

**INFLUENCE OF COMPLIANCE TO FOOD BY PRESCRIPTION ON
NUTRITIONAL STATUS AND DRUG ADHERENCE AMONG HIV AND AIDS
CLIENTS AT JARAMOGI TEACHING AND REFERRAL HOSPITAL, KENYA.**

BY

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DECLARATION

I declare that this thesis is my original work and has not been presented previously for examination in Maseno University or any other University. No part of this work should be published without the prior knowledge or acknowledgement of the author and/or Maseno University's permission.

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DEDICATION

This work is dedicated to my late mother Anne Sarah Nekesa Okwisya and my uncle Justus NandikoveOkwisya; my all-time companion Martin Mandilah and our beloved children Gift Sarah Muyundo, Sam Caleb Mandilah and Sandra Anne Chasi Mandilah.

ABSTRACT

Human immunodeficiency virus (HIV) infection is a major global health problem. Evidence exists on links between nutrition and HIV and AIDS. The Food by Prescription (FBP) in the various Patient Support Centres in Kenya aims at improving nutritional status and drug adherence among people living with HIV and AIDS in poor resource settings. The programme anticipates that within a period of 3-6 months, nutritional status should improve. However, inability to attain the required improvement in weight within this period may not necessarily mean the program is not effective but could suggest non-compliance as alluded to, though not measured in some studies. There is limited information on whether compliance to Food by prescription will lead to improved nutritional status and improved drug adherence hence improved quality of life given challenges of inadequate food in poor resource settings. Additionally, socio-demographic factors may have an influence on compliance, nutritional status and drug adherence hence may vary achievement of the aim of the food by prescription program. The objectives of this study were to: assess compliance to the Food by Prescription, nutritional status and drug adherence across socio-demographic characteristics and establish association between compliance and nutritional status and compliance and drug adherence. The study was conducted at Jaramogi Teaching and Referral Hospital, Patient Support Centre in Kisumu Central Sub County, Kenya. Three hundred and six respondents out of the 1200 clients enrolled in the food by prescription on foundation plus were selected by systematic random sampling. In across sectional study, questionnaires and focus group discussions were used to collect data. Data was analyzed using descriptive statistics and bivariate logistic regression analysis. Low level of compliance was observed (25.7%). More compliance was observed among; respondents who do not share the FBP, males, respondents aged 46 years and above and married respondents. Participants had either moderate (76.9%) or severe acute malnutrition (23.1%). Moderate malnutrition was mostly observed among; respondents that earn above Ksh.20, 000, married, males and respondents aged between 26-35 years. Severe acute malnutrition was mostly observed among; respondents, who are divorced, had completed secondary education, aged 46 years and above. Drug adherence was high (86.7%) and was mainly observed among; respondents who do not share the Food by Prescription, do not stay with children less than 5 years and earn Ksh.20, 000 and above. Compliance to food by prescription was associated with nutritional status: (OR 3.27; 95% CI 1.48-7.19; $P = 0.00$) but not to drug adherence. Compliance may influence nutritional status but respondents will adhere to medication instructions even if they don't comply with the Food by Prescription. Health care workers need to involve family members during enrolment of clients in the program to help them understand the importance of compliance.

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CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

Human immunodeficiency virus/acquired immune deficiency syndrome (HIV and AIDS) is one of the world's most serious health and development challenges which affected an estimated 33 million people worldwide and was responsible for 2 million deaths by the end of 2007 (UNAIDS, 2015). The World Health Organization (WHO) 2016 report indicates that there were approximately 36.9 million people living with HIV at the end of 2016 (WHO, 2016). The vast majority of people living with HIV (PLHIV) are located in low- and middle-income countries, with an estimated 25.5 million living in Sub-Saharan Africa (UNAIDS, 2017). Kenya was rated as one of the four HIV 'high burden' countries in Africa with about 1.63 million people living with HIV infection at the end of 2016 with a prevalence rate of 5.9% according to Kenya AIDS response report (NAS COP, 2016). The epidemic is geographically diverse, ranging from a high prevalence of 26.0% in Homa Bay County to a low one of 0.4% in Wajir County. Kisumu County prevalence is 3.4 times higher than the national prevalence at 19.9% and is ranked the third highest national, as per the Kenya HIV county profile report (NAS COP, 2016).

In recent years, there has been considerable progress in understanding the biological mechanisms responsible for the relationship between HIV and AIDS and nutrition, to identify nutrition interventions that may improve the quality of life for PLHIV. This nutrition support is normally offered in a context of extreme deprivation, economic hardship, social stigma, endemic malnutrition and food scarcity (Piwoz & Preble, 2000). The Kenya National HIV and AIDS Strategic Plan and the National Health Sector Strategic Plan (2005) underlined the need to effectively address malnutrition among people living with HIV infection and those

affected by the pandemic. In line with this position and with support from the President's Emergency Fund for AIDS Relief (PEPFAR), USAID/Kenya initiated a Food by Prescription (FBP) program in collaboration with the National AIDS and STI Control Program (NASCOP) in the Ministry of Health (MOH). The program provides a high energy, high protein supplement in the form of Fortified Blended Flour (FBF) which is used to make porridge for PLHIV.

This intervention is one of the programs that link nutritional support with treatment of HIV. Such interventions reflect the increasing recognition among governments, donors and implementers of the need for integrating nutrition support into clinical care for PLHIV (Byron, Gillespie, & Nangami, 2008). The nutritional support is provided to malnourished HIV-infected adults, pregnant and lactating women who are HIV positive and orphans and vulnerable children (OVC) who are malnourished but not necessarily HIV positive (Ministry of Health, 2014). The Program objective is to improve quality of life for the PLHIV. However the program implementation in poor resource settings may impede realization of the program objective of reducing energy and nutrient deficits in PLHIV due to potential sharing of food with other family members, occasioned by challenges of food scarcity.

Studies on Food by Prescription program have been done. A study by Nagata *et al.* (2014) found that only 13% of the clients achieved the expected BMI for exit into the FBP of $> 20 \text{ kg/m}^2$ and suggested non-compliance due to sharing especially in households with less food availability as a possible explanation. Similar suggestions of sharing were elicited in the study done by Gerberg, Lilia and James (2010) in Kenya where more than half of respondents reported altering their consumption from the recommended quantity. Although the studies alluded to non-compliance due to sharing as a potential reason for not meeting the targeted BMI, they did not measure level of compliance to support a conclusion. Despite the former

not addressing level of compliance, so far studies on compliance have been done that measure level of compliance for both adults and children. However, they have reported varied findings. A study done in Ethiopia by Sadler *et al.* (2012); Kebede and Haider (2014) reported compliance to FBP to be very low at 29.4% and 36.3% respectively among adults. On the other hand a study in children aged 6-59 months by Kangethe (2011) reported high levels of compliance (80%). This could possibly be due to the interest that parents have in giving their children the best care hence the high compliance level reported by Kangethe (2011). Adults on the other hand are more likely to make sacrifices that may compromise compliance to FBP.

The aim of FBP is to improve the nutritional status of PLHIV, which in turn is used in such programmes as an exit and entry criterion. It is important to measure nutritional status at this point since it keeps on changing especially among PLHIV (Food and Nutrition Technical Assistance II Project (FANTA-2, 2009). Additionally, BMI is an index that uses weight, which reflects short-term nutritional status and keeps on changing (Gibson, 2005) thus each individual nutritional study, needs to measure it since you cannot rely on secondary data. In order to improve nutritional status of PLHIV and quality of life for PLHIV compliance to the FBP is important. So far, findings from studies conducted have shown the possibility of improved nutritional status for clients on FBP (Nagata *et al.*, 2014). Although Cantrell *et al.* (2008) have elicited findings to the contrary. The differences observed could be possibly because of non-compliance to the FBP as proposed by findings of Nagata *et al.* (2014); thus, the need to determine whether compliance influences nutritional status of PLHIV on FBP in poor resource setting since evidence on the same is limited.

Another aim of FBP is to improve drug adherence among PLHIV. Adherence to drugs among HIV and AIDS clients is essential for optimal response and to reduce development of ART resistance (Tiyou, Belachew, Alemseged, & Biadgilign, 2010). High levels of adherence have been reported in Sub Saharan Africa ((Tuller *et al.*, 2010; Weiser *et al.*, 2010; Wilson, 2016). Karanja (2013) reported similar findings. However low levels of drug adherence have been reported by Mugoh, Kabiru and Mwaniki, (2016); Talam, Gatongi, Rotich and Kimaiyo, (2008). This suggests varied drug adherence in different settings. Whether or not Food by Prescription is able to achieve its aim of improving drug adherence is best assessed by determining whether or not the two are associated; and would be beneficial if indeed providing the FBP would lead to better adherence to drugs, hence better health outcomes. Studies that have been done on ART (Endevelt & Gesser Edelsburg, 2014) have focused on efficacy and have not addressed association with compliance to nutritional status. It still remains unclear therefore, whether compliance to nutritional interventions will improve drug adherence and nutritional status particularly in poor resource settings. This information was sought by the current study.

A large and growing body of evidence shows that socio demographic factors can influence health outcomes. These factors are therefore likely to influence associations observed between compliance, nutritional status and drug adherence. Findings have reported better compliance and nutritional status among male (FANTA-2, 2009) ; Sadler *et al.* (2012). Contrary findings on compliance have been reported with female having better compliance (Kebede & Haider, 2014); Sadler *et al.*, 2012). Studies have also reported varied findings on drug adherence. Study by Mugo *et al.* (2016) reported that respondents earning less had better adherence as compared to higher income earners. Findings to the contrary were reported by Karanja (2013). In each setting therefore, it is unclear how socio-demographic

factors may influence associations between compliance, nutritional status and drug adherence. This study therefore addresses the potential influence of these factors on relationships of interest to this thesis.

1.2 Statement of the Problem

Good nutrition is critical for people living with HIV and AIDS (Murrah & Kiare, 2001). However, HIV and AIDS reduce the household's ability to produce and buy food thus reducing the capacity of the affected households to obtain an adequate amount of food (Ministry of Health, 2006b). Food by prescription aims to improve nutritional status, and drug adherence and by extension, quality of life. The programme anticipates that within this period of 3-6 months, nutritional status should be improved to the extent that the individual is able to support him/herself without any special consideration of whether the client comes from poor resource settings. A client being in the programme more than 3 months may not mean that it is not effective but could be as a result of the client not taking the FBP as required. Although non-compliance due to sharing especially in poor resource settings has been alluded to in studies done on FBP as a possibility for clients not achieving the targeted BMI, it has not been measured to support a conclusion in the poor resource settings. Moreover, there is limited information on whether compliance to FBP regimen will influence nutritional status and drug adherence.

BMI which is an index that uses weight reflects short term nutritional status and keeps on changing (Gibson, 2005) thus each individual nutritional study needs to measure it since you cannot depend on secondary data. Hence given that is what will be used to assess nutritional status in the current study, it has to be measured. Drug adherence has been reported but findings have been varied in different settings. Moreover, studies conducted also focused more on efficacy; it still remains unclear therefore, whether compliance to nutritional

interventions will improve drug adherence and nutritional status particularly in poor resource settings. Additionally, findings on Socio demographic factors and its influence on compliance, nutritional status and drug adherence have been varied. However in each setting therefore, it is unclear how socio-demographic factors may influence associations between compliance, nutritional status and drug adherence thus the need to assess socio demographic among HIV and AIDS infected persons on FBP in a setting where HIV infection poses new challenges like JOOTRH where the programme was implemented and evidence is limited.

1.3 Main Objective

To assess the association between compliance to Food by Prescription with nutritional status, drug adherence among People Living with HIV and AIDS at Jaramogi Teaching and Referral Hospital, Kenya.

1.4 Specific Objectives

- 1.4.1 To assess the level of compliance to Food by Prescription regimen among People Living with HIV and AIDS at Jaramogi Teaching and Referral Hospital across socio demographic characteristics.
- 1.4.2 To assess nutritional status among People living with HIV and AIDS on Food by prescription at Jaramogi Teaching and Referral Hospital across socio demographic characteristics.
- 1.4.3 To assess drug adherence among People Living with HIV and AIDS on Food by Prescription at Jaramogi Teaching and Referral Hospital across socio demographic characteristics.
- 1.4.4 To establish the association between level of compliance to Food by Prescription and nutritional status among People Living with HIV and AIDS on Food by Prescription at Jaramogi Teaching and Referral Hospital.

1.4.5 To establish the association between level of compliance to Food by Prescription and drug adherence among People Living with HIV and AIDS on Food by Prescription at Jaramogi Teaching and Referral Hospital.

1.5 Research Questions

1.5.1 What proportion of respondents are compliant to the Food by Prescription regimen across socio demographic characteristics?

1.5.2 What is the nutritional status distribution of respondents across socio demographic characteristics?

1.5.3 What proportion of respondents adhere to their drugs across socio demographic characteristics?

1.6 Null Hypothesis

H₀₁ There is no association between level of compliance to Food by Prescription and nutritional status.

H₀₂ There is no association between level of compliance to Food by Prescription regimen and drug adherence.

1.7 Significance of the Study

It was envisaged that results from this study would contribute to the existing knowledge and evidence based information on level of compliance to Food by Prescription (FBP), drug adherence and nutritional status among PLHIV on FBP in Jaramogi Teaching and Referral Hospital. Compliance to FBP in the study was very low and influences nutritional status but not drug adherence. The information would inform the service providers on the magnitude of the problem of non-compliance at JOOTRH and the need to improve compliance of FBP among clients since it may be beneficial to improve nutritional status hence quality of life

which is the FBP objective. This will also inform the government, donors and other implementers, who have so far shown increased recognition to integrate nutrition support into clinical care for PLHIV to modify interventions, especially in poor resource settings since sharing plays a role in the success of the program desired objective which is the quality of life of the PLHIV.

