms in the country do not capture adequate data for decision making and there has been no feedback on the effectiveness of these programmes.

CHAPTER 3: METHODS

3.1 Study design

This was a cross sectional study where data on utilization of iron and folic acid supplements and associated factors were collected at the same time. This cross sectional study had both descriptive and analytical components where proportions were determined (the level of receipt and use of supplements as well as the prevalence of anaemia). Further, factors associated with use of the supplements were determined in the analytical analysis between factors (exposure variables) and compliance (outcome variables).

3.2 Study site and popluation

The study was conducted at Nyeri Provincial General Hospital. This is a regional government referral hospital in the central province of Kenya. The hospital offers routine and specialized health services, including maternal and child health clinics. The hospital offers iron and folic acid supplementation services to pregnant women during the antenatal clinic. This is in line with the national guideline for micronutrient deficiency control (MOPHS. 2008). Residents are mainly of the Kikuyu ethnic group who earn their living through subsistence farming, cash crop farming and small businesses. The Kikuyus' mainly depend on a plant products based diet with 'githeri' (a mix of maize and beans) as the staple food. Animal based products are considered special and are mostly reserved for special occasions. The hospital is located between latitude 0° 25' south and longitude 36° 57' east. It is located approximately 1755 meters above sea

level. Figure 3.1 shows Nyeri town where the study site is located. The study was conducted among pregnant women attending antenatal clinic (ANC) at Nyeri PGH. The inclusion criteria were pregnant women visiting ANC who had a previous visit to an antenatal clinic for care during the current pregnancy and also gave consent.

3.3 Definition of compliance

Women who ingested iron and folic acid supplements for more than four days in a week were considered to have high compliance while those who ingested the supplements for four days or less in a week were considered to have low compliance (Binetou and Robert, 2007).

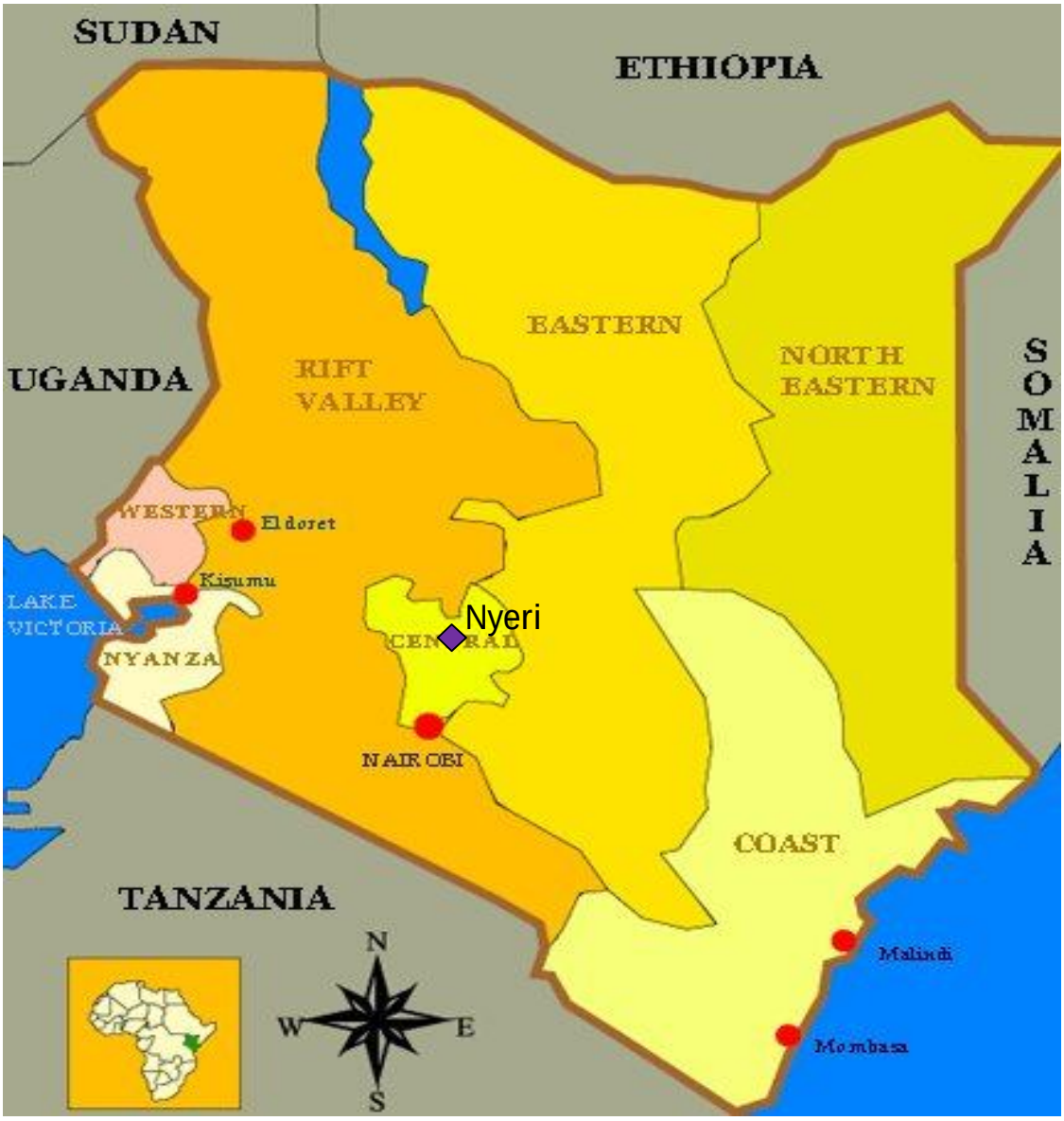

Figure 3.1: Map of Kenya showing the location of Nyeri town

(Source: http://www.kenya-advisor.com/kenya-travel-advice.html)

3.4 Sample size and sampling procedure

Three hundred and seventy seven women was the minimum sample as determined using the formula below:

$n= (z^2pq)/d^2$

Where n is the sample size, z equals $(1-\alpha)/2$ percentile of a standard normal distribution, d is the absolute precision, p is the expected proportion and q = 1-p.

Assumptions:

A 95% confidence level, estimated rate of use of iron supplements among pregnant women of 69% (Binetou and Robert, 2007) and a precision of 0.05

Therefore $n=1.96^2 *0.69*0.31/0.05^2$ n =328

Adjusting for non response rate of 15%, the final calculated minimum adjusted sample size was 377. Pregnant women attending the ANC in October 2010 were enrolled. On average 15 to 20 women were enrolled each day excluding weekends as the clinic was not open on weekends. Only women who had at least one prior visit to an ANC during the current pregnancy were included to ensure that they had an opportunity to be offered the supplements. Systematic random sampling was used to select study participants. The sampling frame was estimated from the ANC register by calculating the average number of women who would be seen in one month, the period when the study was to be implemented. Approximately 865 are seen per month, this was divided by the minimum adjusted sample size (377) to give the sampling interval (2.3). A random number was picked as the starting point and then every second woman who met the inclusion criteria was included in the sample until the required sample size was reached. If a woman

refused to participate in the study the next woman who agreed to participate and met the inclusion criteria was recruited and then every other 2nd woman thereafter was recruited.

3.5 Data collection

3.5.1 Questionnaire

A semi structured questionnaire was pretested in a site similar to the study site. Issues raised during the pretesting were corrected before the final questionnaire (appendices 1A and 1B) in English and Kikuyu was printed. The data collected during the pretesting was used to pretest the data entry and analysis template. The independent study variables included socio demographic factors, health seeking behavior and utilization of supplementation services, environmental factors and medical information. The dependent variables were low and high compliance to folic acid and iron supplementation.

3.5.2 Determination of anaemia

Prevalence of anaemia was determined by measuring Hb concentration from three hundred and sixty one pregnant women who gave consent for Hb testing. Twenty women out of 381 women interviewed did not give consent for Hb testing. Haemoglobin concentration was measured directly from one drop of capillary blood via finger prick and measured using a portable HEMOCUE B-Hb photometer (appendix 2). The sample collection procedure was first explained to each subject using the informed consent form (appendix 3A and 3A). If the subject was uncomfortable with the procedure, any

questions she had were answered. After giving informed consent and putting on a fresh pair of disposable latex gloves, the participant's fingertip was warmed, cleaned with alcohol, and punctured with a lancet. The first two drop of blood was discarded; the microcuvette was then filled with a single drop of blood. The filled microcuvette was placed into the HemoCue microcuvette holder within one to three minutes of taking the sample, and not later than ten minutes. The haemoglobin value that appeared on the display was recorded. All waste materials and sharps were segregated and disposed appropriately. At the beginning of each day the machine was checked whether it was clean and whether it was in good working order by placing the control microcuvette in the microcuvette holder and checking whether the readings were within 0.3 g/dl of the control value. Based on WHO guideline Hb less than 11g/dl was considered as anaemia (WHO and CDC, 2005). Further the following cut off points were used to define severerity: mild anaemia Hb 9.0 to 10.9 g/dl, moderate anaemia 7.0 to 8.9 g/dl and severe anaemia Hb less than 7 g/dl (INACG, 2002b).

3.6 Recruitment and training of research assistants

The enumerators who were recruited for data collection had a minimum of secondary education. They were trained for two days on questionnaire administration, method of interaction, data collection techniques as well as recording. One of the enumerators who was a laboratory technologist was sensitized on Hb concentration testing. The enumerators were also trained on basic research ethics. The enumerators were closely monitored during the actual data collection to ensure quality of data.