Additionally, Sustainable Development Goal (SDG) 2 aims to end hunger and ensure access by all people in particular poor and people in vulnerable situations. The PLHIV are not an exception hence information on the low compliance among the PLHIV will enable review policy guidelines to partners who provide FBP to at least explore ways to improve compliance to the FBP among PLHIV from poor resource setting; so that they may not end up sharing the FBP as observed in the current study hence contributing to achievement of Sustainable Development Goal (SDG 2).

1.8 Assumptions

Clients enrolled in the program are food insecure because they are from poor resource settings.

1.9 Scope of the Study

This study enrolled clients above 18 years of age on Foundation Plus, who had been in the program for at least two months. Generalization were be made only within this population

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

The human immunodeficiency virus/acquired immune deficiency syndrome (HIV and AIDS) is a global pandemic. HIV and AIDS and malnutrition present a synergetic relationship, with HIV reducing food intake, increasing the frequency and severity of opportunistic infections, while malnutrition can induce immune-depression (Ministry of Health, 2006b). Adequate nutrition is therefore necessary to maintain the immune system, manage opportunistic infections, optimize response to medical healthy levels of physical activity, and support optimal quality of life for People Living with HIV and AIDs {PLHIV} (Piwoz & Preble, 2000). Nutrition interventions can improve health outcomes and are an integral part of HIV care at any stage of the disease and throughout the life cycle (MOH, 2006b). The Government of Kenya in keeping with global recognition that good nutrition is essential for the promotion of health and quality of life of all people, particularly PLHIV, has identified good nutrition as a key component of the national response to the HIV and AIDS epidemic (MOH, 2014). However it is important to have evidence based information on whether the nutrition interventions being implemented meet the set objectives or not.

Great strides have been made over the last 20 years in the long-term management of HIV infection in developing countries. This has resulted in improved immune function, reduced mortality, and prolonged survival (Sadler *et al.*, 2012). Recognizing the global HIV and AIDS pandemic as one of the greatest health challenges of our time, whilst in office, former President of the United States of America, George W. Bush announced the President's Emergency Plan for AIDS Relief (PEPFAR) in 2003. Kenya is one of the 15 focus countries for the PEPFAR fund which supports comprehensive HIV and AIDS prevention, treatment

and care programs. The program entered the adaptation/replication phase in March 2008 with new funding for five years (Castleman, Seumo-fosso & Cogill, 2003; FANTA-2, 2009).

The Food by Prescription (FBP) product (Foundation Plus ®) is flour formulated as nutritionally dense supplemental energy flour (450 Kcal per 100 grams). It is a rich source of energy, protein, vitamins and minerals that help in recovery from illness fight against diseases and give the body extra energy boost. The added energy is in the form of vegetable oil and sugar. Ingredients are precooked whole maize and soy beans with vegetable oil, cane sugar and fortified with vitamins and minerals. An adult enrolled in the program is provided with 30 sachets per month each having 300g of flour that is to be taken three times a day for the prescribed period (Serving per meal should be 100g flour which is to be mixed with 500ml of water). At the time of the study, ready-to-use therapeutic food (RUTF) was not yet routinely provided however there were plans to incorporate RUTF into the program. According to the national protocol, RUTF alone is used to treat severe under-nutrition in 6-59 month-old children. In treatment of severe under-nutrition in older children and adults, a combination of RUTF and FBF is recommended (Ministry of Health, 2006b).

The intake of the flour aims to maximize the effectiveness of medical and pharmacological treatments, prevent development of specific nutrient deficiencies, optimize nutrition status, immunity and overall well-being, prevent and manage medication side effects; prevent weight loss and lean body mass and facets of malnutrition, and finally to minimize health costs (Ministry of Health, 2006b). It is given to clients who are 11years and above, with a BMI of <18.5, not pregnant who are HIV and AIDS positive. After three months of supplementation the individual is assessed and discharged from the program if a BMI> 20 has been attained. However, if the BMI is < 20 the recipient remains in the program and is re-assessed after another 3 months. In the event that after another 3 months a BMI> 20 is not

achieved, individuals are discharged from the program regardless of the BMI (Ministry of Health, 2006b). These individuals are referred to the clinicians for further assessment to establish whether there's another reason for the low BMI. The goal of the FBP intervention is to restore patients to healthy nutritional status; FBP guidelines state that adults should be discharged when their BMI improves to $> 20 \text{ kg/m}^2$ (FANTA-2, 2009).

In a study by Nagata *et al.* (2014), in Nyanza, only 13% of clients attained the FBP discharge criteria of BMI $>20\text{kg/m}^2$. This low rate of attainment may indicate that the program's set discharge criterion is unrealistic to attain for most participants especially in poor resource settings. There are several potential reasons for low rate of attainment of program discharge criteria. Patients living in households with less food available may be more likely to share their FBP. There is need therefore to determine levels of compliance and whether they could be a reason for not meeting these set discharge criteria.

2.2 Level of Compliance to Food by Prescription

The overarching goal of nutritional interventions is to prevent malnutrition and restore good nutritional status of malnourished PLHIV with a view to maintaining their productivity and immune function capacities. These interventions also aim at improving adherence to treatment (FANTA-2, 2009). Individual's response to the chronic disease process results in increased nutrient requirements and changes in nutrient use. As shown in Table 2.1 below, it is estimated that energy needs increase by 10 percent in asymptomatic HIV-infected adults and by 20-30% in symptomatic HIV-infected adults (WHO, 2003). Thus, the FBP program's objective is to provide energy and nutrient-dense food products along with nutrition assessment, counseling and clean, safe water to PLHIV who were malnourished or at risk of malnutrition. FBP intervention was designed to supplement an existing diet, rather than to provide a primary food source, but participants living with severe food insecurity may not

have regular access to other adequate food thereby making the FBF provided to be the primary food for family survival (Sadler *et al.*, 2012).

Table 2.1 Nutritional requirements for People Living with HIV and AIDs

HIV Stage/category	Requirement/day
Healthy HIV-Uninfected Adults	1,990 and 2,580 kilocalories
Adult, HIV-Infected (early/ asymptomatic stage)	10% additional kilocalories (200-260 kilo calories). This translates into a food equivalent of about an additional one mug of thick enriched porridge taken during the course of the day
Adults, HIV-Infected (advanced/ symptomatic stages)	20-30% additional kilo calories (420 to 630 kilo calories), depending on severity of condition. This translates into a food equivalent of an extra two to three mugs of thick enriched porridge taken during the course of the day.

Source; World Health Organisation, (2003)

Although compliance is key for the program to be effective, HIV and AIDS impacts negatively by reducing the household's ability to produce and buy food. Adults with HIV are less able to work on their land or earn income from other activities. Increased health costs require household money needed for food (Ministry of Health, 2014). Food consumption in such circumstances has been found to drop by 40 % (Loevinsohn & Gillespie, 2003; Young, Wheeler, McCoy, & Weiser, 2014). So far a number of studies have been conducted on food by prescription. A study by Nagata *et al.* (2014) found that only 13% of the clients achieved the expected BMI for exit into the FBP of $> 20 \text{ kg/m}^2$ and suggested non-compliance due to sharing especially in households with less food availability as a possible explanation. Studies in developing countries indicate that people living with HIV and AIDS in poor resource

settings are often unable to follow optimal food and nutritional recommendations for antiretroviral therapy due to lack of access to the foods required (Castleman *et al.*, 2003). In the event of such non-compliance, implications are that there is more likelihood of clients overstaying in the program and hence program objectives are not met. Similar suggestions of sharing were elicited in the study by Gerberg *et al.* (2010) in Kenya where more than half of respondents reported having altered their consumption from the recommended quantity. Although possibility of non-compliance was cited in the study, both studies did not measure level of compliance among respondents.

However, studies done in Ethiopia by Sadler *et al.* (2012); Kebede and Haider (2014) were able to measure compliance and reported compliance to FBP to be very low at 29.4% and 36.3% respectively. The low levels of compliance have implications on achievement of the program objective. Although FBP is not meant to be the primary source of food at the household. Clients on FBP are likely to depend on the FBP as their primary source of food and or share it with household members which may lead to non-compliance. Sharing of FBP at home may thus be a contributor to non-compliance with FBP and the reason for inadequate nutrient intake (Sadler *et al.*, 2012). Sharing particularly among women with young dependents or HIV-positive spouses is likely to be high due to their central role in household food resource allocation and perceived social obligation (Nagata, Magerenge, Young, Oguta Weiser, 2011). However in a study by Kangethe (2011) in Kenya levels of compliance were reported to be very high which is almost 2 times that reported in the Ethiopian study (80%). However, the focus was among children aged 6-59 months. Although high compliance was reported, sharing was also observed among the 20% that did not comply. Moreover, among this age cohort HIV and AIDS is not an admission criterion hence any other child from the family within the same age cohort and is moderately or severely malnourished is allowed to

be enrolled in order to minimise sharing (MOH, 2006b). This could explain the high compliance observed in the study. Despite the fact that studies have been conducted and level of compliance measured, it is important to note that both have been conducted in Ethiopia while the one conducted in Kenya was among children 6-59 months. So far information on levels of compliance in the study site among adults are limited despite the important role compliance plays in achievement of program objective.

In addition, this study considered compliance across socio demographic characteristics of respondents. So far studies have been done on socio demographic characteristics and elicited varied findings. Findings from a study by Kebede and Haider (2014) showed that those with a higher level of education adhere to prescribed FBP. Indeed, it is believed that education influences the choice that a person may take (Villamor *et al.*, 2002). These high levels of education could possibly explain the high compliance among the educated due to the understanding of the benefit of the FBP to their health. Moreover, in a study by Sadler *et al.* (2012) females recovered more than males.

This implies that they might have complied with the FBP. The fact that men tend to access HIV care at a more clinically and/or immunologically advanced stage of disease than women has been documented elsewhere and is likely to explain this finding (Ahoua & Umutoni, 2011). Contrary findings are reported in an assessment conducted in Kenya where more males recovered than females (FANTA- 2, 2009). The findings underlined possible differences in gender behaviours in compliance, with more women sharing the prescribed food than men. Indeed it is possible that women are more unlikely to be compliant to FBP due to sharing of food at home with other family members. This is due to their central role in household food resource allocation and perceived social obligation (Nagata *et al.*, 2011).

Indeed, sharing of FBP is an important socio demographic characteristic in relation to FBP. Findings that reported low FBP compliance have alluded the possibility of sharing (Sadler *et al.*, 2012); (Kebede & Haider, 2014). However, the sharing was mostly with children because they liked the FBP (Kangethe, 2011). Thus, the possibility of households having children likely to be non-compliant. Apart from children sharing was also with HIV + non-malnourished partners and family members (Sadler *et al.*, 2012). Thus, there was a possibility of non-compliance even in such households. However, there is limited information and a conclusion cannot be made in that direction. Although findings of the study may not give conclusion towards the later but will provide useful information on how compliance is distributed among those living with a child and those living with an adult.

Little is known on compliance with age, marital status, and income level and expenditure on food per day. However from studies that have looked at nutritional status of clients on FBP findings have been varied. Some studies reporting better nutritional status which means there's a possibility that compliance was good among the young aged, those with high income and the married (Nagata *et al.*, 2014). Contrary findings have been reported by Mitiku, Ayele, Assefa and Tariku, (2016) who reported under nutrition more among young aged unlike elderly. The effectiveness of FBP should commence with compliance in order to determine whether or not improvement in nutritional status is achieved in HIV and AIDS patients. Non-compliance has implications on cost of the program since clients who do not comply may take longer periods to recover (MOH, 2006b).

2.3 Nutritional Status of People Living with HIV and AIDS

Diet intervention in HIV/AIDS aims at reducing weight loss and maintaining weight. However, mechanisms leading to weight loss are not mutually exclusive, complicating the achievement of weight gain in PLHIV (Piwoz & Preble, 2000). In cases of reduced food

intake, the MOH guidelines (MOH, 2006b) recommend that weight gain may be achieved by treating the immediate cause of the problem, which is oral thrush, mouth sores or providing preferred foods that are soft and well tolerated by infected persons. An increase in protein and energy requirements are recommended for HIV and AIDS infected individuals as a result of wasting due to cachexia, especially during episodes of opportunistic infections (Ministry of Health, 2014). However, according to WHO (2003), there is insufficient evidence to support the need for increased protein requirements for PLHIV over and above that of the uninfected persons. Instead, combining sources of protein to ensure adequacy of essential amino acids which maintain body cell functions is encouraged. Similar recommendations are also made for fats, vitamins and minerals (Ministry of Health, 2006b).

The nutritional status of clients in the Comprehensive Care Clinic (CCC) is done and documented in the records. Periodic nutritional assessment is recommended as one of the critical nutrition practices especially in the CCC (Ministry of Health, 2014). Moreover, it is advocated that nutrition assessment especially among the PLHIV should be done on a monthly basis or during every visit to the clinic by the PLHIV because nutritional status keeps on changing (Ministry of Health, 2006b). In addition, body Mass Index (BMI) is an index that uses weight which reflects short term nutritional status and keeps on changing (Gibson, 2005), thus each individual nutritional study needs to measure it since you cannot depend secondary data. The information obtained on nutritional status was to facilitate establishing the association of compliance to the FBP and nutritional status hence the need to know the nutritional status of clients in the study.

Nutrition assessment which is one of the critical nutrition practices is defined by the Academy of nutrition and dietetics as a systematic method for obtaining, verifying and interpreting data needed to identify nutrition-related problems, their causes and their

significance (Sydney-Smith, 2006). Four different methods are used to collect data for assessing a person's nutritional status: anthropometric, biochemical or laboratory, clinical and dietary (Gibson, 2005). Anthropometry was the method used to determine nutritional status of respondents in this study. As one of the methods of assessing nutritional status anthropometry is defined as a measure of the physical dimensions and gross composition of the body, includes measurement of height, weight and head circumference and use of measurements of skin fold thickness, body density, air-displacement plethysmography, magnetic resonance imaging and bioelectric impedance (Webster-Gandy, Madden, & Holdsworth, 2011).

The BMI of a person is defined as their body mass divided by the square of their height with the value universally being given in units of kg/m^2 (Gibson, 2005). It is a measure of body fat based on height and weight. This is useful for evaluating over-nutrition or under-nutrition, and for monitoring the effect of a nutrition intervention like the one in this study. BMI has limitations of total body fat, for example BMI overestimates total body fat in persons who are very muscular or who have clinically evident oedema, and underestimates body fat in persons who have lost muscle mass (Kondrup, Allison, Elia, Vellas & Plauth, 2003). However, BMI is frequently used and it is recommended as a practical approach for assessing body fat in clinical setting. MUAC is the circumference of the left upper arm, measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromium). It estimates lean body mass in a person. In few studies measuring the impact of food aid on PLHIV body mass index (BMI), Mid Upper Arm Circumference (MUAC) and weight monitoring measurements are the most common indicators, although head circumference, weight for height and bioelectric impedance were also used for the same purpose (Gibson, 2005).

The ideal nutritional assessment method, applicable in the case of HIV and AIDS is controversial because of interpretation (Siobal, 2013). Interpretation of some of the anthropometric measures e.g. weight may be complicated by factors such as fluid overload due to renal or hepatic disease, or fluid deficits due to dehydration from diarrhoea or poor fluid intake. However, weight gain using BMI is commonly used to show impact of food aid on ART programmes among patients and is not burdensome. Moreover, current nutrition and HIV and AIDS registers require measurement of BMI and MUAC of ART patients to enable referral to a feeding programme (WHO, 2014). It was also used as an indicator of nutritional status because it is used to determine both entry into and exit from the FBP program. Although MUAC is also used to determine entry and exit in the program it is only applicable to clients whose weight and height cannot be taken. In this study only BMI was therefore used because none of the respondents was unable to stand for the weight to be taken (Sadler *et al.*, 2012).

In addition this study will go further to check on distribution of nutritional status across socio demographic characteristics. So far studies have shown the younger in age having better nutritional status (Nagata *et al.*, 2014). Younger persons may be more resilient and compliant to FBP than the elderly. Several studies have reported higher food insecurity levels among the elderly. This is due to challenges in completing agricultural labour, difficulty accessing alternate sources of food, dependence on others for food, and having additional medical co-morbidities (Nagata *et al.*, 2014; Leyna, Mmbaga, Mnyika, Hussain, & Klepp, 2010; Laraia, Siega-Riz, Gundersen, & Dole, 2006). The elderly who are physically weak or disabled may also have a greater challenge carrying and transporting large amounts of heavy FBP (FANTA-2, 2009). They may also have lower success rates due to compromised immunity and reluctance to follow the FBP instructions. However, the above findings contradict those

by Mitiku *et al.* (2016) which showed that under nutrition was higher among clients whose age ranged between 18 to 29 years compared to those aged 45 years and above. Persistent depression attack, anxiety, and unhealthy behaviours were found to negatively affect the dietary intake and treatment outcome of the young aged (Kenney, 2000). Indeed, younger adults commonly exhibit less healthy personality traits, and are less emotionally stable to cope with stressful life events and consequences of the disease itself hence they may have poor nutritional status. However, the difference could also be probably related to the difference in psychological makeup and lifestyles between the study areas hence the need to find out the situation in JOOTRH.

Concerning gender, various studies have elicited contradicting findings. A survey conducted by NASCOP in 2015, the proportion of the underweight was higher in males compared to females. This is contrary to findings by Sadler *et al.* (2012) where compared with men, women had a decreased rate of attaining BMI.20kg/m², controlling for all other predictor variables. Although men on average enrol later into HIV care with more advanced HIV progression and lower BMI than women (Nagata *et al.*, 2014), which one would expect to predict poorer nutritional outcomes. However, women may be more likely to be non-compliant to FBP due to sharing of food at home with other family members, particularly to young dependents or HIV-positive spouses, due to their central role in household food resource allocation and perceived social obligation (FANTA-2, 2009). They may thus end up denying themselves and thus compromise their nutritional status. Furthermore, marital status which is the state of either being married or not was also among socio-demographic factors that were looked at across nutritional status. In a study by Mitiku *et al.* (2016) the likelihood of under nutrition was higher among widowed respondents compared to married counterparts. This might be due to the emotion and grief encountered, and loss of spousal support.

The risk of mental illness was lower among married women than the widowed ones (Sherbourne & Hays, 1990). Marital disruption, a stressful life event, elevates the risk of psychological distress thereby contributing to poor dietary habit and health outcomes which adversely affect their nutritional status (Loue & Sajatovic, 2004). There was need to find out whether the same was the case for JOOTRH or whether it was different.

Research has also established that education influences the choice and quality of diet (Villamor *et al.*, 2002). According to Baqui, Arifeen, Amin, and Black (1994), HIV-infected individuals with a higher level of education consume more food and appear healthier than those HIV-infected individuals with a low level of education. These findings are also in line with the findings of Islam, Rahman, and Mahalanabis (1994). A higher educational level could potentially be related to improved nutrition and, in turn, improved immune function through mechanisms such as enhanced hygienic practices; better knowledge about food and food preparation; earlier identification and treatment of infections and better management of household resources.

Similar findings have been reported by Oguntibeju, van den Heever and Van Schalkwyk (2007) where among the various education levels, the proportion of those malnourished decreased with increasing levels of education. Households in low economic strata are prone to food insecurity (Saaka & Shaibu, 2013). Under such circumstance, poor households have limited choices for food with adequate nutritional values Ivers, Cullen, Freedberg, Block, Coates, (2009). They usually adapt to this situation by cutting down the number of basic meals or reducing the amount in each meal Anema, Vogenthaler, Frongillo, Kadiyala, Weiser, (2009). In such households with low income levels there is likelihood to succumb to various forms of under nutrition, (Saloojee, De Maayer, Garenne, Kahn, 2007). These is due

to reduction of basic meals hence may end up with poor nutritional status. However, there is need to find out whether the same is the case for the area under study.

2.4 Drug Adherence

Antiretroviral therapy (ART) is the recommended treatment for HIV. ART involves taking a combination of anti-HIV medications (a regimen) every day (Ministry of Medical services, 2011). ARVs also boost the immunity of the patient and achieves viral suppression (Peter, 2002), thus decreasing their vulnerability to Opportunistic Infections (OIs). Adherence to ART is crucial for treatment success among HIV patients, high levels of adherence is a prerequisite for maintained viral suppression and lowers risk of drug resistance, this in turn will prevent premature morbidity and mortality (Ministry of Medical services, 2011). Adherence to drugs among HIV and AIDS clients is essential for optimal response and to reduce development of ART resistance (Peter, 2002). However, non-adherence to ART is a substantial challenge in poor resource settings where increasing drug resistance is hard to combat using the limited treatment alternatives that are available (Unge, Johansson & Zachariah, 2008). It is estimated that the average rates of non-adherence to antiretroviral therapy to be ranging between 50% and 70% (Scalon & Racheal, 2013).

According to various studies done on ART, adherence was found to be high in sub Saharan Africa compared to North America and these can be explained as means of fulfilling responsibilities and thus preserving social capital essential relationships (Tuller *et al.*, 2010; Weiser *et al.*, 2010; Wilson, 2016). Indeed the restoration of health and the threat of jeopardising what has been gained in case adherence lapses provide powerful motivation for correct use of ART. In the African context, good health is important because it helps preserve relationships. However studies in developing countries indicate that health care providers overestimate adherence to HIV medications of PLHIV, these may be exacerbated

when clients out of desire to please their clinicians to over report adherence (Keese & Sharp, 2005; Tiyou *et al.*, 2010). Additionally, people living in resource limited countries may not be able to follow recommendations for ARV adherence due to lack of access to food (Castleman *et al.*, 2003; Keese & Sharp, 2005).

The uptake of ARV treatment in Kenya has increased gradually over the years. Between 2007 and 2012, there was an increase in ARV use among ART-eligible adults from (40.5 percent) (NASCOP, 2007) to 63 percent (NASCOP, 2013). According to a survey report NASCOP 2015, Adherence to ARV treatment was high with only 123 (7.0 percent) of the 1747 adults on ART reporting missing their ARVs in the previous two weeks preceding the survey. Similar high levels of adherence were observed in a study done in Pumwani Hospital by Karanja (2013) where 91% of the respondents showed perfect adherence levels between 95 and 100%. However, a study in Embu comprehensive care clinic by Mugo *et al.* (2016) drug adherence was reported at 48.2 %. Similar findings of low level adherence emerged among HIV patients attending Moi Teaching and Referral Hospital where it was reported that the overall adherence levels was low for all respondents 43.2% Talam *et al.* (2008). Adherence to antiretroviral therapy is a major predictor of the survival of individuals living with HIV and AIDS, It is also an outcome for PLHIV on FBP therefore it is important to find out adherence levels in JOOTRH whether they are comparable to those reported in other studies.

Adherence to ART can be measured using several methods. The pill count method is where the client brings the pills during visit and the pharmacy does the counting. This method may be affected by the fact that clients can easily dump their pills prior to clinic visits. Pharmacy record monitoring is limited by privacy restrictions and complicated by client's use of multiple pharmacies to refill their drugs. Blood or urine tests that indicate either the presence

of a medication or marker added to the drugs do not demonstrate consistency in adherence measurement (Arnsten *et al.*, 2001; Cantrell *et al.*, 2008; Marston *et al.*, 2004 ; NASCOP, 2014; Tiyou *et al.*, 2010). These can only determine the time when a client took his/her most recent dose, but cannot reveal clients drug adherence levels over a period of time (Weiser *et al.*, 2010). Electronic monitoring devices (MEMS caps) may be used to monitor drug adherence, but MEMS caps are expensive, don't work with a blister pack and record only the opening and closing medication hence yields inaccurate measurement for clients who decant an entire days or weeks regimen at one time (Arnsten *et al.*, 2001).

Self-report to measure adherence just like the others has challenges of overestimation from the client either because they desire to please the health care provider or may feel ashamed to admit that they indeed forgot to take their medicines as instructed by the health care worker (Keese & Sharp, 2005; Wilson, 2016). However this is the most frequently method used despite its associated recall and social desirability biases. Moreover, it has shown accuracy to the advantage that it has a short-time span implying that the memory of medicine intake is likely to be good. In addition it has been shown to correlate with viral load levels thereby making it a useful tool in the context of HIV set up (Giardini *et al.*, 2016).

In addition this study will look at drug adherence across socio demographic characteristics. Studies on income level and marital status have given different findings on drug adherence. Findings at Embu Hospital in Kenya by Mugo *et al.* (2016) reported that respondents earning less had better adherence as compared to higher income earners. Contrary findings emerged in Pumwani CCCs where respondents earning an income of 20,000 Kenyan shillings adhered to ART more than those earning less (Karanja, 2013). This could be attributed to the ability to meet expenses such as transport to the clinic, food and shelter leading to a better way of dealing with economic problems

that can negatively affect adherence. On marital status findings by Mugo *et al.* (2016) reported adherence to ART to be better among the married respondents. Similar findings were elicited by Talam *et al.* (2008) in Moi Teaching and Referral hospital where those who were divorced, widowed or separated had least drug adherence. This might be due to the emotion and grief encountered, and loss of spousal support. The risk of mental illness was lower among married women than widowed (Sherbourne & Hays, 1990). However contrary findings were made in Ethiopia where it found that married had the least adherence to ART (Alemayehu, Kifle, Woldemichael, Sofonias, Belaineh & Kebede, 2008) hence the need to find out in the current study whether the findings are the same or different. The younger adults commonly exhibit less healthy personality traits, and are less emotional stable to cope with stressful life events and consequences of the disease itself (Nagata *et al.*, 2013) hence the possibility of poor drug adherence. According to Talam *et al.* (2008), most clients who failed to adhere to ART treatment were in ages of 36-45 years. However, Mugo *et al.* (2016) found that poor ART adherence among respondents aged 56 years and above. Findings in JOOTRH are scarce hence the need to conduct the study and find out whether they are comparable to other studies.

Social support is a significant predictor of adherence to treatment and PLHIV are encouraged to share their HIV status to ensure drug adherence (Ministry of Medical Services, 2011). In case of non-disclosure among partners, the partner on ART may resort to hiding pills, occasionally skipping medications and failure to keep clinic appointments for refills or review while disclosure on the other hand allow for support which plays a vital role in encouraging good adherence (Karanja, 2013). In a study by Mugo *et al.* (2016), those that had disclosed the status to children had good ART adherence. This could imply

that they could be using the children to remind them to take the medication leading to good adherence to the medication.