3.7 Data management and analysis

Data was entered and analyzed using EPI info statistical package. Descriptive analysis was done to determine the prevalence of anaemia and the level of receipt and use of supplements. Distribution of variables was also evaluated using means. Bivariate analysis was done to elicit factors associated with utilization of iron and folic acid supplementation with odds ratio as the measure of association. Chi-square test was used for categorical variables at 95% confidence interval with alpha level of significance at 0.05. T-test was used to assess significance among the continous variables (p=0.05). Multivariate analysis was then done where factors that had a p value ≤ 0.1 in bivariate analysis were entered in unconditional logistic regression model building process. A stepwise backward elimination procedure was performed to obtain the "final best model" which gave factors independently associated with utilization of iron and folic acid supplementation services. The functional form of the logistic regression model is given below.

$$Log\ (p/1-p) = b_0+b_1x_1+b_2x_2+.....$$

Where:

log - the natural logarithm (base e)

p = probability of being highly compliant (dependent variable)

b_0, b_1 and b_2 are regression coefficients

x_1 and x_2 represents the independent variables entered into the model

3.8 Ethical consideration

Participant's confidentiality was ensured by coding and omitting information that identified the participants. Privacy was maintained during interviews while all the questionnaires have been kept in a lockable cabinet and data entered in a password protected computer. Informed consent was obtained from the participants (appendices 3A and 3B). Apart from pain and discomfort during blood collection, no other distress was encountered. The pregnant women were given haemoglobin results and those found to be anaemic were referred for treatment and other interventions. The research protocol was approved by the KEMRI Ethical Review Committee (appendices 4 and 5). Permission to carry out the research was also obtained from the management of Nyeri PGH.

CHAPTER FOUR: RESULTS

4.1 Socio- demographic characteristics

4.1.1 Age, religion and education level

Three hundred and eighty one women attending antenatal clinic (ANC) at Nyeri Provincial General Hospital were interviewed. Most of the women (72.7%) were aged between 20 to 29 years as shown in Table 4.1. The mean age was 26.3 (±5.0) years and the range was 17 to 47 years.

Table 4.1: Distribution of pregnant women attending ANC at Nyeri PGH by age group, 2010

Age group	Frequency (%) n=381
<20	13 (3.4)
20-24	149(39.1)
25-29	128(33.6)
30-35	67(17.6)
36+yrs	24(6.3)

Most of the respondents (98.7%) were Christians while 1.3% were Muslims. Majority of the women (84.3%) were married while 15.7% were separated, widowed or single. The highest proportion of women (46.5%) had secondary education as their highest level of education (Figure 4.1).

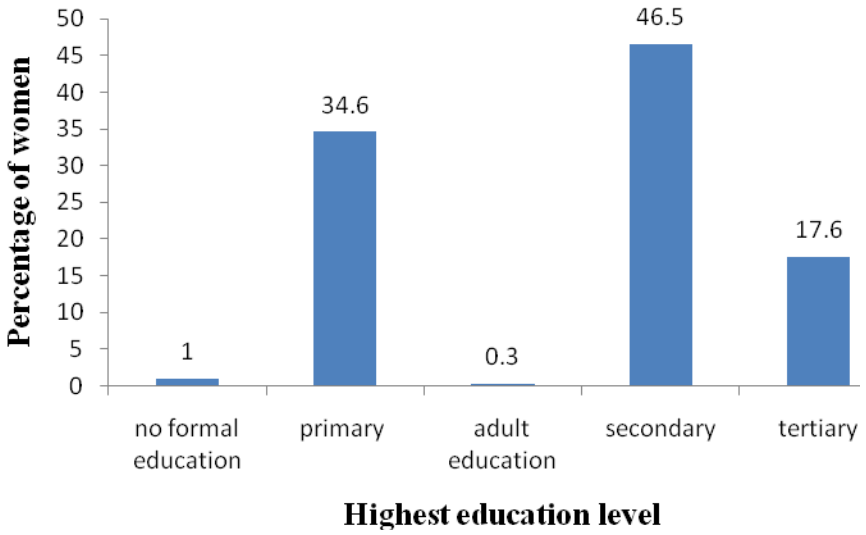

Figure 4.1: Percent distribution of pregnant women attending ANC at Nyeri PGH by highest level of education attained, 2010

4.1.2 Gravidity

Majority of the women (48.8%) were primigravidae and only 9.1% were grandmultigravidae (Figure 4.2). A further 26.2% and 15.7% were on their second or third pregnancy respectively.

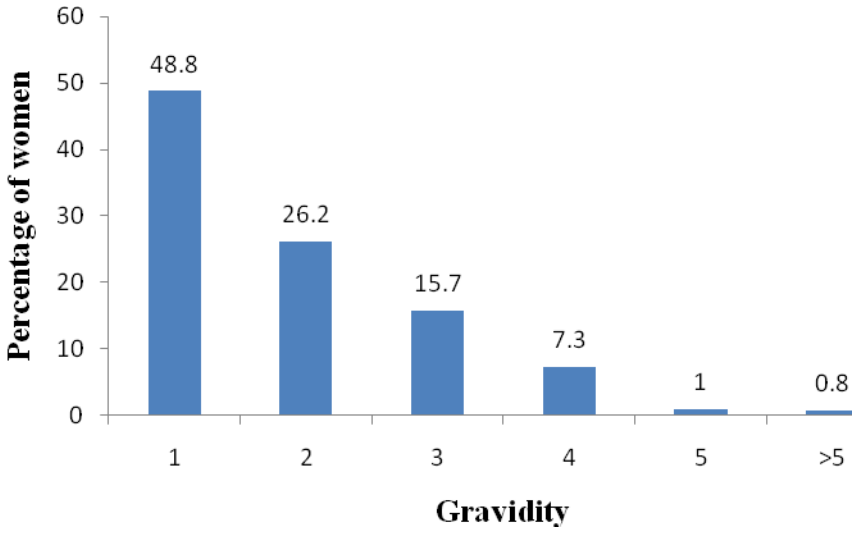

Figure 4.2: Percent distribution of pregnant women attending ANC at Nyeri PGH by gravidity, 2010

4.1.3 Household size

Most women (81.9%) were from households with 2 to 4 members as shown in Figure 4.3. The household sizes ranged from one to seven members.

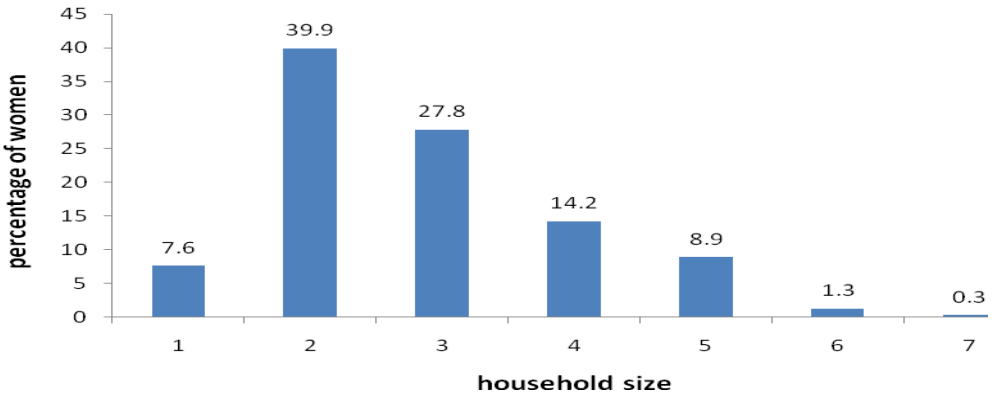

Figure 4.3: Percent distribution of pregnant women attending ANC at Nyeri PGH by household sizes, 2010

4.1.4 Place of residence

Most of the women (92.1%) were from Nyeri County, 2.9% resided in the neighbouring Murang'a County while the rest resided in seven different counties as shown in Table 4.2.

Table 4.2: Distribution of pregnant women attending ANC at Nyeri PGH by county of residence, 2010

County	Frequency (%) n=381
Nyeri	351(92.1)
Murang'a	11(2.9)
Laikipia	7(1.8)
Nyandarua	5(1.3)
Kirinyaga	3(0.8)
Makueni	2(0.6)
Siaya	1 (0.3)
Meru	1(0.3)

4.1.5 Occupation

The highest propotion of women were self employed (35.3%) as shown in Figure 4.4

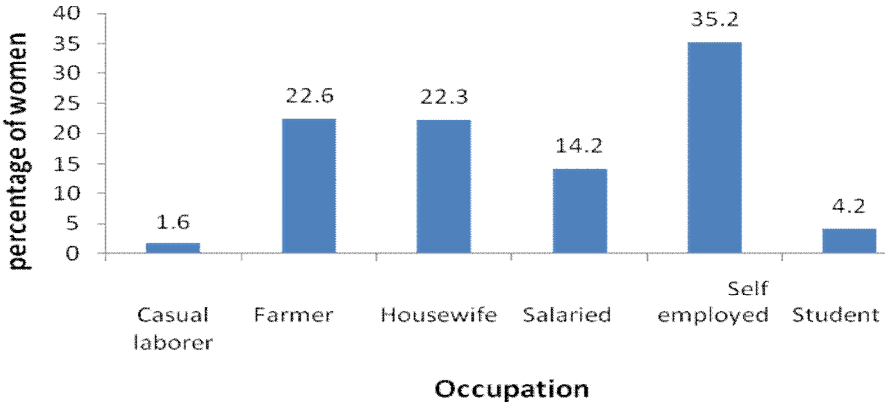

Figure 4.4: Percent distribution of pregnant women attending ANC at Nyeri PGH by occupation, 2010

4.2 Clinical information

Most of the women (61.6%) were in the third trimester at the date of the interview. Those in the first and second trimester were 1.85% and 36.6% respectively. The mean gestation period was 30 (±6.73) weeks and the gestation period ranged from 12 to 40 weeks. The highest proportion (46.6%) of the women had visited the antenatal clinic more than four times as shown in Table 4.3. Majority of the women (73.2%) received nutrition counselling. However 42% and 55.4% did not receive information on folic acid and iron supplements, respectively (Table 4.4).

Table 4.3: Distribution of pregnant women attending ANC at Nyeri PGH by number of antenatal clinic visits, 2010

Number of times women had visited hospital	Frequency (%) n=381
Four times or more	178(46.6)
Three times	75(19.7)
Two times	128(33.7)

Table 4.4: Selected clinical characteristics of pregnant women attending ANC at Nyeri PGH, 2010

Variable	Frequency (%) n=381
Suffered from chronic illness	37 (9.7)
Received nutrition counseling	279 (73.2)
Received information on iron	170 (44.6)
Received information on folic acid	221 (58.0)
Craved and consumed non foods such as soil and stones	131 (34.4)
Meals taken per day (<3 meals)	105 (27.6)

4.3 Prevalence of anaemia

Of the 381 women interviewed, 361 consented to having their finger pricked for the Hb concentrations to be determined. The mean haemoglobin concentration was 12.6 g/dl (±1.2) ranging from 8.3 to16.3 g/dl. The prevalence of anaemia (Hb <11 g/dl) was 7.8%

(28/361). The prevalence of mild anaemia and moderate anaemia was 7.0% and 0.8% respectively. There were no cases of severe anaemia. The prevalence of anaemia among receivers of iron supplements who gave consent for their Hb to be determined was 9.1% (17/187). On further analysis by compliance to iron, the prevalence among the high and low compliant groups to iron supplementation was 10.6% (16/151) and 2.8% (1/36) respectively. On the other hand, the prevalence of anaemia among receivers of folic acid supplements who gave consent for their Hb to be determined was 7.1% (18/254). On further analysis by compliance to folic acid, the prevalence of anaemia among the high and low compliant groups to folic acid supplementation was 7.1% (15/210) and 6.8% (3/44), respectively. There was no significant difference in means of haemoglobin concentration between the high and low compliant groups to iron supplementation as illustrated in Table 4.5. Similarly there was no significant difference in means of haemoglobin concentration (p=0.05) between the high and low compliant groups to folic acid supplementation as illustrated in Table 4.6.

Table 4.5: Haemoglobin concentration by compliance to iron supplementation among women attending ANC at Nyeri PGH, 2010

	High compliant group n=151		**Low compliant group n=36**		
Hb concentration (g/dl)	**Mean ±SD**	**Range**	**Mean ±SD**	**Range**	**P value**
Hb < 11	9.9 ±0.8	8.3 to 10.9	10.9 ±0.0	10.9 to 10.9	0.21
Hb ≥ 11	12.7 ±0.9	11.0 to 15.7	12.9 ±1.0	11.5 to 15.0	0.27

Significance level P=0.05

Table 4.6: Haemoglobin concentration by compliance to folic acid supplementation among women attending ANC at Nyeri PGH, 2010

Hb concentration (g/dl)	High compliant group n=210 Mean ±SD	Range	Low compliant group n=44 Mean ±SD	Range	P value
Hb < 11	9.9 ±0.9	8.3 to 10.9	10.6 ±0.4	10.2 to 10.9	0.18
Hb ≥ 11	12.8 ±1.0	11.0 to16.3	12.8 ±1.0	11.3 to 15.0	0.93

Significance level P=0.05

4.4 Receipt and use iron supplements

About one half (51.2 %) of the women received iron supplements during the index pregnancy. Among the women who received the iron supplements, most (69.1%) received iron supplements from Nyeri PGH. The others got them from; other government facilities (23.2%), bought from a chemist (5.7%), mission hospital (0.5%) and private clinic/facility (1.5%). In addition less than a third of the women (32.3%) were initiated on iron supplements at ≤16 weeks as recommended by World Health Organization. The mean gestation period at initiation was 21±7.2 weeks and the range was 4 to 37 weeks. The women who did not access the supplements gave the following as reasons as to why they did not receive the iron supplements: that they were not offered iron supplements at the facility (83.9%), they were not aware of the programme (14.5%), and they decided not to receive the supplements (1.6%). Iron supplements should be taken daily as recommended in the Kenya National Micronutrient Guideline. However, most of the women (54.6%) did not use (ingest) iron supplements at all in the study population mainly due to lack of supplies as shown in Table 4.7. In addition, 80.5% of those who had supplements used them for more than four days.

The women who used the iron supplements gave different reasons for using with the highest percentage (82.6%) reporting they used the supplements in order to protect themselves from anaemia as shown in Table 4.8. On the other hand, reasons for not using iron supplements differed among the women with 89.4% of those who failed to use reporting failure to use due to lack of supplies as shown in Table 4.9. Among those who

had supplies but failed to use, 40.9% (9/22) reported it was due to the side effects experienced.

Table 4.7: Use of iron supplements among pregnant women attending ANC at Nyeri PGH, 2010

Number of days in a week	Frequency (%) n=381
More than four days in a week	157 (41.2)
One to four days in a week	16 (4.2)
Zero days in a week (received supplies of supplements but never used)	22 (5.8)
Zero days in a week (Never received supplies of supplements)	186 (48.8)

Table 4.8: Reasons for using iron supplements among pregnant women attending ANC at Nyeri PGH, 2010

Reason for using iron supplements	Frequency (%) n=173
To protect oneself from anaemia	143 (82.7)
Because the health worker said one has to take	14 (8.1)
In order to give birth to a healthy baby	15 (8.7)
Don't know	3 (1.7)

Table 4.9: Reasons for not using iron supplements among pregnant women attending ANC at Nyeri PGH, 2010

Reason for not using iron supplements	Frequency (%) n=208
Lack of supplies	186 (89.4)
Due to side effects	9 (4.3)
Did not like the taste of iron supplements	6 (2.9)
Disliked taking drugs	4 (1.9)
Did not know the importance of iron supplements	2 (1.0)
Forgot to take	1 (0.5)

4.5 Factors associated with use of iron supplementation services

There was no significant difference in the compliance to iron supplementation by age, marriage, gravidity, occupation and education level as illustrated in Table 4.10. Need to protect oneself from anaemia was significantly associated with high compliance to iron supplementation (OR=10.9). Health care worker's advice was associated (OR=3.34) with high compliance to iron supplementation. However, this association was not significant (Table 4.11).

Table 4.10: Socio-demographic factors in relation to use of iron supplements among pregnant women attending ANC at Nyeri PGH, 2010

Exposure	High compliant group (n=157) n (%)	Low compliance group (n=38) n (%)	OR (95%CI)	P value
Age in years				
<20	6 (3.8)	1 (2.6)	1.47 (0.17-12.59)	0.59
20-24	53 (33.8)	15(39.5)		
25-29	57 (36.3)	15 (39.5)		
30-35	26 (16.6)	5 (13.1)		
36+	15 (9.5)	2 (5.3)		
Marital status				
Married	135 (86.0)	32 (84.2)	1.15 (0.43-3.07)	0.78
Not married	22 (14.0)	6 (15.8)		
Gravidity				
Primigravidae	74 (47.1)	17 (44.7)	1.10(0.54-2.45)	0.79
Multi-gravidae	83(52.9)	21 (55.3)		
Education level				
No formal education	2 (1.3)	0 (0.0)	1.01 (0.48-2.10)	0.98
Primary level	57 (36.3)	14 (36.8)		
Adult education	1 (0.6)	0 (0.0)		
Higher level	97 (61.7)	24 (63.2)		
Occupation				
Formal employment	16 (10.2)	7 (18.4)	0.87 (043-1.77)	0.70
Informal employment	98 (62.4)	21 (55.3)		
Not employed	43 (27.4)	10 (26.3)		
Residence				
Nyeri county	148 (94.3)	36 (94.7)	0.91 (0.19-4.41)	0.63
Other counties	9 (5.7)	2 (5.3)		

Significance level P=0.05

Table 4.11: Bivariate analysis of possible factors associated with use of iron supplements among pregnant women attending ANC at Nyeri PGH, 2010

Exposure	High compliant group (n=157) n (%)	Low compliant group (n=38) n (%)	OR (95%CI)	P value
Number of visits to the ANC				
< 4 visits	63 (40.1)	16 (42.1)	0.92 (0.45-1.89)	0.82
≥4 visits	94 (59.9)	22 (57.9)		
Source of iron supplements				
Government hospital	144 (91.7)	35 (94.6)	0.63 (0.06-3.00)	0.43
Other sources	13 (8.3)	2 (5.4)		
Gestation at initiation of iron supplements				
≤16 weeks	50 (32.3)	13 (34.2)	0.92 (0.43-1.94)	0.82
>16 weeks	105 (67.7)	25 (65.8)		
Craving for non food items				
Yes	69 (44.2)	10 (27.0)	2.14 (0.97-4.72)	0.056
No	87 (55.8)	27 (73.0)		
Received information on iron				
Yes	132 (84.1)	29 (78.4)	1.46 (0.06-3.55)	0.41
No	25 (15.9)	8 (21.6)		
Presence of anaemia				
Yes	30 (20)	7 (20.0)	1.00 (0.40-2.51)	1.00
No	120 (80.0)	28 (80.0)		
Need to protect oneself from anaemia				
Yes	131 (83.4)	12 (31.6)	10.9 (4.89-24.37)	<0.001*
No	26 (16.6)	26 (68.4)		
Because the health worker advised				
Yes	13 (8.3)	1 (2.6)	3.34 (0.42-26.3)	0.20
No	144 (91.7)	37 (97.4)		

*significant factor at P=0.05

Multivariate analysis (iron supplementation)

Logistic regression analysis revealed that need to protect oneself from anaemia (OR=12.2) was an independent factor significantly associated with high compliance to iron supplementation as illustrated in Table 4.12.

Table 4.12: Factor independently associated with use of iron supplements among pregnant women attending ANC at Nyeri PGH, 2010

Exposure	Odds ratio (95% CI)	Coefficient	Standard error	Z-Statistic	P- value
To protect oneself from anaemia	12.2 (5.32-28.53)	2.51	0.43	5.86	<0.001*

*Significant factor at P=0.05

4.6 Receipt and use of folic acid supplements

Two hundred and sixty four (69.3%) of the women received folic acid supplements during the index pregnancy. Among the women who received folic acid supplements, most of them (68.4%) received from Nyeri PGH. The others got them from; other government facilities (25.1%), bought from chemist (4.2%), mission hospital (0.8%) and private clinic/facility (1.5%). In addition, among those who received the supplements, most of the women 80.7% (213/264) were initiated on folic acid supplementation after 12 weeks of pregnancy despite the fact that folic acid supplementation began after the first trimester is too late to prevent birth defects. The mean gestation period at initiation on the supplements was 20.3 (±7.2) weeks. The range was 4 to 36 weeks. The women who did not access the supplements gave the following as reasons as to why they did not receive the supplements: that they were not offered folic acid supplements at the health facility (73.2%), they were not aware of the programme (24.1 %), and they decided not to receive the supplements (1.8%). Those who used (ingested) the folic acid supplements in the study population were 62.2%. However, frequency of use of the supplements differed among the women despite the fact that folic acid supplements should be taken daily. Of those who received the folic acid supplements, 82.2% used the supplements for more than four days in a week as shown in Table 4.13. The women gave varying reasons for using folic acid supplements with the highest proportion (54%) saying they used the supplements in order to improve general health (Table 4.14). In addition, reasons for not using folic acid supplements differed among the women with 81.3% failing to use the supplements due to lack of supplies as shown in Table 4.15.