Moreover studies by Byron *et al.* (2008); Gerberg *et al.* (2010) indicate that FBP improves drug adherence. This could be explained by the fact that food lessens the drug side effects such as Nausea, vomiting and metallic taste (Ministry of Health, 2014). Although FBP is intended only for the individual client, there may be differences in how people at different stages of life share and allocate their FBP based on food insecurity situation in different households (Sadler *et al.*,2012). Food insecurity is emerging as an important barrier to ART adherence, especially in poor resource settings. In poor resource settings, a number of qualitative studies have identified food insecurity as a potential risk factor for ART non-adherence (Bukusuba, Kikafunda& Whitehead, 2007).

In Rwanda, 76% of patients interviewed described fear of “having too much appetite and not enough to eat” as an obstacle to their ART adherence (Kayitenkore, Shutes, &Austr, 2006). In Zambia, the belief that ART must be taken with food caused patients to skip doses in the absence of available or accessible food (Sanjobo, Frich & Fretheim, 2008). In Kenya, researchers found that a fear of taking medications on an empty stomach to be a common reason for refusing to take ART, even with free access to medications (Unge, Johansson& Zachariah, 2008). However, findings tend to point to the fact that food insecurity where the client is forced to share FBP which leads to poor adherence. It was important to find out if the situation is similar or different at JOOTRH.

2.5 Association between Compliance and Nutritional Status of People Living with HIV and AIDs on Food by Prescription

The goals of FBP is to boost nutritional status of malnourished PLHIV in order to improve their energy and immune function(FANTA 2, 2009). As in other countries in East Africa, a significant number of PLHIV in Kenya are malnourished (Panagides, Graciano, Atekyereza, Gerberg & Chopra, 2007 ; Gerberg, *et al.*, 2010). Furthermore, the FBP program targeting HIV-infected individuals operates within an environment in which malnutrition is highly prevalent among the PLHIV (Nagata *et al.*, 2011). The situation is characterized by “critical and deteriorating nutrition conditions throughout the country, including in areas not previously experiencing significant global acute malnutrition rates” (Gerberg *et al.*, 2010).In periods and locations of severe food insecurity and nutrition crises, FBP clients are more likely to depend on the FBF as their primary source of food and/or share it with household members which may lead to non-compliance. This in turn may undermine improvement in nutritional status of the clients and eventually the quality of life as well. This may have implications on achievement of the program objective. Despite the presence of all these factors that could lead to non-compliance there is limited documented evidence on whether or not they could impede the realization of the program objective.

In a study conducted in Ethiopia by Sadler *et al.* (2012). FBP participants were 3.1 times as likely to have ever reached a BMI of 18.5kg/m² compared to those not receiving FBP. However while nutritional outcomes in the intervention area were significantly better than those seen in the comparison group, recovery rates overall, as defined by the program, were low in both groups (11.3% in FBP vs. 7.4% in comparison). Recovery rates went up considerably (to 42% in the FBP group) if only those participants who complied with the FBP program protocol (i.e., did not default) were considered. This suggests that there is a possibility of an association between compliance and nutritional status. This possibility is

supported by results of the Aid Star study where participants reported that they looked healthier and were able to engage in social events and other activities (Gerberg *et al.*, 2010; Panagides *et al.*, 2007), which implies that they could have had a better nutritional status as a result of complying to FBP.

However, so far little has been done to examine relationships on compliance to intake of FBF and nutritional status especially in poor resource settings. Therefore necessitating the need for more research to look into this. The findings that could be obtained from literature to compare with findings of this study only focused on uptake of the FBF/supplementary food among the HIV positive malnourished and nutritional status. The association of compliance to FBP with nutritional status was not considered. However given that nutrition interventions are increasingly being advocated to prevent malnutrition and restore good nutritional status of malnourished PLHIV with a view to maintain their productivity and immune function capacities it is good to look into compliance to FBP and its association to provide more studies to compare and make conclusions.

2.6 Association between Compliance to FBP and Drug Adherence in People Living with HIV and AIDs on Food by Prescription

The integration of nutrition support into HIV programs aspires to achieve one or more Objectives. Food as an incentive to improve ART adherence, both as a draw to the clinic for ARTs and as a means of improving patient adherence with the drug regimen through the palliative effects of food on ART side effects and toxicity, leading to better clinical outcomes. While several studies have demonstrated a significant effect of FBP on ART adherence (Cantrell, *et al.*, 2008; Sadler *et al.*, 2012). This study seeks to further confirm whether beyond being associated compliance to the FBP will translate to better nutritional status It was not clear whether in the context of patients attending clinic at the JOOTRH, poor drug

adherence is associated with poor food intake, denoted by compliance to FBP which aims to improve nutritional status hence adherence to drugs. In a study by AMPATH program in western Kenya, where food supplementation facilitated ARV adherence, 78 % of clients reported the access of food lessened side effects of ARVs including increased appetite, dizziness and vomiting which are side effects of ARVs (Byron *et al.*, 2008). Moreover in a study in Zambia, food supplementation program in Lusaka for patients on ARV reported improved drug adherence compared to controls without supplementation but the effects were not noticeable during the first 6 months (Cantrell *et al.*, 2008). An assessment by Aid Star clients reported improved adherence to ARV with FBP (Gerberget *et al.*, 2010). This indicates that the aim of improving adherence to drugs by providing FBP is achievable. However, there was need to look at compliance to the FBP considering that it may or may not contribute to the achievement of drug adherence hence quality of life for the PLHIV.

2.7 Conceptual Framework

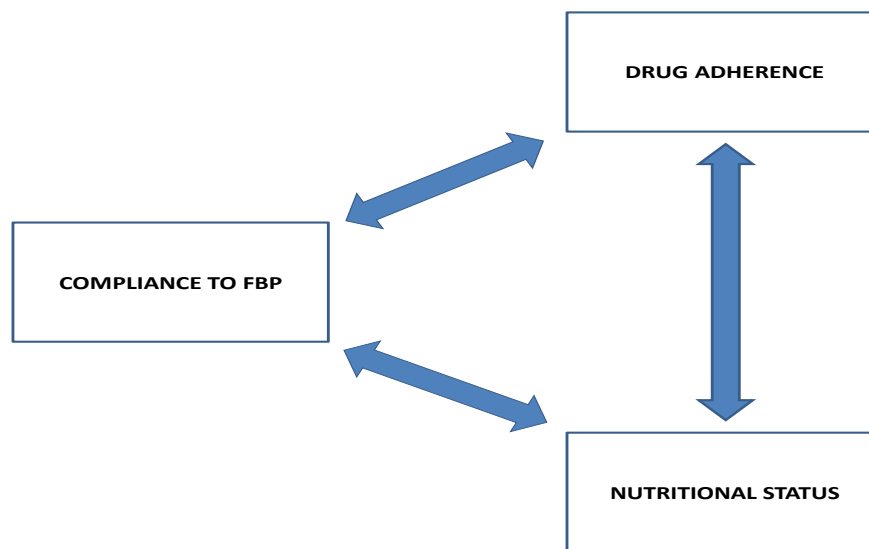


Figure 2.1: Association between Compliance, Drug Adherence and Nutritional Status (Castleman *et al.*, 2003)

On the basis of the Food and Nutrition Technical Assistance (FANTA) framework, an operational framework was developed to include the variables under investigation which comprise compliance to the FBP, nutritional status and drug adherence. Any immune impairment as a result of HIV and AIDS can contribute to poor nutrition (micronutrient deficiency, weight loss, muscle wasting) (Castleman *et al.*, 2003). Poor nutritional status leads to an impaired immune system, these lead to increased vulnerability to infections and faster progression from HIV to AIDS, increased infections demand increased nutritional needs. However, due to malabsorption and decreased food intake, malnourished persons cannot meet these demands hence poor nutritional status. FBP as a nutrition intervention helps PLHIV maintain and improve their nutritional status. However, compliance to the FBP may be influenced by poverty which can lead to sharing of the FBP which some clients experience, and availability of the FBP which may depend on the distance of the residence from the source of the FBP.

Drug adherence to ARV is required at Ninety-five percent adherence for maximum viral suppression (Naidoo, Peltzer, Louw, Matseke, McHunu & Tutshana, 2013; Tuller *et al.*, 2010), hence the FBP program aims to improve the drug adherence. However drug adherence may also be influenced by pill burden, side effects of the drugs and lack of food as reported in a previous study (Kenya National Bureau of Statistics, 2015; NASCOP, 2016). Improved drug adherence may boost the immune response hence reduce susceptibility to opportunistic infections such as oral thrush and Tuberculosis (Grinspoon *et al.*, 1999). With improved immune response, the increased nutrition needs are more likely to be met hence improved nutritional status. There is evidence that individuals with HIV and AIDS infection may increase their survival by aiming for a BMI of 25– 30 (WHO, 2003). Furthermore a study conducted in the Southern India state showed that good nutrition greatly improves quality of life of people living with HIV and AIDS (Peters, 2002). Effective nutrition intervention therefore helps break the vicious cycle of malnutrition brought on by HIV and AIDS by helping individuals maintain and improve nutritional status, boost immune response, manage frequency and severity of symptoms and improve adherence to ART and other medical treatment.

2.8 Operational Framework

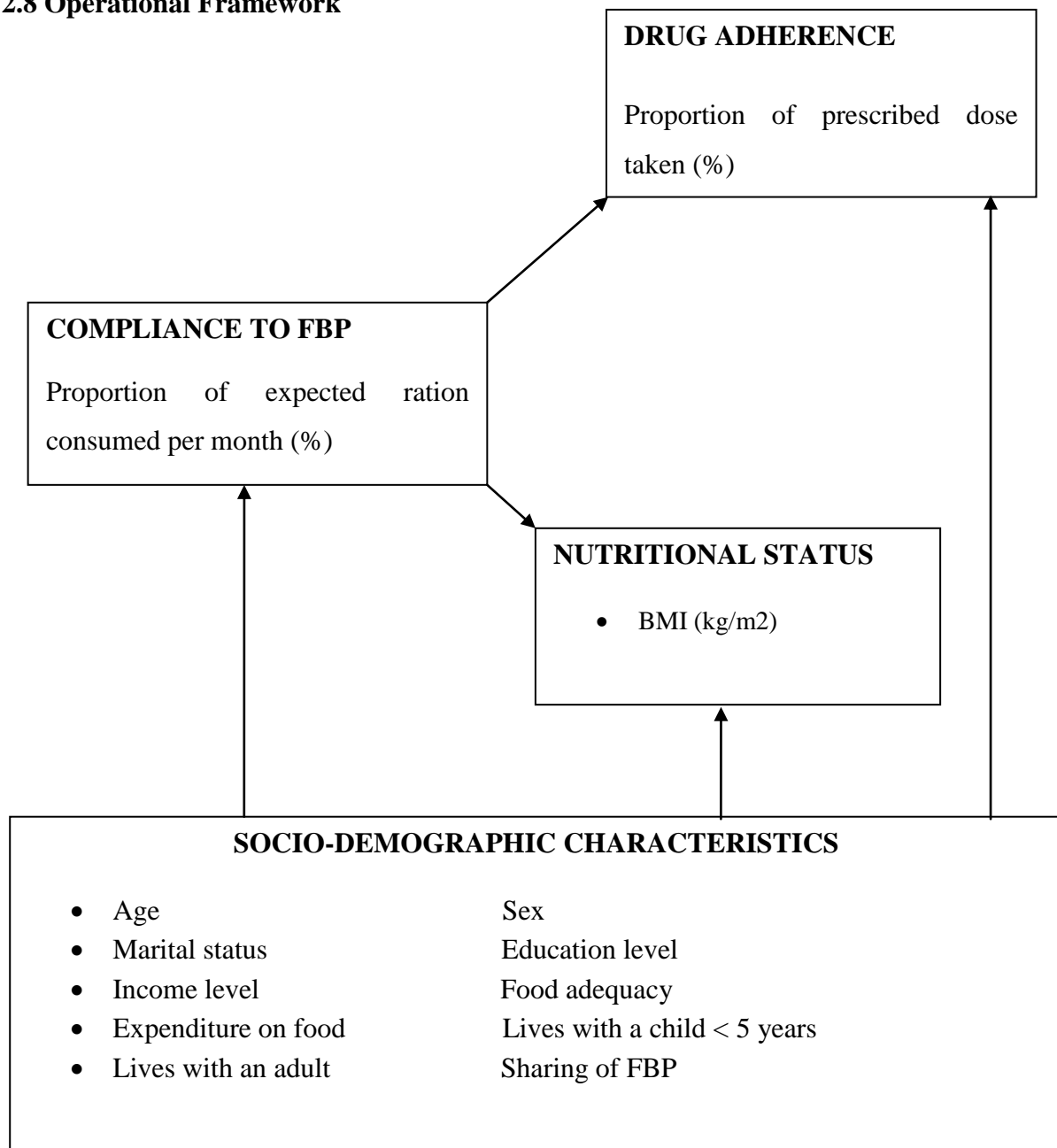


Figure 2.2: Association between Compliance, Drug Adherence and Nutritional Status (Castleman *et al.*, 2003)

In this study, nutritional status was determined based on BMI while drug adherence was defined as the ability of a respondent to take medicines as directed while compliance was defined as the ability of the respondent to take 81 cups of porridge for a period of one month (equivalent to 90 %). In addition, this study also examined the distribution of compliance,

nutritional status and drug adherence across various socio demographic characteristics as seen in Figure 2.2 above. Although the conceptual frame work considered the association of all the three variables in this study the focus was only on association between compliance and drug adherence and compliance and nutritional status.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Study Area

The study was conducted in Kisumu Central Sub County, Kenya at the Jaramogi Teaching and Referral Hospital (JOTRH) Patient Support Centre (PSC). The hospital is situated 3.5 km from Kisumu city centre along the Kisumu-Kakamega road. The Latitude of JOTRH is -0.089 and the Longitude is 34.771. The hospital has been in existence for over 100 years, having been established in the early 1900s to cater for the health needs of the workers at the then port town of Kisumu. It serves a catchment with a population of over 5 million people in counties in the former Nyanza, Western and Rift Valley region. The facility is a public hospital and serves people of both high and low socio-economic status. Moreover, it is one of the hospitals where Food by Prescription (FBP) program was piloted before being rolled out in the entire country. Being a referral hospital, it has a high number of clients enrolled in the FBP program, and was thus an appropriate focal point for the study.