Table 4.13: Use of folic acid supplements among pregnant women attending ANC at Nyeri PGH, 2010

Number of days in a week	n	(%)	N=381
More than four days in a week	217	(57.0)	
One to four days in a week	20	(5.2)	
Zero days in a week (received supplies of supplements but never used)	27	(7.1)	
Zero days in a week (Never received supplies of supplements)	117	(30.7)	

Table 4.14: Reasons for using folic acid supplements among pregnant women attending ANC at Nyeri PGH, 2010

Reason for using folic acid supplements	Frequency (%) n=237
To improve general health	128 (54)
To protect oneself from anaemia	50 (21.1)
Because the health worker said one should take	36 (15.2)
In order to give birth to a healthy baby	31 (13.1)
Friends/ relatives encouraged one to take	1 (0.4)
Others reasons	2 (0.8)

Table 4.15: Reasons for not using folic acid supplements among pregnant women attending ANC at Nyeri PGH, 2010

Reasons for not using folic acid supplements	Frequency (%) n=144
Lack of folic acid supplements supplies	117 (81.3)
Did not like the taste of folic acid supplements	6 (4.2)
Did not know the importance of folic acid supplements	5 (3.5)
Dislike taking drugs	4 (2.8)
Due to side effects	7 (4.9)
Forgot to take the folic acid supplements	3 (2.1)
Due to religious/cultural beliefs	2 (1.4)

4.7 Factors associated with use of folic acid supplementation services

There was no significant difference (p=0.05) in the compliance to iron supplementation by age, marriage, gravidity, occupation, and education level (Table 4.16). Need to improve general health (OR=5.03) and health care worker advice (OR=8.85) were significantly associated with higher compliance to folic acid supplementation. Need to give birth to a healthy baby (OR=2.17), presence of anaemia (OR=2.16) and need to protect oneself from anaemia (OR=2.20) were factors associated with high compliance. However, these associations were not significant (Table 4.17).

Table 4.16: Socio-demographic factors in relation to use of folic acid supplements among pregnant women attending ANC at Nyeri PGH, 2010

Exposure	High compliant group (n=217) n (%)	Low compliant group (n=47) n (%)	OR (95% CI)	P value
Age in years				
<20	8 (3.7)	1 (2.1)	1.76 (0.21-14.43)	0.50
20-24	78 (35.9)	21 (44.7)		
25-29	78 (35.9)	14 (29.8)		
30-35	37 (17.1)	8 (17.0)		
36+	16 (7.4)	3 (6.4)		
Residence				
Nyeri county	215 (99.1)	47 (100)	Undefined	0.51
Other counties	2 (0.9)	0 (0.0)		
Marital status				
Married	180 (82.9)	40 (85.1)	0.85 (0.35-2.05)	0.72
Not married	37 (17.1)	7 (14.9)		
Level of education				
No formal education	1 (0.5)	1 (2.1)	0.93 (0.48-1.79)	0.82
primary level	75 (34.5)	17 (36.2)		
Adult education	1(0.5)	0 (0.0)		
Higher level	140 (64.5)	29 (61.7)		
Occupation				
Formal employment	27 (12.4)	5 (10.6)	1.36 (0.72-2.58)	0.34
Informal employment	135 (62.2)	28 (59.6)		
Unemployed	55 (25.3)	14 (29.8)		

Significance level p=0.05

Table 4.17: Bivariate analysis of possible factors associated with use of folic acid supplements among pregnant women attending ANC at Nyeri PGH, 2010

Exposure	High compliant group (n=217) n (%)	Low compliant group (n=47) n (%)	OR (95% CI)	P value
Number of clinic visits				
<4 times	105 (48.4)	20 (42.6)	1.27 (0.67-2.39)	0.47
≥4 times	112 (51.6)	27 (57.4)		
Source of folic acid				
Government hospital	203(93.5)	42 (93.3)	1.04 (0.29-3.76)	0.46
Other sources	14 (6.5)	3 (6.7)		
Craved non food items				
Yes	88 (40.7)	14 (30.4)	1.57 (0.79-3.11)	0.13
No	128 (59.3)	32 (69.6)		
Received information on folic acid				
Yes	179 (82.5)	35 (77.8)	1.35 (0.61-2.95)	0.46
No	38 (17.5)	10 (22.2)		
To give birth to a healthy baby				
Yes	28 (12.9)	3 (6.4)	2.17 (0.63-7.47)	0.16
No	189 (87.1)	44 (93.6)		
To protect oneself from anaemia				
Yes	45 (20.7)	5 (10.6)	2.20 (0.82-5.88)	0.11
No	172 (79.3)	42 (89.4)		
To improve general health				
Yes	118 (54.4)	9 (19.1)	5.03 (2.3-10.91)	<0.001*
No	99 (45.6)	38 (80.9)		
Health worker advised				
Yes	35 (16.1)	1 (2.1)	8.85 (1.18-66.28)	0.011*
No	182 (83.9)	46 (97.9)		

*Significant factors at P=0.05

Multivariate analysis (folic acid supplementation)

Logistic regression analysis revealed that need to improve general health (OR=20.82) and because health care worker advised to take (OR=56.02) and to protect oneself from anaemia (14.10) were independent factors significantly associated (p=0.05) with high compliance to folic acid supplementation as illustrated in Table 4.18.

Table 4.18: Factors independently associated with use of folic acid supplements among pregnant women attending ANC at Nyeri PGH, 2010

Exposure	Odds ratio (95% CI)	Coefficient	Standard error	Z-Statistic	P- value
To improve general health	20.82 (8.65-50.11)	3.04	0.45	6.78	<0.0001*
Because health worker advised	56.02 (7.11-441.24)	4.03	1.05	3.82	0.0001*
To protect oneself from anemia	14.10 (4.79-41.53)	2.65	0.55	4.80	<0.0001*

*Significant at P=0.05

CHAPTER FIVE: DISCUSSION, CONCLUSIONS & RECOMMENDATIONS

5.1 DISCUSSION

5.1.1 Prevalence of anaemia

This study showed that anaemia was less common in this population than in most studies from rural and urban settings in East Africa (WHO and CDC, 2008). However, the finding of a mean Hb concentration of 12.6 g/dl is comparable with results obtained in pregnant women in Awassa Southern Ethiopia (Geis *et al.*, 2003) where a mean Hb concentration of 12.3 g/dl was reported. It is also comparable to another study in Jima town, south-western Ethiopia where a mean Hb concentration of 11.9 g/dl was reported (Desalegn, 1993). Another study found similar findings in the highlands of Tanzania at an average altitude of 1750 meters where a mean Hb before adjustment for altitude was 12.1 g/dl (Sven *et al.*, 2001). In many industrialized countries mean Hb concentration in pregnancy is around 12 g/dl (WHO and CDC, 2008).

The prevalence of anaemia in the study subjects is relatively low compared to the findings of Mwaniki *et al* (1999) which showed that in central and mid west highlands of Kenya where the study site is located, the prevalence of moderate and severe anaemia was 7.5% and 14.1% respectively (Mwaniki *et al*, 1999). The prevalence of anaemia was also much lower than that reported in studies conducted in Kisumu Kenya (Ouma *et al*, 2008) and North Eastern Nigeria (Kagu *et al*, 2007) where the prevalence was 69.1% and 72.0% respectively. The low prevalence of anaemia in the study population may be attributed to higher level of education and low parity among the women. There was no significant difference in means of haemoglobin concentration between the high and low

compliant groups to folic acid and iron supplementation. The lack of a difference by compliance may be attributed to late initiation on supplementation suggesting that the women may not have taken the supplements long enough to result to a difference between those who complied and those who did not comply. This suggests the importance of initiating women on supplementation early and also ensuring consistent supply of the supplements throughout pregnancy if the programme is to to have an impact. These findings differ with findings from Nigeria by Dairo and Lawovin (2006) where the mean haemoglobin concentration level was higher among women complying with iron supplementation compared with those not complying.

5.1.2 Utilization of iron supplementation services and associated factors

The study showed that more than half (54.6%) of the women attending ANC at Nyeri PGH never used (ingested) iron supplements during the index pregnancy. This coverage of the iron supplementation programme is low compared to the coverage of a similar programme in Vietnam where a survey showed 97% of the participants took some iron tablets during their last pregnancy (Aikawa *et al.,* 2006). Women failed to take the supplements mainly due to lack of supplies as 48.8% of the women never received the supplements. This agrees with a review done by Galloway and Mcguire (1994) who found that lack of supplies was the most common reason why women did not take iron supplements. The study done in Vietnam showed that the most important reason for taking iron tablets among adult women was frequent supply of iron tablets (Aikawa *et al.,* 2006). In addition, Mora (2002) stated that one critical issue to be addressed in iron supplementation programmes for women of child bearing age was to secure a continued

supply of iron supplements at distribution points by developing effective management and monitoring systems. Majority of the women (67.7%) were initiated on the supplement after 16 weeks while WHO (2006) recommends at least 6 months supplementation with iron supplements during pregnancy or if 6 months of supplementation cannot be achieved during the pregnancy, supplementation during the postpartum period to continue or the dosage to be increased to 120 mg iron during pregnancy.

Though most women (54.6%) never used iron supplements in the overall sample, compliance was high (80.5%) among those who received the supplements. This is comparable to a study conducted in Philippines (Pamela *et al.*, 2007) which showed that women took 85% of pills given each month. This is also comparable to a study done in Malaysia which found that the compliance to iron supplementation was 74% (Saerah and Hanafiah, 2006). However, this does not agree with findings from Nigeria which showed a compliance rate of 37.5% to iron supplementation (Dairo and lawovin, 2006).

Side effects remained a setback to iron supplementation as a high proportion 40.9% (9/22) of women who failed to take the iron supplements among those who received the supplements reported that it was due to side effects. This may be explained by the fact that most women did not receive adequate information when they were being given the supplements. These findings do not agree with the findings from the study conducted in Mali where among the benefits most frequently reported was supplements eliminated some side effects such as nausea and vomiting. This could be explained by the consistent health messages that were given in the Mali study including advance warning that iron

supplements may cause side effects (Aguayo *et al.*, 2005). Moreover, side-effects were traditionally considered the major obstacle to compliance, leading many to advocate for weekly instead of daily supplementation. However, some recent studies have shown that side-effects have a limited influence on compliance especially when it is unclear how women distinguish the symptoms associated with taking iron tablets and those associated with pregnancy (Hyder *et al.*, 2002).

The only factor independently associated with compliance to iron supplementation was to prevent anaemia. This is similar to the findings of Binetou and Robert (2007) who found that women's awareness that iron supplements would remedy anaemia was a motivating factor for compliance. In this study health care worker advice was associated with high compliance though the association was not significant. However, only a limited number of women were given any information on iron supplements (44.6%). This could negatively affect the supplementation programme as inadequate counseling by health-care providers has also been documented as a major barrier to compliance in developing countries (Galloway and Mc Guire, 1994, Galloway *et al.*, 2002 and Oluwatoyin, 2000). In a study done in Malaysia women who did not get adequate information regarding iron supplementation were at a higher risk of non-compliance compared to those given adequate information (Saerah and Hanafiah, 2006). In another study conducted in India there was a significant improvement in knowledge on prevention of anaemia and iron deficiency through multiple teaching methods (Rajaratnam *et al.*, 1998). In addition, Mora (2002) also cited systematic counseling as one of the strategies to enhance compliance to iron supplementation. This shows that

health care worker advice and counseling should be an integral part when offering supplementation services.

In a study done in Nigeria single and teenage mothers and those aged 35 years and above were less likely to be compliant. Married women, those in urban location, and those aged 20-29 years were more compliant with iron supplementation (Dairo and Lawovin, 2006). This was however not the case in this study as there was no significant difference in compliance to iron supplementation by age and location. In another study conducted in Malaysia working women were found to be compliant to iron supplementation compared to housewives (Saerah and Hanafiah, 1998). However in this study there was no significant difference by occupation to iron supplementation.

5.1.3 Utilization of folic acid supplementation services and associated factors

This study showed that more than a third of the women (37.8%) never used (ingested) folic acid supplements during the index pregnancy mainly due to lack of supplies. In addition more than two- fifths (57%) of the women ingested the folic acid supplements for ≤ four day in a week when they had supplies. However, this is higher than findings from a study done in Puerto Rico where only 30% of women consumed folic acid and only 21% reported to consume it at least 4 times in a week (Lourdes *et al.,* 2008). The women had limited access to folic acid supplements as 30.7 % of the women were never given folic acid supplements supplies during the index pregnancy. This may lead to increased prevalence of maternal anaemia and neural tube defects as scientific evidence indicated that the strategy with the greatest impact in reducing the prevalence of

maternal anaemia and neural tube defects is supplementation (Wharton and Booth, 2001).

Despite the fact that folic acid supplementation initiated after first trimester is too late to prevent birth defects only 18.9% (50/264) were initiated on the supplements during the first trimester. This may lead to increased risk of neural tube defects in this population as women with low folic acid supply in combination with low blood vitamin B12 levels were found to have increased risk of neural tube defects (Padmanabhan, 2006). In another study carried out in China, women were offered 400 µg folic acid tablets to take before pregnancy. The rates of neural tube defects (NTD) were compared between women who took and those who did not take folic acid supplements. Folic acid supplementation resulted in a 41% to 79% decline in the incidence of neural tube defects (Berry *et al.,* 1999). In North America folate deficiency was significantly decreased primarily due to folic acid fortification of the food supply but the need for adequate folate intake prior to conception and during the early weeks of pregnancy remained a significant concern to reduce the risk for the development of neural tube defects as described by Scholl and Johnson (2000).

Compliance to folic acid supplementation in the entire sample (n=381) was higher (57%). This is comparable to the findings of Binetou and Robert (2007) in Senegal where overall compliance to folic acid and iron supplementation was 69%. The women who were given folic acid supplements reported high compliance of 82.2% (217/264) to folic acid when they had supplies. This is comparable to findings of a study conducted in

Mali where compliance to folic acid/iron supplementation was 92.2% (Aguayo *et al.*, 2005).

Perceived side effects was a setback to folic acid supplementation as the highest proportion of women 25.9% (7/27) who failed to take the supplements among those who received supplements reported it was due to side effects. This shows that women may not have known which of the two supplements caused side effects as side effects have mainly been associated with iron supplementation in different studies (Ekstrom *et al.*, 1996, Binetou and Robert, 2007). This indicates there is need of health workers to give health messages when dispensing the supplements especially on the side effects that may result from iron supplements and not from folic acid supplements.

Health workers advice was an independent factor significantly associated with high compliance. This is in agreement with the findings of researchers in Mali who also found a strong link between counseling by health care workers and compliance (Aguayo *et al.*, 2005). The researchers in Mali reported that pregnant women complied with supplementation when they were given minimum, consistent, and easily understandable information and counseling. However, only slightly more than half of the women (58.0%) were given any information on folic acid. This could negatively affect utilization of the services. This was found to be the case in a study done in Senegal which showed that the quality of counseling during the antenatal visit was a very important determinant of compliance to supplementation (Binetou and Robert, 2007).

Need to protect oneself from anaemia was also an independent factor significantly associated with high compliance. This is similar to the findings of Binetou and Robert

(2007) who found that women's awareness that iron and folic acid would remedy anaemia was a motivating factor for compliance. Similar findings were reported in Nepal where increased blood was a perceived benefit among women (Bharati *et al.,* 2009). The other independent factor significantly associated with high compliance was to improve general health. This is in agreement with findings in Senegal where perceived health benefit was a motivating factor to compliance (Binetou and Robert, 2007). This is also in agreement with the study conducted in Nepal where improvement in health was one of the major perceived benefit reported by the women (Bharati *et al.,* 2009). Feeling healthy was also one of the most frequently mentioned benefits in the study done in Mali (Aguayo *et al.,* 2005).

In the study conducted in Nepal older age, later gestational age at initiation and literacy were significantly associated with high compliance (Bharati *et al.,* 2009). In another study done in Puerto Rico, having high school education or beyond was significantly associated with consumption of folic acid supplements (Lourdes *et al.,* 2008). However, these factors were not significantly associated with high compliance to folic acid supplementation in this study. Need to give birth to a healthy baby was not significantly associated with high compliance. However, it was one of the most frequently reported reasons for using the supplements. This agrees with the findings of Aguayo *et al.,* (2005) where one of the most frequently mentioned benefits of supplementation was the newborn/baby is healthy. Need to protect oneself from anaemia was also not independently associated with high compliance. However, it was frequently mentioned as a motivating factor. This is similar to the findings of Binetou and Robert (2007) who

found that women's awareness that iron and folic acid would remedy anaemia was a motivating factor for compliance. Similar findings were reported in Nepal where increased blood was a perceived benefit among women (Bharati *et al.*, 2009).

5.2 CONCLUSIONS

The prevalence of anaemia in this population was not of major public health importance according to WHO classification.

Compliance to iron and folic acid supplementation was high among the women who received the supplements. However, inadequate supply of the supplements was a major barrier to effective iron and folic acid supplementation. Other setbacks to iron and folic acid supplementation were: late initiation on supplementation, insufficient information on iron and folic acid supplementation given to the women and side effects.

On the other hand, desire to protect oneself from anaemia was a motivating factor for high compliance to iron supplementation while receiving health care worker's advice desire, to protect oneself from anaemia and desire to improve general health were motivating factors for high compliance to folic acid supplementation.

5.3 RECOMMENDATIONS

- The ministries of health should ensure consistent supplies of iron and folic acid supplements in order to improve access of the supplements by the women.
- The ministries of health should sensitize and train health care workers to provide easily understandable information on the health benefits that the supplements confer during pregnancy in order to improve utilization of iron and folic acid supplements.
- Health care workers should provide information regarding side effects resulting from iron supplementation in order to improve compliance.
- The ministries of health should sensitize community members on the importance of seeking antenatal care early in order to get timely supplementation services and reap more benefits from the supplementation programme.
- Future research on iron and folic acid supplementation should focus on how health care worker's and clients interact during the antenatal visit and on the health care worker knowledge attitude and practices as health care workers advice is an important determinant of compliance.

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APPENDICES

APPENDIX 1A: Questionnaire for determination of receipt and use of supplements and associated factors (English version)

Identifying information

Questionnaire number_____ ANC serial number_____

Date of interview_____/_____/_____ Interviewer initials_____

Socio-demographic information

Respondent (pregnant woman)

1. Age_____

2. Date of birth_____

3. Residence: District_____ Division_____

4. Religion Christian____ Muslim____ Traditionist____ Others specify___

5. Marital status: Married_____ divorced _____ Separated ____

Single_____ widowed _____ other specify _____

6. Education level:

Highest education level attained	**Tick one**	**Completed /not completed**
Primary		
Secondary		
College		
Vocational training		
Adult education		
None (illiterate)		

7. Occupation Salaried employee_____ Farmer_____

Self employment/ business___ Casual laborer____

Student_____ Housewife_____

Other specify_____

8. Number of children (gravidity) _____

9. Number of people living in the household_____

10. Number of people less than five years living in the household_____

Spouse information

11. Age_____

12. Education level

Highest education level	**Tick one**	**Completed /not completed**
Primary		
Secondary		
College		
Vocational training		
Adult education		
None (illiterate)		

13. Occupation Salaried employee_____ Farmer_____

Self employment/ business_____ Casual laborer____

Student_____ Other specify_____

14. Religion Christian____ Muslim____ Traditionist_____ Others specify_____

Clinical information and associated factors

Q15. How many weeks is the pregnancy during this visit **(gestation; confirm from ANC card)** _____

Q16. How many times have you visited the antenatal clinic during the current pregnancy **(confirm from ANC card)** _____

Folic acid supplements

Q17.a. Have you received folic acid supplement during the current pregnancy?