3.2 Study Design

This study was conducted using a cross sectional study design. Data was collected once and analysed.

3.3 Study Population

The target population consisted of adult clients attending Jaramogi Odinga Odinga Teaching and Referral Hospital Patient Support Centre and enrolled for the Food by Prescription (FBP) program in Kisumu Central Sub County. A total of 5000 clients were enrolled in the food by prescription program in the patient support centre (PSC). These included the children on first food-(Fortified blended flour recommended for malnourished children below 11 years who met the set criteria), pregnant and lactating mothers on advantage (fortified blended flour for

pregnant and lactating mothers who meet the set criteria). However, out of the 5000 clients, 1500 were enrolled to receive foundation plus flour and had low Body Mass Index (BMI) of $< 18.5 \text{ kg/m}^2$, 80 percent were aged 18 years and above (1200). This population was suitable for the study since it was one of the target populations for the pilot Food by Prescription program.

3.3.1 Inclusion Criteria

Clients enrolled in the FBP program on Foundation Plus for at least 3 months and above 18 years of age and who consented to participate in the study were interviewed.

3.3.2 Exclusion Criteria

Clients enrolled in the FBP on foundation plus but were inpatient.

3.4 Sample Size Determination

Respondents in this study were recruited daily over a period of four months.

The sample size was calculated using the Creative Research Systems (2003) formula applied when the population is infinite. This sample was generated as follows:

$$SS = \{Z^2 \times (P) \times (1-P)\} \div C^2$$

Where: SS=Sample size;

Z=1.96 (for 95% level of confidence);

P=0.5 (the worst percentage that can ever pick a choice);

C=0.05 (confidence interval)

$$SS = \{(1.96)^2 \times (0.5) \times (1-0.5)\} \div (0.05)^2$$

SS=384.16 patients

However, since the population was made up of 1200 patients, correction for finite population was made as follows:

$$\text{New SS} = \text{SS} \div \{1 + (\text{SS}-1) \div \text{Pop}\}$$

$$\text{New SS} = 384.16 \div \{1 + (384.16-1) \div 1500\}$$

$$\text{Final SS} = 291 \text{ patients}$$

An additional 5% of the study population was added to cater for non-response rate (Degu & Yig saw, 2006); hence, the sample size was $291 + 5\% = 306$.

3.5 Sampling Procedure

The proportion of women to men attending PSC was 2:1. A sample of 306 respondents comprising 204 females and 102 males were selected. Respondents were recruited daily over a period of four months using systematic random sampling (Bair & Blair, 2015). A list of respondents enrolled in the Food by Prescription Foundation Plus programme was prepared from which respondents were selected for a period of four months. A separate list was prepared for male and female. The k^{th} (K^{th}) was estimated by dividing the size of the target population by the desired sample size.

$$\text{Population} = 1200$$

$$\text{Sample size} = 306$$

$$K = 1200/306 = 4$$

Then, starting at the beginning of the list every 4th client was selected. Since there is an appointment diary, those expected for a particular clinic day were listed and interviewed after being seen by the clinician

3.6 Data Collection Tools

In this section the various tools used for data collection and information collected by each tool are described in detail.

3.6.1 Questionnaire

3.6.1.1 Socio demographic Characteristics

Socio demographic questionnaire was used to collect basic information about the respondent.

These included; sex, marital status, education level and socio-economic information.

3.6.1.2 Compliance to Food by prescription questionnaire guide

This guide was used to collect information on how respondents take the food by prescription and some of the reasons why they do not take the FBP as instructed by the health care worker (Appendix VII, Section 2).

3.6.1.3 Drug Adherence Questionnaire Guide

This guide was used to elicit information on drugs that the respondent was using, how they took them and some of the reasons why they do not take the drugs as instructed by the health care worker (Appendix VII).

3.6.2 Anthropometrics Assessment

A table was provided where information on respondents' weight and height were recorded.

This information was used to classify respondents according to the nutritional status classifications based on BMI detailed (Appendix VII).

3.6.3 Focus Group Discussion Guide

A focus group discussion guide (Appendix VIII) was used for the focus group discussion.

This helped gather information from respondents about perception on factors that influence compliance to the FBP regimen because it was able to generate ideas that could not be obtained in individual interviews. The information was also used to countercheck the information obtained from individual interviews.

3.7 Data Collection Procedures

In this section, the procedures that were followed to collect data using the instruments listed above are described.

3.7.1 Questionnaire

3.7.1.1 Socio-demographic Characteristics

Upon identification of the respondents to be interviewed using systematic sampling procedure, a healthcare worker would inquire from the respondent if they would be willing to participate in the study. If they agreed, they would be referred to the researcher. However, before proceeding to administer the questionnaire, informed consent to participate in the study was obtained from the respondents after which they appended their signature on a consent form. Then the researcher proceeded with the administration of the socio demographic questionnaire (Appendix VII). This was used to understand the characteristics of respondents in the study. The questionnaire comprised both closed and open-ended questions. Respondents that did not know how to write/read, guidance was provided.

3.7.1.2 Level of Compliance to Food by Prescription Questionnaire

This section elicited information on how the respondent had been using the food by prescription and compliance and nutritional status (Appendix VII). The guide comprised both closed and open-ended questions.

3.7.1.3 Drug Adherence Questionnaire

The questionnaire elicited information on the type of drug respondents were taking and how they were taking it (Appendix VII). It also generated information on the proportion of respondents that were adhering to the drugs they were taking, whether respondents appreciated that the FBP helped them adhere to the drugs they were taking and compliance to

food by prescription regimen and drug adherence. The interview comprised both closed and open-ended questions

3.7.2 Focus Group Discussion

A focus group discussion guide was used to guide focus group discussions. Separate focus group sessions were conducted for male and female respondents. The male FGD was labelled as FGD 1 and the female FGD was labelled as FGD 2. Each group comprised of 8 discussants and a moderator. Two focus groups sessions were conducted until no new information was generated. Thus a total of 2 focus group discussion sessions were conducted. The conversation was recorded and later transcribed.

3.7.3 Anthropometrics Assessment

3.7.3.1 Height Measurement

Height was measured in the upright position, to the nearest 0.1 cm using a stadiometer. Measurements were taken with the respondent bare foot, standing with heels together, arms held straight down to the sides, legs straight and shoulders relaxed. The head was positioned in the Frankfort horizontal plane. Heels, buttocks, scapulae and the back of the head were against the vertical board of the stadiometer. Just before the readings were taken, the respondent was asked to inhale deeply, hold the breath and maintain an erect posture while the headboard is lowered upon the highest point of the head with enough pressure to compress the hair. Two readings were taken. Where a difference of more than 0.5 cm was noted a third measurement was taken and the two closest values were used. The height measurement consisted of an average of two accepted measurements.

3.7.3.2 Weight Measurement

Body weight was measured using a beam balance scale with non-detachable weights (SECA 881, SECA GMBH & CO., Germany). The respondent was required to stand at the center of the scales platform with minimal underclothing and with the body weight equally distributed on both feet. The measurement was read to the nearest 100g (0.1kg). Two measurements were taken in immediate succession. Where the difference between readings exceeded 100g, a third measurement was taken. The average of the two closest readings was recorded as the weight measurement. The scales were calibrated periodically and after the scale had been moved; and the standard 10 kg weights used to validate the scales on each measurement day.

3.8 Pre-testing

The questionnaires were pre-tested to assess the clarity of the questions and whether the responses adequately captured the information required to meet the objectives of the study. Lists of clients on FBP were obtained from Kisumu County Hospital. respondents on foundation plus who met the criteria were extracted from the list. The list formed the sampling frame. The 10 % of the sample size were randomly selected (30 participants) to participate in the pre-testing exercise to enable get feedback from questions that may not be clear in the questionnaire (Connelly, 2008). The questionnaire was administered and modifications made where questions were not understood. These participants were not included in the main study.

3.9 Measurement of Variables

3.9.1 Level of Compliance to Food by Prescription

The formula below was used to calculate the level of compliance to FBP.

No of porridge cups taken during past month x 100

No of cups that were to be taken during that month

Compliance >90% or a client able to take 81 cups (250ml) of porridge was considered compliant to FBP regimen whilst below 90 % was defined as non-compliant. Compliance to FBP regimen was a categorical variable: compliance to food regimen Yes ($\geq 90\%$) or No ($\leq 90\%$) (Gerberg *et al.*, 2009; Ministry of Health, 2006b).

3.9.2 Nutritional Status

Nutritional status was the main outcome variable. The indicator of nutritional status in this study was Body Mass Index (BMI). BMI was calculated using the following formula:

$BMI = \text{Weight (kg)}/\text{Height (m}^2\text{)}$; and classified into categories of nutritional status as indicated in Table 3.1.

Table 3.1 BMI classification

BMI Kg/M ²	CLASSIFICATION
<16	Severely malnourished
17-18.4	Moderate/Mild malnourished
18.5-25.0	Normal
26-30	Overweight
30+	Obese

Source: (Gerberg *et al.*, 2010; Ministry of Health, 2006b)

3.9.3 Drug Adherence

Medication adherence needs to be 95% in order to obtain optimal suppression of HIV and AIDS (Peter, 2002). On the basis of the grading used to calculate adherence indicated below, drug adherence was defined as $\geq 95\%$ compliance to drug regimen (Grade A) while adherence below 95 % (grade B and C) was defined as non-adherence.

No of doses of Drug taken X 100%

No of prescribed doses

Drug adherence categories was graded as follows:

A = 95% to 100%

B = <95% to 90%

C = < 90 %

Drug adherence was a categorical variable: drug adherence Yes (Grades A) or No (Grade B and C).

3.9.4 Socio-demographic Characteristics

In this study, these included respondent's age, sex, marital status, education level, income level, food adequacy, expenditure on food, sharing of FBP, food source, lives with an adult and lives with children less than 5 years

Age: This was categorised in 4 levels 18-25 years, 26-35 years, 36-45 years and 46 years and above.

Sex: Sex was in male and female categories.

Marital status: This was categorized as follows; married, single, Divorced, widow/widower, cohabiting or other specify. In the bivariate analysis it was categorised into 2 groups either married or unmarried (Single, Divorced widow/widower and cohabiting)

Education level: This consisted of 5 levels. Those with primary education (1-4years), primary education (5-8years), secondary education (1-3years), completed secondary education and college. In the bivariate analysis, education was in 2 levels primary up to incomplete secondary and completed secondary to college in one group.

Income level: This was categorised in 7 levels; those earning less than 1000, 1000-2999, 3000-4999, 5000-6999, 7000-19999 and above 20,000. In the bivariate analysis, income was in two groups those earning 3000 and those earning above Ksh. 3000 per month.

Food adequacy: This was categorised into two. Those who perceived food was adequate reported (Yes), those who did not perceive food was adequate (No).

Expenditure on food: This was taken as either in two either those who spent less than 120 per day or those who spent more than 120 per day on food.

Sharing of FBP: This was categorised into two. Those who had shared reported (Yes), those who did not shared (No.)

Food source: This was categorised into two. Those whose main source of food was from the farm and those whose main source of food was through purchase.

Lives with an adult: This was categorised in two. Those who lived with child less than 5 years reported (Yes), those who did not live with child (No)

Lives with children less than 5 years: This was categorised in two. Those who lived with an adult reported (Yes), those who did not live with an adult reported (No).

3.10 Data Analysis

3.10.1 Quantitative Data

Data was entered, cleaned and analysed using Statistical Package for Social Sciences (SPSS) version 20. Socio-demographic characteristic was analyzed using descriptive statistics (means, frequencies, percentages) and bivariate logistic regression analysis measuring association between compliance to Food by Prescription and compliance to Food by prescription on nutritional status. Odds Ratios with 95% confidence interval and p values \leq 0.05 was used to demonstrate presence of an association.

3.10.2 Qualitative Data

The qualitative data gathered on compliance, drug adherence of respondent's through focus group discussions were analyzed. Broad themes were first identified according to the focus

group discussion guide. The prevalent themes that were identified formed broad categories. For instance to further find out the reasons for non-compliance, thematic analysis of qualitative data was used to identify reasons for non-compliance. All transcripts were read several times and simultaneously coded to explore potential conceptual and content-related themes. The quotes included in the results were typical views expressed by the participants and were used to exemplify emergent themes

Table 3.2 Summary of Data Analysis Plan

Objective	Method of Analysis
To assess the level of compliance to Food by Prescription regimen of respondents across socio demographic characteristics.	<ul style="list-style-type: none"> • Frequencies and percentages were used to assess levels of compliance and distribution across socio demographic characteristics. • Bivariate logistic regression was used to identify socio demographic factors that may influence compliance • Quantitative data was analyzed with prevalent themes
To establish nutritional status of respondents across socio demographic characteristics	<ul style="list-style-type: none"> • Frequencies and percentages were used to assess levels of nutritional status and distribution across socio demographic characteristics. • Bivariate logistic regression was used to identify socio demographic factors that may influence nutritional status • Quantitative data was analyzed with prevalent themes
To assess drug adherence of respondents across socio demographic characteristics	<ul style="list-style-type: none"> • Frequencies and percentages were used to assess levels of drug adherence and distribution across socio demographic characteristics. • Bivariate logistic regression was used to identify socio demographic factors that may influence drug adherence.
To establish the association between level of compliance to FBP and nutritional status	<ul style="list-style-type: none"> • Bivariate logistic regression was used to establish whether there was an association between FBP and nutritional status • P values ≤ 0.05, Adjusted Odds Ratios with 95% confidence interval (95% CI) were used to demonstrate association.
To establish the association between level of compliance to Food by Prescription and drug adherence	<ul style="list-style-type: none"> • Bivariate logistic regression was used to establish whether there was an association between FBP and drug adherence • P values ≤ 0.05, Adjusted Odds Ratios with 95% confidence interval (95% CI) were used to demonstrate association

3.11 Ethical Considerations

A Research Permit to conduct the study was sought from the Ministry of Science and Technology (Appendix IV and V) and ethical clearance from the JOOTRH Ethical Review Board (Appendix III) after presentation of the research proposal to the Medical Superintendent, consent of the respondents to participate in the study was sought after potential participants were briefed on the research procedures and assured of confidentiality. Only those who signed informed consent forms were considered for participation. Each respondent had one signed consent form (Appendix VI).

CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter presents the results which have been structured into socio-demographic characteristics, followed by compliance to food by prescription, nutritional status, drug adherence and effect of compliance on nutritional status and drug adherence. Data analysis was analysed using descriptive statistics (means, frequencies, percentages) and bivariate logistic regression analysis measuring association. Significance was assumed at $P \leq 0.05$. Odds ratios (OR) and 95% CI are used to demonstrate the association. Socio-demographic characteristics were adjusted for in association between compliance and nutritional status and drug adherence.

4.2 Socio-demographic Characteristics

A total of 306 respondents from Jaramogi Oginga Odinga Teaching and Referral Hospital (JOORTH) in Kisumu County were recruited into the study. Of the 306 respondents, 300 completed the study. Two of the respondents were transferred to other clinics, three declined to continue and one died. Demographic characteristics of the patients including residence, age, marital status, education, religion and size of household are shown in Table 4.1.

The mean age of the respondents was 29.3 ± 9.7 with over 76% being below the age of 35 years. About 33% were males. Over 54% of the sampled population was married. Thirty-five percent of the respondents had attained high school education and above and forty percent of these respondents earned less than Ksh. 1000 per month or did not know how much their monthly income was. Respondents who lived with an adult as part of the family members were 73.7% while those who lived with children less than 5 years were 73%. Among respondents, only 18% said they had adequate food for the family members. Food was mainly

sourced by purchasing (89.3%) and 71.7% reported sharing the FBP. More than 60 % of the respondents said they spent more than Ksh. 120 on daily food purchase.

Table 4.1: Distribution of Socio-demographic Characteristics

n=300

Socio Demographic characteristic	Categories	Frequency (n)	Percent (%)
Respondents age	18-25 years	145	48.3
	26-35 years	85	28.3
	36-45 years	56	18.7
	46 years and above	14	4.7
Respondents sex	Male	101	33.7
	Female	199	66.3
Marital Status	Single	74	24.7
	Married*	163	54.3
	Divorced	9	3.0
	Widow/Widower	54	18.0
Level of Education	Primary	36	12.0
	Did not complete secondary	153	51.0
	Completed Secondary	29	9.7
	College	82	27.3
Income level	Less than 1000	122	40.7
	1000-2999	111	37.0
	3000-4999	35(36)	11.7(12)
	5000-19,000*	8	2.7
	above 20,000	24	8.0
Lives with Adult	Yes	221	73.7
	No	79	26.3
Lives with children of < 5 Years	Yes	219	73.0
	No	81	27.0
Adequacy of food	Yes	54	18.0
	No	246	82.0
Main source of food	Purchase	268	89.3
	Farm	32	10.7
Shared FBP	Yes	215	71.7
	No	85	28.3
Expenditure on food per day	Up to Kshs 120	111	37.0
	More than Kshs 120	189	63.0

Key = *Only one respondent reported cohabiting and therefore was combined with “married”. In addition only one respondent earned Ksh. 5000-6999 and therefore the case was included in those earning 5000-19,000

4.3 Compliance to Food by Prescription in People Living with HIV and AIDs

Figure 4.1 below shows compliance to FBP. Compliance to food by prescription was 25.7% while the rest were non-compliant. Therefore compliance in this population is low.

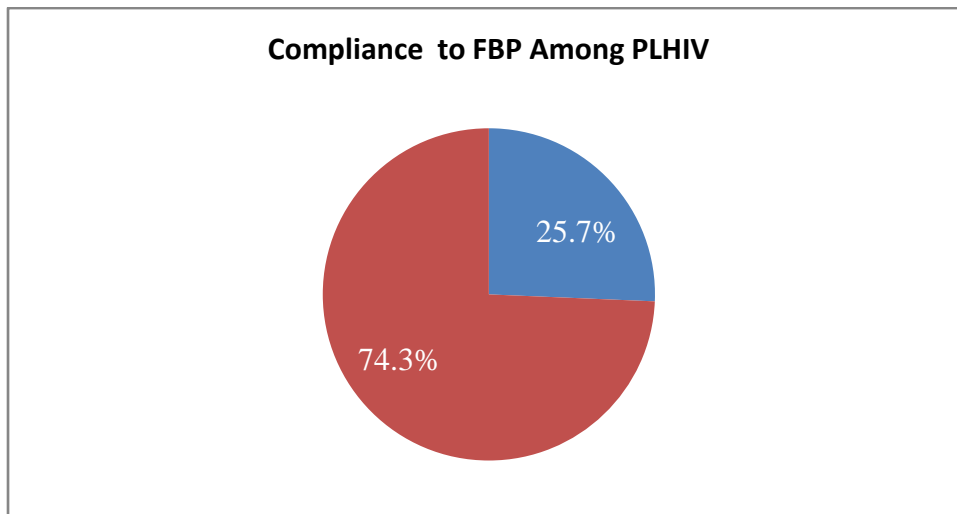


Figure 4.1 Pie chart Showing Compliance to FBP among PLHIV

4.3.1 Assessment of Level of Compliance to Food by Prescription across Socio-demographic Characteristics

To assess the level of compliance to FBP across socio-demographic characteristics, the distribution of level of compliance proportions across these characteristics was first determined followed by determination of socio demographic factors that are associated with non-compliance in this population group. Table 4.2 below shows the distribution of compliance to FBP across demographic characteristics of the respondents. Compliance was observed among; respondents who do not share the FBP (49.4%), males (38.6%), respondents aged 46 years and above (35.7%) and married (30.7%). Low compliance was observed among; respondents earning Ksh. 5000-19,000 (0%), whose main source of food was from the farm (9.4%), had up to primary education (11.1 %) and shared the FBP (16.3%).

Table 4.2: Distribution of Compliance across Socio-demographic characteristics among People Living with HIV and AIDs on Food by Prescription

n=300

Variable	Group Characteristic	Compliance to FBP	
		Yes n (%)	No n (%)
Respondents age	18-25 years	29(20)	116(80)
	26-35 years	25(29.4)	60(70.6)
	36-45 years	18(32.1)	38(67.9)
	46 years and above	5(35.7)	9(64.3)
Respondents sex	Male	39(38.6)	62(61.4)
	Female	38(19.1)	161(80.9)
Marital Status	Married	50(30.7)	113(69.3)
	Single	15(20.3)	59(79.7)
	Divorced	2(22.2)	7(77.8)
	Widow/Widower	10(18.5)	44(81.5)
Level of Education	Primary	4(11.1)	32(88.9)
	Did not complete secondary	46(30.1)	107(69.9)
	Completed Secondary	8(27.6)	21(72.4)
	College	19(23.2)	63(76.8)
Income level	Less than 1000	26(21.3)	96(78.7)
	1000-2999	31(27.9)	80(72.1)
	3000-4999	8(22.9)	27(77.1)
	5000 -19,000	0(0)	8(100)
	above 20,000	12(50)	12(50)
Lives with Adult	Yes	64(29.0)	157(71.0)
	No	13(16.5)	66(83.5)
Lives with children of < 5 Years	Yes	50(22.8)	169(77.2)
	No	27(33.3)	54(66.7)
Adequacy of food	Yes	15(27.8)	39(72.2)
	No	62(25.2)	184(74.8)
Main source of food	Farm	3(9.4)	29(81.1)
	Purchase	74(27.6)	194(72.4)
Shared FBP	Yes	35(16.3)	180(83.7)
	No	42(49.4)	43(50.6)
Expenditure on food per day	Up to Kshs 120	21(18.9)	90(83.7)
	More than Kshs 120	56(29.6)	133(70.4)

4.3.2 Socio-demographic Characteristics Associated with Compliance to Food by Prescription

Table 4.3 below shows socio-demographic characteristics associated with compliance to FBP using bivariate logistic regression. A total of eight out of eleven socio-demographic characteristics demonstrated significance in determining compliance. Respondents aged between 18- 30 years (22.2%) were less likely to comply with FBP (OR: 0.62; 95% CI: 0.37-1.05; $P<0.05$). These indicated that the respondents aged 30 years (31.5%) and above are more likely to comply with FBP compared to ones aged 18 – 30 years. More males (38.6%) were likely to comply with FBP (OR: 2.67; 95% CI: 1.56-4.55; $P=0.001$). This indicates that males were 2.67 times more likely than females to comply with FBP. Those who were married (30.9%) were more likely to comply with FBP (OR: 1.84; 95% CI: 1.07-3.14; $P=0.02$) than those who were not (19.6%). Respondents living with an adult were 2.07 times more likely to comply to FBP than those not living with an adult (OR: 2.07; 95% CI: 1.07-4.01; $P=0.03$). Those living with children < 5 years were less likely to comply with FBP compared to those without children <5 years (OR: 0.59; 95% CI: 0.34-1.04; $P<0.001$). Those who purchased food were more likely to comply with FBP (OR: 0.27; 95% CI: 0.08-0.92; $P=0.026$). Respondents who shared the FBP were less likely to comply to FBP compared to those that did not share the FBP (OR: 0.60; 95% CI: 0.37-1.05; $P<0.000$). Those who spent more than Kshs. 120 per day on food were more likely to comply with FBP than those who spent less Kshs. 120 per day. Level of education, monthly income and food adequacy were not associated with compliance to FBP indicating that they may not influence compliance to FBP.

Table 4.3: Socio-demographic Characteristics Associated with Compliance to Food by Prescription

n=300

Variable	Grouping Characteristic	Compliance with FBP		OR	95% CI	P Value
		Yes	No			
(n = 300)		77 (25.7)	223 (74.5)			
Age range	18-30	42 (22.2)	147 (77.8)	0.62	0.37-1.05	0.05
	Above 30	35 (31.5)	76 (68.5)			
Participant sex	Male	39 (38.6)	62 (61.4)	2.67	1.56-4.55	<0.00
	Female	38 (19.1)	161 (80.9)			
Marital Status	Married	50 (30.9)	112 (69.1)	1.84	1.07-3.14	0.02
	Not Married	27 (19.6)	111 (80.4)			
Level of Education	Primary to incomplete secondary	50 (26.5)	139 (73.5)	1.12	0.65-1.92	0.68
	Complete secondary and above	27 (24.3)	84 (75.7)			
Monthly Income	Less than 3000	57 (24.5)	176 (75.5)	0.67	0.39-1.16	0.37
	More than 3000	20 (29.9)	47 (70.1)			
Lives with Adult	Yes	64 (29)	157 (71)	2.07	1.07-4.01	0.03
	No	13 (16.5)	66 (83.5)			
Lives with children of < 5 Years	Yes	50 (22.8)	169 (77.2)	0.59	0.34-1.04	0.05
	No	27 (33.3)	54 (67.7)			
Food is adequate	Yes	15 (27.8)	39 (72.2)	1.14	0.59-2.21	0.70
	No	62 (25.2)	184 (74.8)			
Main source of food	Farm	3 (9.4)	29 (90.6)	0.27	0.08-0.92	0.03
	Purchase	74 (27.6)	194 (72.4)			
Shared FBP	Yes	35(16.3)	180(83.7)	0.60	0.37-1.05	0.00
	No	42(49.4)	43(50.6)			
Expenditure on food per day	Up to 120	21 (18.9)	90 (81.1)	0.55	0.31-0.98	0.04
	More than 120	56 (29.6)	133 (70.4)			

NB: Data is generated using bivariate logistic regression. Numbers in brackets are proportions. Values in bold are statistically significant at $P \leq 0.05$

4.3.3 Information from Focus Group Discussion on Compliance to Food by Prescription among People Living with HIV and AIDs

Focus Group Discussions were conducted to obtain information that would support quantitative data on compliance to FBP from respondents. Five themes that emerged from the discussions are presented in Table 4.4 below. These were: sharing of the FBP, stigma, poverty, opportunistic infections and drug side effects.

The respondents all confessed that they were not the only consumers of the porridge prepared using the flour. They raised various reasons for their non-compliance. This non-compliance applied to both male and female respondents. Porridge was mainly shared with children, spouse, caretaker and other bedridden patients who were not able to pick the flour.

Stigma as a reason for non-compliance was reflected in both FGD 1 and FGD 2. Stigma prevented some clients from collecting the FBP as scheduled due to fear of being seen carrying the flour. Some reported fear of being seen by others while others reported that because of the packaging of the flour, they did not want to collect it therefore those who collected the flour as scheduled ended up helping them by sharing their portion of flour. This led to the respondents not taking the prescribed quantity of porridge leading to non-compliance.