Yes _____ **(go to Q18)** No _____ **(go to Q22)**

Q18a. How many weeks were you pregnant when you first received folic acid supplement? **(Confirm from card)**_____

b. What was the source of the folic acid supplement?

i. Nyeri PGH antenatal clinic _____

ii. I bought from a chemist / pharmacy _____

Other source of folic acid supplement (please specify) _____

Q19.a. Have you been using the folic acid supplement?

Yes_____ **(go to Q19b)** No _____ **(go to Q19c)**

b. How many days in a week did you take folic acid supplements (average)_____

c. What are the reasons for using the folic acid supplements? **(Do not read choices)**

i. In order to give birth to a healthy baby_____

ii. To protect myself from anaemia_____

iii. To improve general health _____

iv. Because the health worker said I have to take_____

v. My spouse encouraged me to take_____

vi. My friends/relative encouraged me to take_____

vii. Don't know_____

viii. Others specify _____

d. What are the reasons for not using the folic acid supplement **(Do not read choices)**

i. I don't know the importance of folic acid supplement_____

ii. I get enough folic acid from the diet_____

iii. I forgot to take the folic acid supplement_____

iv. I did not like the taste of folic acid_____

v. I dislike taking drugs_____

vi. Due to religious/cultural beliefs_____

vii. Was not aware of the folic acid supplementation programme_____

viii. Due to side effects_____

Please specify the side effect _____

ix. Other reasons for not using (please specify) _____

Q20. a. In the previous visit to the antenatal clinic did you receive folic acid supplement?

Yes____ **(go to Q21)** No_____ **(go to Q22)**

Q21.a. In the past one month have you been using the folic acid supplement?

i. I have not been taking the folic acid supplement in the past one month _____

ii. I have been taking the folic acid supplement rarely in the past one month _____

iii. I have been taking the folic acid supplement sometimes _____

iv. I have been taking the folic acid supplements on most of the days (often) in the last one month _____

v. I have been taking the folic acid supplement on all days in the past one month___

b. In the past one week did you use the folic acid supplement?

Yes ____ **(go to Q21c)** No____ **(go to Q24)**

c. How many days in the past one week did you use the folic acid supplement? _____

Q22. If no please give reason for not receiving folic acid supplement

i. I was not offered the folic acid supplement at facility_____**(go to Q24)**

ii. Was told folic acid supplements were out of stock_____ **(go to Q24)**

iii. Was not aware of the programme_____ **(go to Q24)**

iv. I decided not to receive the folic acid supplement offered to me _ **(go to Q23)**

v. Other reason **(specify)_____ (go to Q24)**

Q23. Please give reason for declining to receive **(go to Q24)**

i. I don't know the importance of folic acid supplement_____

ii. I get enough folic acid supplement from the diet_____

iii. I did not like the taste of folic acid supplement_____

iv. I dislike taking drugs_____

v. Due to religious/cultural beliefs_____

vi. Due to anticipated side effects_____

vii. Due to side effects in previous pregnancies_____

Please specify the side effect experienced in previous pregnancy _____

Other reason please specify _____

Iron supplement

Q24. a. Have you received iron supplement during the current pregnancy?

Yes_____ **(go to Q24b)** No _____ **(go to Q29)**

b. How many weeks were you pregnant when you started taking iron supplement?

(Confirm from ANC card) _____

c. What was the source of the iron supplement?

a. Nyeri PGH antenatal clinic _____

b. I bought from a chemist/ pharmacy _____

Other source of iron supplement (please specify) _____

Q25a. Have you been taking the iron supplement?

Yes _____ **(go to Q25b)** No_____ **(go to Q25c)**

b. How many days in a week did you take iron supplement? (average) _____

c. What are the reasons for taking the iron supplement? **(Do not read choices)**

i. In order to give birth to a healthy baby_____

ii. To protect myself from anaemia_____

iii. To protect myself from infections_____

iv. Because the health worker said I have to take_____

v. My spouse encouraged me to take_____

vi. My friends/relative encouraged me to take_____

vii. Don't know_____

viii. Others specify_____

d. What are the reasons for not taking the iron supplement? **(Do not read choices)**

i. I don't know the importance of iron supplement_____

ii. I get enough iron from the diet_____

iii. I took another formulation of iron supplement

iv. I forgot to take_____

v. I did not like the taste_____

vi. I dislike taking drugs_____

vii. Due to religious/cultural beliefs_____

viii. Was not aware of the iron supplementation programme_____

ix. Due to side effects_____

Please specify the side effect _____

Q26. In the previous visit to the antenatal clinic did you receive iron supplement?

Yes____ **(go to Q27)** No_____ **(go to Q29)**

Q27. What was the source of the iron supplement?

a. Nyeri PGH antenatal clinic _____

b. I bought from a chemist/ pharmacy _____

Other source of iron supplement (please specify) _____

Q28.a. In the past one month have you been taking the iron supplement offered to you?

i. I have not been taking the iron supplement in the past one month _____

ii. I have been taking the iron supplement rarely in the past one month _____

iii. I have been taking the iron supplements sometimes _____

iv. I have been taking iron supplements on most of the days (often) in the last one month___

v. I have been taking the iron supplements on all days in the past one month _____

b. In the past one week did you take the iron supplement offered to you?

Yes ____ No____

c. If yes how many days of the week did you take the iron supplements? _____

Q29. If no please give reason for not receiving iron supplement

i. I was not offered the iron supplement at facility_____ **(got to Q31)**

ii. Was told iron supplements were out of stock_____ **(go to Q31)**

iii. Was not aware of the programme_____ **(go to Q31)**

iv. I decided not to receive the iron supplement offered to me_____ **(go to Q30)**

v. Other reason **(specify)_____ (go to Q31)**

Q30. Please give reason for declining to receive iron supplement **(go to 31)**

i. I don't know the importance of iron supplement_____

ii. I did not like the taste of iron supplement_____

iii. I dislike taking drugs_____

iv. Due to religious/cultural beliefs_____

v. Due to anticipated side effects_____

vi. Due to side effects in previous pregnancies_____

Please specify the side effect experienced in previous pregnancy _____

vii. Other reason please specify _____

Q31. How many nutrition education sessions have you attended? _____

Q32. Have you been given any information on folic acid supplement during the education session? yes__ No___

Q33. Have you been given any information on iron supplement during the counseling session? Yes__ No___

Q34. Have you been on prescribed medication in the last one month?

Yes_____ **(go to Q35)** No____ **(go to Q38)**

Q35. Did you take all the prescribed medication as instructed?

Yes____ **(go to Q36)** No____ **(go to Q37)**

Q36. Give reasons for taking all the prescribed medication _____

Q37. Give reasons for not taking all the prescribed medication _____

Q38. Do you suffer from any chronic illness? Yes_____ no_____

Q39. a. Have you craved for non food items?

Yes_____ **(go to Q39b)** No_____ **(go to Q40)**

b. Which non food item have you craved for?

(i) Soil (ii) Stones (iii) Others specify _____

c. Have you been consuming the non food item craved for? Yes___ No___

d. If yes how often _____

Q40. a. Do you take tea with meals? Yes _____ No____

b. If yes how often? _____

Q41 a) How many meals do you usually have in a day? _____

b) How many snacks do you usually have in a day? _____

Q42. a. Are you enrolled in a food supplementation programme? Yes_____ no_____

b. If yes which food items are offered to you? _____

Q43.What is the haemoglobin level recorded in the ANC card_____

Date of the test_____

Q44.What was the gestation when the haemoglobin testing recorded in the ANC card was done **(confirm from card)** _____

Q45. What is the haemoglobin level during this current visit _____

APPENDIX 1B: Questionnaire for determination of receipt and use of supplements and associated factors (Kikuyu version)

Gicunji kia mbere: (identifying information)

Namba ya bomu_____ Namba ya kiriniki _____

Mweri _____

Ritwa ria uria uroria ciuria_____

Gicunji gia keri (socio demographic information)

1. Wina miaka iigana? _____

2. Waciarirwo mweri cigana? _____

3. Uikaraga ku? District _____ division_____

4. Wi wa ndini iriku?

i) Mukiristo ___ ii) muithiramu ___ iii) muhindi ____ iv) ndini ya kinduire __

Hanja ingi_____

5. Wi muhiku? i) ndi muhiku ____ ii) ndiri ndahika ____ iii) nitwatiganire_____

iv) ndi mutumia wa ndigwa _____

6. Ukinyitie githomo ha?

Haria ukinyitie githomo	**Iyuria ithandukuini rimwe**	**Nindarikirie/ ndiarikirie**
Primary		
Thekondari		
Korenji		
Kothi		
Githomo kia ngumbaru		
Ndithomete ona hanini		

7. Urutaga wira uriku? i) kwandikwo____ ii) kurima ___ iii) kwiyandika/biacara ____

iv) kibarua ____ v. ndi murutwo _____ vi. ndindaga mucii __ vii) haja ingi____

8. Ugite ciana cigana (gravidity) _____

9. Kwanyu muikaraga andu aigana aria muriaga kuma nyungu imwe? _____

10. Kwanyu guikaraga andu aigana a thi wa miaka itano aria muriaga nyungu imwe?___

Maundu ma mwendwa waku

11. Mwendwa waku ena miaka iigana? _____

12. Mwendwa waku akinyitie githomo ha?

Haria akinyitie githomo	**Iyuria ithanduku-ini rimwe**	**Niarikirie/ ndarikirie**
Primary		
Thekondari		
Korenji		
Kothi		
Githomo kia ngumbaru		
Ndathomete ona hanini		