Poverty as a reason for non-compliance was reported in both FGD 1 and 2. Most participants reported having inadequate resources to buy food that were at high prices. They attributed these high prices to the post-election violence “Ocampo 6” and “food insecurity.” Participants further explained that “if the government could improve their economic status they would be able to afford to buy other foodstuffs”. They therefore view the government as their main source of help in enabling them to have income generating activities that would enable them to access food.

Opportunistic infections was mentioned as one of the hindrances to taking the FBP as prescribed. This was only reflected in FGD 1. The discussants reported severe opportunistic infections make them lose appetite, hindering them from taking the porridge hence interfered with compliance to the consumption of the FBP given.

Drug side effects only featured in FGD 2. Respondents were concerned that the drugs they were taking had strong side effects that in turn affected their compliance to food by prescription. According to one participant:

“...side effects like metallic taste, vomiting makes one not able to finish quantity of porridge one is supposed to take in a day.”

Table 4.4: Information from Focus Group Discussion on Compliance to Food by Prescription

Themes	Participants Quotes	FGD Number*
Sharing	<i>"...This porridge only assists if used every day. Now that it is used by the respondent their children and other people who are bedridden and are unable to pick their supply so, it is not enough for the one month given"</i>	FGD 1
	<i>"At the facility we are taught that you are supposed to consume the flour alone but when you get home you eat with your child and the mother who has prepared the porridge or whoever takes care of you? ..."</i>	FGD 2
Stigma	<i>"If we would be given this flour more than 2 bags so that we can help those who fear coming to the hospital to pick these flour ..."</i>	FGD 1
	<i>"We have some of us who don't like being seen carrying the flour because it is associated with PLHIV due to the packaging and these makes them to come for the flour occasionally "</i>	FGD 2
Poverty	<i>"When we go home, at times circumstances force us to share with other people, because you know these Ocampo 6..." (Slang' for food insecurity)..."</i>	FGD 2
	<i>"Here we are taught that you are supposed to consume the flour alone but when you get home you eat with your child and the mother who has prepared for you who takes care of you since there's no any other food in the house? ..."</i>	FGD 1
	<i>"...we request the government to take us for some education so that we are taught on small things that we can be able to do so that we get money hence we do not depend on the flour alone. So if you get your money you can use it to buy other food to be eaten alongside the porridge given so that we don't share"</i>	FGD1
Opportunistic Infections	<i>"opportunistic infections such mouth sores, makes you very weak, loss appetite and cannot even take the unga [flour], as instructed by the nutritionist..."</i>	FGD 2
Drug Side effects	<i>"We take the porridge before taking the medicine, then after taking that porridge we take the drug but at times these drugs we are taking have very bad side effect like metallic taste, vomiting that may not enable you finish the quantity of porridge you are to take in a day...."</i>	FGD 1

*The FGD where the quote indicated was made

4.4 Nutritional Status of People Living with HIV and AIDs

Figure 4.2 below shows nutritional status of respondents. Nutritional status of the respondents was assessed using BMI. Majority of the respondents had moderate malnutrition (76.9 %) while the rest had severe malnutrition. None had normal nutritional status.

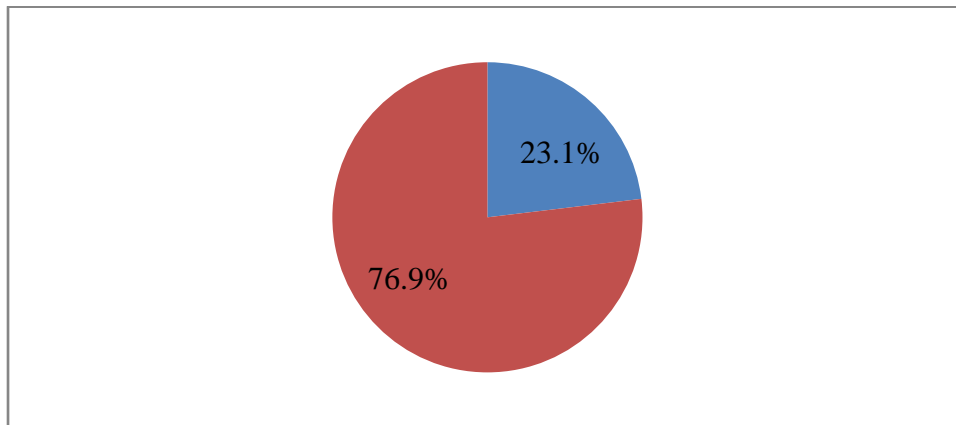


Figure 4.2 Nutritional Status of People Living with HIV and AIDs on Food by Prescription

4.4.1 Assessment of Nutritional Status across Socio-demographic Characteristics

To assess nutritional status across socio demographic characteristics, the distribution of nutritional status proportions across these characteristics was first determined followed by determination of socio demographic factors that are associated with nutritional status in this population group.

Table 4.5 below shows distribution of nutritional status across demographic characteristics of the respondents. Moderate malnutrition was observed among; respondents that earn above Ksh.20, 000 (95.8%), married (82.2%) males (80%) and respondents aged between 26-35 years (80). Severe acute malnutrition was observed among; respondents, who are divorced (44.4%), had completed secondary education (69%) were aged 46 years and above (71.4%).

Table 4.5 Distribution of Nutritional Status across Socio-demographic Characteristics

n=300

Variable	Group Characteristic	Level on nutritional status	
		Moderate malnutrition n(%)	Severe malnutrition n(%)
Respondents age	18-25 years	108(74.5)	37(25.5)
	26-35 years	68(80)	17(20)
	36-45 years	44(78.6)	12(21.4)
	46 years and above	10(71.4)	4(28.6)
Respondents sex	Male	81 (80)	20 (20)
	Female	149 (74.9)	50 (25.1)
Marital Status	Single	49(66.2)	25(33.8)
	Married	134(82.2)	29(17.8)
	Divorced	4(44.4)	5(55.6)
	Widow/Widower	43(79.6)	11(20.4)
Level of Education	Primary	2(75)	9(25)
	Did not complete secondary	118(77.1)	35(22.9)
	Completed Secondary	20(69.0)	9(31.0)
	College	65(79.3)	17(20.7)
Income level	Less than 1000	95(77.9)	27(22.1)
	1000-2999	80(72.0)	31(28)
	3000-4999	26(74.3)	9(25.7)
	5000-19,000	6(75)	2(25)
	above 20,000	23(95.8)	1(4.2)
Lives with Adult	Yes	174 (79.1)	47 (20.9)
	No	56 (70.9)	23 (29.1)
Lives with children of < 5 Years	Yes	172 (78.9)	47 (21.1)
	No	58 (71.6)	23 (28.4)
Adequacy of food	Yes	39 (73.6)	15 (26.4)
	No	191 (77.6)	55 (22.4)
Main source of food	Purchase	26 (81.3)	6 (18.8)
	Farm	204 (76.4)	64 (23.6)
Shared FBP	Yes	170 (79.1)	45 (20.9)
	No	60(71.4)	25(28.6)
Expenditure on food per day	Up to Kshs 120	84(75.7)	27(24.3)
	More than Kshs 120	146(77.7)	43(22.3)

4.4.2 Socio-demographic Characteristics Associated with Nutritional Status

Table 4.6 below shows socio- demographic characteristics associated with nutritional status using bivariate logistic regression analysis. There was a significant difference in nutritional

status in those who were married and those that were not married (OR: 2.01; 95% CI: 1.16-3.47; $P=0.012$). Married respondents were 2.01 times more likely to be moderately malnourished than severely malnourished. None of the other socio demographic characteristic variables had a p value of ≤ 0.05 .

Table 4.6 Socio-demographic Characteristics Associated with Nutritional Status

Variable	Grouping Characteristic	Level of Nutritional status		OR	95% CI	P Value
		Moderate malnutrition n (%)	Severe malnutrition n (%)			
(n=300)	Nutritional Status	230 (76.9)	70 (23.1)			
Age range	18-30	141 (74.6)	48 (25.4)	0.69	0.39-1.24	0.21
	Above 30	89 (80.9)	22 (19.1)			
Participant sex	Male	81 (80)	20 (20)	1.43	0.80-2.59	0.24
	Female	149 (74.9)	50 (25.1)			
Marital Status	Married	133 (82.6)	29 (17.4)	2.01	1.16-3.47	0.01
	Not Married	97 (70.3)	41 (29.7)			
Level of Education	Primary to incomplete Secondary	145 (76.7)	44 (23.3)	0.97	0.55-1.70	0.91
	Complete secondary and above	85 (77.3)	26 (22.7)			
Monthly Income	Less than 3000	175 (75.1)	58 (24.9)	1.09	0.63-1.90	0.74
	More than 3000	55 (71.4)	12 (25.6)			
Lives with Adult	Yes	174 (79.1)	47 (20.9)	1.55	0.87-2.79	0.14
	No	56 (70.9)	23 (29.1)			
Lives with children < 5 Years	Yes	172 (78.9)	47 (21.1)	1.48	0.83-2.65	0.18
	No	58 (71.6)	23 (28.4)			
Adequacy of food	Yes	39 (73.6)	15 (26.4)	0.80	0.41-1.58	0.53
	No	191 (77.6)	55 (22.4)			
Main source of food	Farm	26 (81.3)	6 (18.8)	1.34	0.53-3.40	0.54
	Purchase	204 (76.4)	64 (23.6)			
Shared FBP	Yes	170 (79.1)	45 (20.9)	1.51	0.85-2.69	0.16
	No	60(71.4)	25(28.6)			
Expenditure on food per day	Up to Kshs 120	84(75.7)	27(24.3)	0.89	0.51-1.56	0.69
	More than Kshs 120	146(77.7)	43(22.3)			

NB: Data is generated using bivariate logistic regression. Numbers in brackets are proportions. Values in bold are statistically significant at $P\leq 0.05$

4.4.3 Information from Focus Group Discussion on Nutritional Status

The perceived reasons for lack of improvement in weight since commencement of FBP were poverty which led to sharing of food, side effects of the FBP, stock out of the FBP and dislike of the taste of the FBP. Focus Group Discussions were conducted to obtain information that would support quantitative data on nutritional status from the interviews with individual

respondents. Respondents appreciated the flour as it helped them improve nutritional status; gained strength and added weight. Comments on nutritional status were elicited in the FGD 1 and 2 as indicated below

“ ...frequency of infections goes down, we gain energy to do our daily activities and look healthier (FGD:1)

“The porridge has helped us a lot, long before we used to fall down because we did not have energy, but since we started using these porridge it has helped us gain strength and add weight (FGD:2)

4.5 Drug Adherence in People Living with HIV and AIDS

Drug adherence is usually classified as taking more than 95% of the dosage in the required manner and timing. Anyone who had ever missed more than 5% of the treatment or prophylaxis due was classified as not being adherent to treatment.

Figure 4.3 below shows drug adherence among respondents. The proportion of respondents who adhered to the drug regimen was 86.7%. Which means drug adherence in this population was high.

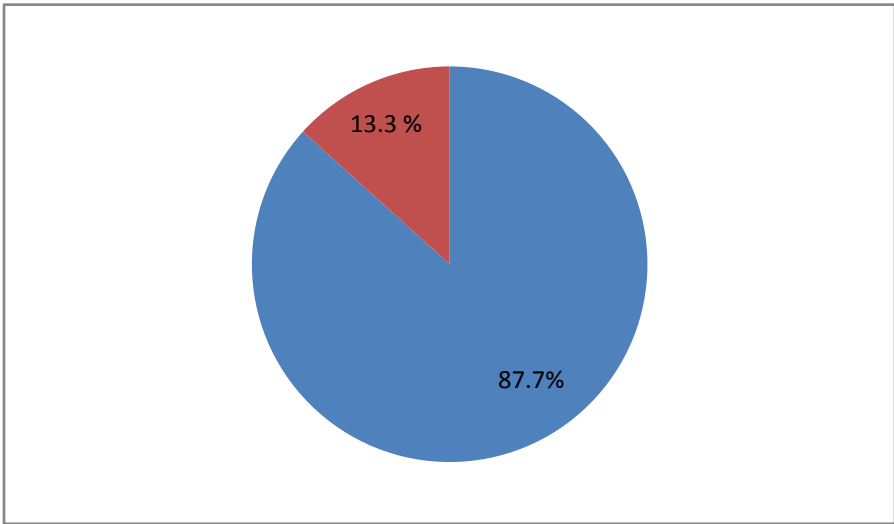


Figure 4.3 Drug Adherence of People Living with HIV and AIDs

4.5.1 Assessment of Drug Adherence across Socio-demographic Characteristic

To assess drug adherence across socio demographic characteristics, the distribution of drug adherence proportions across these characteristics was first determined followed by determination of socio-demographic factors that are associated with drug adherence in this population group.

Table 4.7 below shows the distribution of drug adherence across socio-demographic characteristics of the respondents. Drug adherence was observed mainly among; respondents who do not share the food by prescription (92.9%), did not stay with children less than 5 years (92.6%) and earn Ksh. 20,000 and above (91.7%). Comparatively lower drug adherence was observed among; respondents that were divorced (66.7%), earned between 5000 to 19,000 Ksh. (75%) and reported food to be adequate (77.8%).