13. Mwendwa waku arutaga wira uriku? i) Kwandikwo ___ ii) kurima ___ iii) biacara ____ iv) kibarua ___ v) ni murutwo ___ vi) atindaga mucii ___ vii) haja ingi_____

14. Mwendwa waku ni wa ndini iriku? i) mukiristo __ ii) muithiramu__ iii) muhindi __ iv) Ndini ya kinduire Hanja ingi_____

Gicunji gia gatatu (Clinical information and associated factors)

15. Ukoretwo wi muritu ciumia cigana riu? _____**(rora kandi-ini ya kiriniki)**

16. Ucereire kiriniki ya atumia aritu maita maigana kuma woha nda ino_____ **(rora kandi-ini ya kiriniki)**

Maundu megie "folic acid"

17. Niuhetwo "folic acid" kuma woha nda ino? iii ____ aca ____

18a. Waheirwo "folic acid" ria mbere nda ina ciumia cigana? ____ **(rora kandi-ini ya kiriniki)**

b.Wahereirwo "folic acid" ku?

i. Thibitarii-ini nene ya nyiri _____

ii. Kuma nduka-ini ya ndawa _____

iii. Kuma thibitariri-ini ingi ya thirikari _____

iv. Kuma thibitari-ini ya miceni ____

v. Kuma thibitari-ini ya "private" kana ya mundu kiumbe _____

19a. Niukoretwo ukinyua "folic acid" iii ____ aca _____

b. Uhuthiraga "folic acid" maita maigana hari wiki? (Average) _____

c. Ni itumi iriku citumaga uhuthire "folic acid" **(ndugathome hanja)**

i. Nigetha ngie mwana wina abia njega _____

ii. Nigetha ngiriririe unyihu wa thakame mwiri-ini _____

iii. Nigetha ngie na afya njega ya mwiri _____

iv. Niundu murigitani augire nyue "folic acid" _____

v. Mwendwa wakwa andarire nyue "folic acid" _____

vi. Andu a nyumba kana arata mandarire nyue "folic acid" _____

vii. Gutiri gitumi giatumire nyue “folic acid” _____

viii. Hanja ingi_____

c.Ni itumi iriku ciatumire wage kuhuthira “folic acid” **(ndugathome hanja)**

i. Ndiui bata wa “folic acid” _____

ii. Irio iria ndiaga niciheaga “folic acid” yakuigana _____

iii. Nikuriganirwo ni kunyua “folic acid” _____

iv. Ndikenagio ni uria “folic acid” icamaga _____

v. Ndikenagio ni kunyua ndawa o yothe _____

vii. Niundu wa ndini kana unduire _____

viii. Niundu wa mathina maria marehagwo ni “folic acid” _____

- Ni mathina mariku wiciragia marehagwo ni “folic acid”_____

viii. Hanja ingi _____

20a. Rita ria muico guthii kiriniki niwaheirwo “folic acid”? iii __ aca __

b. Waheirwo “folic acid” kuma ku?

i. Thibitari-ini nene ya nyiri _____

ii. Kuma nduka-ini ya ndawa _____

iii. Kuma thibitariri-ini ingi ya thirikari _____

iv. Kuma thibitari-ini ya miceni ____

v. Kuma thibitari-ini ya “private” kana ya mundu kiumbe _____

vi. Hanja ingi_____

21a. Hari mweri umwe uria uhitukite niukoretwo ukinyua “folic acid”

i. Ndikoretwwo ngihuthira “folic acid” _____

ii. Huthirite “folic acid” thiku nini _____

iii. Huthirite “folic acid”thiku nyingi _____

iv. Huthirite ”folic acid” thiku ciothe _____

v. Huthiraga “folic acid” rimwe na rimwe _____

b. Hari kiumia kimwe kiria kihitukite niunyuite “folic acid”? iii _____ aca ____

c. Hari kiumia kimwe kihituku unyuite “folic acid” thiku cigana? _____

22. Ni maundu mariku matumire wage kuheo “folic acid”

i. Ndiaheirwo folic acid kiriniki-ini _____

ii. Nderirwo gutiri ”folic acid” _____

iii. Ndiamenyaga atumia aritu nimaheagwo “folic acid” _____

iv. Nikurega ndaregire kuheo “folic acid” _____

v. Hanja ingi _____

23. Ni maundu mariku matumire urege kuheo “folic acid”?

i. Ndiui bata wa “folic acid” _____

ii. Irio iria ndiaga niciheaga “folic acid” yakuigana _____

iii. Nikuriganirwo ni kunyua “folic acid” _____

iv. Ndikenagio ni uria “folic acid” icamaga _____

v. Ndikenagio ni kunyua ndawa oyothe _____

vii. Niundu wa ndini kana unduire _____

viii. Niundu wa mathina maria marehagwo ni “folic acid” _____

- Ni mathina mariku wiciragia marehagwo ni “folic acid”_____

ix. Hanja ingi _____

Maundu megie “iron”

24a. Niuhetwo “iron” kuma woha nda ino? iii ____ aca ____

b. . Waheirwo “iron” ria mbere nda ina ciumia cigana? _____ **(rora kandi-ini ya kiriniki)**

c. Wahereirwo “iron” ku? _____

i. Thibitarii-ini nene ya nyiri _____

ii. Kuma nduka-ini ya ndawa _____

iii. Kuma thibitariri-ini ingi ya thirikari _____

iv. Kuma thibitari-ini ya miceni _____

v. Kuma thibitari-ini ya “private” kana ya mundu kiumbe _____

vi. Hanja ingi_____

25a. Niukoretwo ukinyua “iron” iii ____ aca _____

b. Unyuaga “iron” thiku cigana he wiki? (average)_____

c. Ni itumi iriku citumaga uhuthire “iron” **(ndugathome hanja)**

i. Nigetha ngie mwana wina abia njega _____

ii. Nigetha ngiriririe unyihu wa thakame mwiri-ini ____

iii. Nigetha ngie na “iron” yakuigana mwiri-ini _____

iv. Niundu murigitani augire nyue “iron” _____

v. Mwendwa waakwa andararire nyue “iron” _____

vi. Andu a nyumba na arata mandarire nyue “iron” _____

vii. Gutiri gitumi giatumire nyue “iron” ____

viii.Hanja ingi_____

d. Ni itumi iriku ciatumire wage kuhuthira “iron” **(ndugathome hanja)**

i. Ndiui bata wa “iron” ___

ii. Irio iria ndiaga niciheaga “iron” yakuigana ____

iii. Nikuriganirwo ni kunyua “iron”____

iv. Ndikenagio ni uria “iron” icamaga _____

v. Ndikenagio ni kunyua ndawa oyothe_____

vii. Niundu wa ndini kana unduire ______

viii.Niundu wa mathina maria marehagwo ni “iron” ______

- Ni mathina mariku wiciragia marehagwo ni “iron”_____

ix.hanja ingi _____

26a. Rita ria muico guthii kiriniki ya atumia aritu niwaheirwo “iron”? iii __ aca __

27. Waheirwo “iron”kuma ku? **(ndugathome hanja)**

i. Thibitariiini nene ya nyiri ______

ii. Kuma nduka-ini ya ndawa ______

iii. Kuma thibitaririini ingi ya thirikari _____

iv. Kuma thibitari-ini ya miceni _____

v. Kuma thibitari-ini ya “private” kana ya mundu ______

vi. Hanja ingi_____

28a. Hari mweri umwe uria uhitukite niukoretwo ukinyue “iron” **(ndugathome hanja)**

i. Ndikoretwo ngihuthira “iron” _____

ii. Huthirite “iron” thiku nini ______

iii. Huthirite “iron” thiku nyingi _____

iv. Huthirite “iron” thiku ciothe _____

v. Huthiraga “iron” rimwe na rimwe _____

b. Hari wiki imwe iria ihitukite niunyuite “iron”? iii _____ aca _____

c. Hari kiumia kiu kimwe kihituku unyuite “iron” thiku cigana ? _____

29. Ni maundu mariku matumire wage kuheo “iron”? **(ndugathome hanja)**

i. Ndiaheirwo “iron” kiriniki-ini _____

ii. Nderirwo gutiri ”iron” _____

iii. Ndiamenyaga atumia aritu nimaheagwo “iron” _____

iv. Nikurega ndaregire kuheo “iron” _____

v. Hanja ingi _____

30. Ni maundu mariku matumire urege kuheo “iron”? **(ndugathome hanja)**

i. Ndiui bata wa “iron” _____

ii. Irio iria ndiaga niciheaga “iron” yakuigana _____

iii. Nikuriganirwo kunyua “iron” _____

iv. Ndikenagio ni uria “iron” icamaga _____

v. Ndikenagio ni kunyua ndawa oyothe _____

vii. Niundu wa ndini kana unduire _____

viii. Niundu wa mathina maria marehagwo ni “iron” _____

- Ni mathina mariku wiciragia marehagwo ni “iron”_____

ix. Hanja ingi _____

31. Uthomithitio uhoro wa mirire maita maigana? _____

32. Niwatariirio uhoro wa folic acid? iii _____ aca _____

33. Niwatariirio uhoro wa “iron”? iii _____ aca _____

34. Hari mweri umwe ucio uhitukite niwandikiirwo ndawa ni ndagitari? iii __ aca ___

35. Niwanyuire ndawa ciothe uria watariirio? Iii _____ aca _____

36. Ni maundu mariku matumire unyue dawa uria watariirio ni ndagitari? _____

37. Ni maundu mariku matumire wage kunyua dawa uria watariirio ni ndagitari? _____

38. Niukoretwo na murimu ukoretwo ugiguthumbura ihinda inene? iii____ aca___

39a. Niukoretwo ukiriria kuria indo itariagwo ni andu? iii ____ aca____

b.Ni indo iriku ukoretwo ukiriria itariagwo ni andu?

i) tiri _____ ii) mahiga _____ iii. hanja ingi _____

c. Ni ukoretwo ukiria indo icio itariagwo ni andu ukoretwo ukiririria? iii ___ aca ___

d. Ukoretwo ukiria indo ici itariagwo ni andu maita maigana?_____

40a. Niurianagiria irio na cai? iii _____ aca _____

b.Ukoretwo ukirianiria irio na cai maita maigana? _____

41a. Uriaga irio nyingi (main meals) maita maigana muthenya? _____

b.Uriaga “snacks” maita maigana muthenya? _____

42a. Niwiyandikithitie murandi-ini o wothe waguteithio na irio? iii ___ aca _____

b. Uheagwo irio iriku murandi-ini ucio wiyandikithitie? _____

43. Githimi gia thakame uria iigana mwiri-ini kiria kiandikitwo kandi-ini ya kiriniki ___

44. Nda yari na ciumia cigana ugithimirwo githimi gia thakame uria iigana? _____

45. Thakame iigana atia mwiri-ini kuringana na githimi kia umuthi? _____

APPENDIX 2: Procedure for haemoglobin concentration testing

- At the beginning of each day the machine was checked whether it was clean and in good working order. The control microcuvette was placed into the microcuvette holder and checked whether the readings were within 0.3 g/dl of the control value.
- Hands were washed with soap and water and dried thoroughly with a clean paper towel before and after testing each participant.
- The participant was identified with the questionnaire number. The procedure was first explained using the consent form and any questions answered. It was made clear that the participants could with draw at any point from the study.
- The subjects were asked to sit comfortably in a chair where there was no danger of falling in case one would faint. The subject was asked to extend the hand. It was ensured that the hand was extended below the heart and the fingers were straight but relaxed.
- All supplies to be used were assembled on the work table before testing and a fresh pair of snug fitting disposable latex gloves were put on. The microcuvette container was then closed.
- The participant's middle or the ring finger was chosen for the finger stick.
- The participant's finger was felt for warmth. If the finger was cold, the finger was rubbed vigorously to warm it.
- The participant's finger was held for the finger stick using a rolling motion to massage the finger from the top knuckle towards the finger tip in order to

increase blood flow.The participant's finger tip was cleaned with a wet gauze pad with alcohol.

- The participant's finger was dried with a clean, dry gauze pad.
- The lancet was held with the middle finger and thumb. The index finger was used to trigger the needle.
- Gentle pressure was applied to firm the skin so that the lancet went deeper into the finger.
- A rolling motion was again used to massage the subject's finger from the top knuckle towards the finger tip to increase blood flow. The finger was punctured with a sharp, quick motion. Gentle pressure was applied to the wrist, palm, and top knuckle to initiate blood flow.
- The first and second drops of blood were wiped away. The third drop was sampled.
- The tip of the microcuvette was placed in the middle of the blood drop filling the microcuvette completely with a single drop of blood in one step.
- The microcuvette was inspected for air bubbles by holding it up to the light.
- Any excess blood from the flat sides of the microcuvette was wiped with a clean gauze pad.
- The filled microcuvette was placed into the HemoCue microcuvette holder within one to three minutes of taking the sample, and not later than ten minutes.
- The microcuvette was gently slid into the microcuvette holder and into the machine until the stop point was reached.

- While the HemoCue machine was reading the sample, a Band-Aid was applied to the puncture.
- After approximately 45 seconds, the haemoglobin value that appeared on the display was recorded. All the waste materials and sharps were segregated and disposed appropriately during and after the procedure

APPENDIX 3A: Consent form (English version)

Questionnaire number_____

Date: _____ Interviewer's initials: _____

Iron and folic acid supplements are offered to pregnant women in Kenya. We are conducting a study in Nyeri Provincial General Hospital to determine the receipt and use of the supplements and associated factors. We will also determine the prevalence of anaemia. We would like you to be part of this study by allowing us to interview you. You are free to participate or not to participate. Refusal to participate will not result in the loss of benefits that you are otherwise entitled to. If you decide to participate we will ask you questions and then collect a small blood sample from a finger prick. All the information you give to us will be treated as confidential.

The finger prick may cause some temporary pain in your finger and you may also be upset when you see blood. The procedure is routinely used and presents almost no risk. The amount of blood that is sampled is very small and will not worsen any anaemia that you may already have. There will be no more than one test done. The result of the test will be communicated to you immediately after the blood sample is taken. If you are anaemic, you will be referred for treatment and follow-up. In the event of any questions please contact: **Lucy Gathigi Telephone number 0721948454 or address P.O. BOX 21, KIGANJO** or **the Chairman KEMRI National Ethical Review Committee, P.O BOX. 54840 00200, Nairobi or telephone number 2722541, 2713349, 0722 205901 email info@kemri.org.**

By signing this form you indicate that the consent form has been explained to you by the investigator. You were given an opportunity to ask questions, all of which have been answered to your satisfaction and that you have chosen to participate.

Participant's name: _____

Signature or thumb print: _____ Date: _____

Name of person obtaining consent: _____

Signature _____ Date: _____

APPENDIX 3B: Consent form (kikuyu version)

Bomu yagitwitikira kunyitanira utuiria-ini

Namba ya bomu_____ Mweri

_____

Ritwa ria uria uroria ciuria _____

Atumia aritu nimaheagwo “iron” na “folic acid” macerera kiriniki cia atumia aritu thiini wa bururi wa Kenya. Nitureka utuiria guku thibitari-ini nene ya Nyiri. Bata wa utuiria uyu ni kumenya uria atumia aritu maheagwo “iron” na “folic acid” , na kumenye uria macihuthagira. Ningi nitukwenda kumenya gicunji kia atumia aritu aria mari na thina wa kwaga thakame miri-ini yao. Nitukwenda gukuria ciuria na tuguthime uria thakame yaku iigana. Wina uhuru wa gwitikira kana kurega kunyitanira utuiria-ini. Wetikira kunyitanira uturia-ini nitugukuria ciuria cii bomui-ini iria iroria uhoro ukonainii na uria utumagira “iron” na “folic acid”. Ningi nitugugutheca kara gaku natuoe githimi kinini gia thakame. Maundu maria mothe ugutwira nitukumaiga me thiri nene.

Twatheca kara gaku wahota kuiguia ruo kahinda kanini. Ningi nouigwe uru nikuona thakame. Githimi giki nigikagwo kaingi na kaingi na gitikoragwo ki ugwati. Thakame iria ukurutwo ni nini na ndingituma thina uria ungikorwo naguo wa kwaga thakame uingihe. Tutiguguthima makiria ma githimi kimwe. Ningi nitugukuhe maumirira ma githimi gia thakame ohau hau. Wakorwo na thina wa unyihu wa thakame nitugugutuma kwi murigitani uthondekwo na ningi urumirirwo uria ugima waku wa mwiri urathii.

Wakorwo na kiuria o giothe kigainie na utuiria uyu no utukinyire na njira ici: **Lucy Gathigi ithanduku ria marua 21 Kiganjo.** Kana **namaba ya thimu 0721 948 454.**

Ningi noukinyire **muikariri giti wa National Ethic Review Committee KEMRI ithanduku ria marua 54840 00200, Nairobi** kana **namba cia thimu 2722541, 2713349, 0722 205901** kana na **email info@kemri.org.**

Wetikira gwikira thaini bomu-ini ino nikuga ati niwataririo maundu mothe maria mari bomu-ini ino ni uria ugukuria ciuria na ati niworia ciuria ciothe iria uma nacio ciigainii na utuiria uyu na waiganira na hanja iria waheo.

Ritwa ria uria uretikira kunyitanira utuiriaini _____

Thaini kana kirore_____ Mweri_____

Ritwa ria uria watariria utuiria _____

Thaini _____ Mweri _____

APPENDIX 4: Approval letter from KEMRI Scientific Steering Committee

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840 - 00200 NAIROBI, Kenya
Tel: (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

ESACIPAC/SSC/6657

8th July, 2010

Lucy N. Gathigi

Thro'
Director, CPHR
NAIROBI

Forwarded
09/07/2010

REF: SSC No. 1866 (New) – Utilization of iron and folate supplementation services and associated factors in pregnancy among women attending Nyeri provincial Hospital, Kenya

I am pleased to inform you that the above-mentioned proposal, in which you are the PI, was discussed by the KEMRI Scientific Steering Committee (SSC), during its **169th meeting** held on **6th July, 2010** and has since been approved for implementation by the SSC.

Kindly submit 4 copies to the Secretary SSC as soon as possible.

The SSC however, advises that work on this project can only start when ERC approval is received.

Sammy Njenga, PhD
SECRETARY, SSC

APPENDIX 5: Approval letter from KEMRI Ethical Review Committee

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840 - 00200 NAIROBI, Kenya
Tel: (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

KEMRI/RES/7/3/1 **September 20, 2010**

TO: **MS. LUCY NYANDIA GATHIGI,**
PRINCIPAL INVESTIGATOR

THRO': **DR. YERI KOMBE,**
THE DIRECTOR, CPHR,
NAIROBI

RE: **SSC PROTOCOL NO.1866 (*INITIAL SUBMISSION*): UTILIZATION OF IRON FOLATE SUPPLEMENTATION SERVICES AND ASSOCIATED FACTORS IN PREGNANCY AMONG WOMEN ATTENDING ANTENATAL CLINIC AT NYERI PROVINCIAL HOSPITAL, KENYA**

Make reference to your letter dated September 5, 2010 received on September 20, 2010. Thank you for your response to the issues raised by the Committee. This is to inform you that the issues raised during the 181st meeting of the KEMRI/ERC meeting held on 10th August 2010, have been adequately addressed.

Due consideration has been given to ethical issues and the study is hereby granted approval for implementation effective this **20th day of September 2010,** for a period of twelve (12) months.

Please note that authorization to conduct this study will automatically expire on **19th September 2011.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by **27th July 2011.**

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the ERC prior to initiation. You may embark on the study.

Yours sincerely,

R. C. KITHINJI,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICS REVIEW COMMITTEE