Table 4.7 Distribution of Drug Adherence across Socio-demographic Characteristics among People Living with HIV and AIDs

n=300

Variable	Group Characteristic	Drug Adherence	
		Yes n (%)	No n (%)
Respondents age	18-25 years	127(87.6)	18(12.4)
	26-35 years	73(85.9)	12(14.1)
	36-45 years	48(85.7)	8(14.3)
	46 years and above	12(85.7)	2(14.3)
Respondents sex	Male	84 (83.2)	17 (16.8)
	Female	176 (88.4)	23 (11.6)
Marital Status	Single	66(89.2)	8(10.8)
	Married	144(88.3)	19(11.7)
	Divorced	6(66.7)	3(33.3)
	Widow/Widower	44(81.5)	10(18.5)
Level of Education	Primary	32(88.9)	4(11.1)
	Did not complete secondary	132(86.3)	21(13.7)
	Completed Secondary	26(89.7)	3(10.3)
	College	70(85.4)	12(14.6)
Income level	Less than 1000	105(86.1)	17(13.9)
	1000-2999	96(86.5)	15(13.5)
	3000-4999	31(88.6)	4(11.4)
	5000-19,000	6(75)	2(25)
	above 20,000	22(91.7)	2(8.3)
Lives with Adult	Yes	194 (87.8)	27 (12.2)
	No	66 (83.5)	13 (16.5)
Lives with children of < 5 Years	Yes	185 (84.5)	34 (15.5)
	No	75 (92.6)	6 (7.4)
Adequacy of food	Yes	42 (77.8)	12 (22.2)
	No	218 (88.6)	28 (11.4)
Main source of food	Purchase	26 (81.3)	6 (18.8)
	Farm	234 (87.3)	34 (12.7)
Shared FBP	Yes	181 (84.2)	34 (15.8)
	No	79 (92.9)	6 (7.1)
Expenditure on food per day	Up to Kshs 120	98 (88.3)	13 (11.7)
	More than Kshs 120	162 (85.7)	27 (14.3)

4.5.2 Socio-demographic Characteristics Associated with Drug Adherence

Table 4.8 below shows socio-demographic characteristics associated with drug adherence. Sharing the FBP and perceived food adequacy were associated with reduced drug adherence. Those who shared FBP were less likely to adhere to drugs than those who did not share FBP (OR: 0.4; 95% CI: 0.16-1.00; $P=0.04$). Equally, those who perceived food to be adequate were less likely to adhere to drugs than those who perceived food as not being adequate (OR: 0.45; 95% CI: 0.21-0.95; $P=0.03$). The other variables showed no association with drug adherence.

Table 4.8: Socio-demographic Characteristics associated with Drug Adherence

Variable	Grouping Characteristic	Drug Adherence		OR	95% CI	P Value
		Yes n(%)	No n(%)			
(n=300)	Adherence	260 (86.7)	40 (13.3)			
Age range	18-30	162 (85.7)	27 (14.3)	0.80	0.39-1.61	0.53
	Above 30	98 (88.3)	13 (11.7)			
Participant sex	Male	84 (83.2)	17 (16.8)	0.65	0.33-1.27	0.20
	Female	176 (88.4)	23 (11.6)			
Marital Status	Married	143 (88.4)	19 (11.7)	1.35	0.69-2.63	0.38
	Not Married	117 (84.8)	21 (15.2)			
Level of Education	Primary to incomplete Secondary	164 (86.8)	25 (13.2)	1.03	0.52-2.04	0.94
	Complete secondary and above	96 (86.5)	15 (13.5)			
Monthly Income	Less than 3000	201(86.3)	32 (13.7)	0.92	0.74-1.80	0.80
	More than 3000	59 (88.1)	8 (11.9)			
Lives with Adult	Yes	194 (87.8)	27 (12.2)	1.42	0.69-2.9	0.34
	No	66 (83.5)	13 (16.5)			
Lives with children of < 5 Years	Yes	185 (84.5)	34 (15.5)	0.44	0.18-1.08	0.06
	No	75 (92.6)	6 (7.4)			
Main source of food	Farm	26 (81.3)	6 (18.8)	0.63	0.24-1.64	0.34
	Purchase	234 (87.3)	34 (12.7)			
Adequacy of food	Yes	42 (77.8)	12 (22.2)	0.45	0.21-0.95	0.03
	No	218 (88.6)	28 (11.4)			
Expenditure on food per day	Up to 120	98 (88.3)	13 (11.7)	1.26	0.62-2.55	0.52
	More than 120	162 (85.7)	27 (14.3)			
Shared FBP	Yes	181 (84.2)	34 (15.8)	0.4	0.16-1.00	0.04
	No	79 (92.9)	6 (7.1)			

NB: Data is generated using bivariate logistic regression. Numbers in brackets are proportions. Values in bold are statistically significant at $P \leq 0.05$

4.5.3 Reasons Given by People Living with HIV and AIDs for Non-Adherence to Drug

The reasons reported by respondents for not adhering to drugs are shown in Figure 4.4 below.

These included: too many pills, forgetting to take the pills, travelling, being too sick and not having adequate food to take with the drugs. Majority of the respondents (65%) mentioned lack of food as the reason for missing drugs.

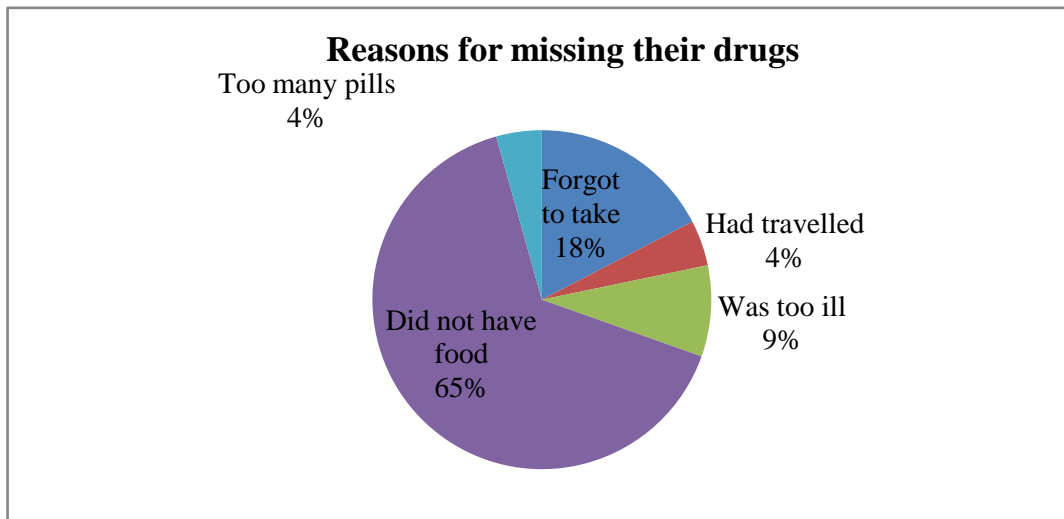


Figure 4.4: Reasons Given by People Living with HIV and AIDs for Non-Adherence to Drug

4.5.4 Data from Focus Group Discussions on drug adherence

Findings from the focus group discussions revealed that the porridge helped the respondents to take their medicines hence improved their drug adherence. This featured in both FGD 1 and 2 as shown below:

“.....medicine when taken without food is poisonous so you cannot take medicine if you have not eaten and also the virus eats the body, so this flour is the one that assists us because it has a mixture of many foods inside, even if you don’t eat other foods you are okay.”(FGD1: Male discussants)

“ We always take the porridge before taking medicine, because this helps reduce side effects of the drugs and so we adhere to the dosage and time instructed at the facility”(FGD2: Female discussant)

4.6 Association between Compliance and Nutritional Status

Table 4.9 below shows association between compliance and nutritional status. Compliance to FBP had an influence on the nutritional status of respondents (OR: 3.27; 95% CI: 1.48-7.19; $P=0.002$). Those who were compliant to FBP were 3.27 times more likely to be moderately rather than severely malnourished, thus they had a better nutritional status. Those who complied even when adjusted for socio-demographic characteristics were even more likely (4.5 times) to be moderately malnourished rather than severely malnourished (OR: 4.50; 95% CI: 1.76-11.51; $P=0.00$).

Table 4.9: Association between Compliance and Nutritional status

		Level of nutritional status		OR	95% CI	P Value
		Moderate malnutrition	Severe malnutrition			
Compliance (Crude Analysis)	Yes	69 (89.6)	8 (10.4)	3.27	1.48-7.19	0.00
	No	161 (72.5)	62 (27.5)			
Adjusted Analysis*				4.50	1.76-11.51	0.00

NB: Numbers in brackets are proportions. Significance was determined by Pearson Chi-square analysis. Values in bold are statistically significant at $P \leq 0.05$.; *Adjusted for Age ,sex, Sharing FBP, Source of food, Marital status, lives with a child ,Lives with adult and lives with an adult

4.7 Association between Compliance and Drug Adherence

Table 4.10 below shows association between compliance and drug adherence. More than 93% of those who were compliant to FBP were adherent to drugs. Those who were compliant to FBP were almost 3 times more likely to adhere to drugs as compared to those who were not compliant to FBP (OR: 2.68; 95% CI: 1.01-7.11; $p=0.04$). However, when adjusted for socio demographic characteristics, compliance had no influence on drug

adherence (OR: 1.95; 95% CI: 0.67-5.70; $p=0.22$), indicating an influence of these factors on the initially observed association

Table 4.10: Association between Compliance and Drug Adherence

		Drug Adherence		OR	95% CI	P Value
		Yes	No			
Compliance (Crude Analysis)	Yes	72 (93.5)	5 (6.5)	2.68	1.01-7.11	0.04
	No	188 (84.3)	35 (15.7)			
Adjusted Analysis*				1.95	0.67-5.70	0.22

NB: Numbers in brackets are proportions. Significance was determined by Pearson Chi-square analysis. Values in bold are statistically significant at $P \leq 0.05$. *,*Adjusted for Age ,sex, Sharing FBP, Source of food, Marital status ,lives with a child, Lives with adult, lives with an adult and food adequacy

CHAPTER FIVE

DISCUSSION

5.1 Socio-demographic Characteristics of Respondents

Participants of this study reflect a population who are mainly females of reproductive age, married; having little formal education and earning less than 3000 Kenya shillings a month. The findings on gender distribution are comparable to those observed in the ART program in Kenya; ratio of female to male of 2:1 (Kenya National Bureau Statistics, 2015; NASCOP (2014). Food in this sub-group is mostly purchased, with most participants spending more than Kshs. 120 a day on food. The group represents women in the productive age bracket, who normally should contribute to meeting family needs including food. As expected, these recipients are mainly from households with food insecurity which is the criterion used for admission into the FBP program (Gerberg *et al.*, 2010; Ministry of Health, 2006b). Moreover, FBP targets PLHIV who are malnourished from low resource settings; hence the findings from the current study confirm that indeed the recipients of the FBP are the people in need of the flour. Although HIV and AIDS is prevalent in all populations, data from most countries suggest that it is more pronounced among those who are in the reproductive and productive age group (Anabwani & Navario, 2005; Laah & Ayiwulu, 2010). This is similarly corroborated by the data from the current study where majority were within the reproductive age bracket.

5.2 Compliance of People Living with HIV and AIDs on Food by Prescription

Findings show that there is a high burden of compliance in the study population. Just over a quarter of the PLHIV in the current study, consume the FBP as required indicating very low compliance. Similar findings were reported by (Sadler *et al.*, 2012; Kedede & Haider, 2014) who reported compliance to FBP to be at 29.4% and 36.3% respectively. The low levels of

compliance have implications on achievement of the program objective since the clients may overstay in the program not because the program is not effective but due to non-compliance. Although contrary findings were reported by Kangethe (2011). The varying age cohort of focus may possibly explain the difference observed in the current study and the previous one by Kangethe (2011).

Compliance appears to be found mainly among male respondents who are married, aged 46 years and above. Findings on gender behaviours in compliance are similar to those in a study conducted in Kenya where males recovered than female (FANTA-2, 2009). The quick recovery was attributed to the compliance to the FBP. The findings underlined possible differences in gender behaviours in compliance, with more women sharing the prescribed food than men. Contrary findings on sex are reported by Sadler *et al.* (2012). Females on FBP recovered more than the male implying they might have complied with FBP. This could be because men tend to access HIV care at an advance stage of the HIV infection (Ahoua & Umutoni, 2011). Women are more likely to share the FBP than men hence possibility of them being non-compliant, this is due to their central role in household food resource allocation and perceived social obligation (Nagata *et al.*, 2011). In the event that food is not available at home, then most likely the female would have to share thus non-compliance observed in the study is likely to occur.

Although little has been documented on compliance and marital status, findings can be explained by the support married receive unlike the unmarried (Sherbourne & Hays, 1990), hence could lead to them complying to FBP. However, these are important findings that help us understand the implication of marital status on compliance to FBP. In addition young aged respondents were less likely to comply with FBP. Similar findings have been reported by

Mitiku *et al.* (2016) who reported under nutrition more among young aged population. The under nutrition among the young aged could be possibility due to non-compliance to FBP. Contrary findings have been reported by Nagata *et al.* (2014) where non-compliance was reported to be among the aged. Despite the challenges that the elderly may have that may impact on food security, the study findings suggest that this is possibly due to the understanding of the importance of the FBP then they may tend to comply unlike the young age who may not.

The findings on sharing where compliance appears to be among respondents who do not share FBP and those who shared were less likely to comply to FBP. Moreover, those with children less than 5 years were less likely to comply and those living with an adult were more likely to comply. Sharing of the FBP was also alluded to in the FGD where respondents reported that they were not the only consumers of the FBP given. Similar findings on sharing have been reported as a possibility in studies that reported low FBP compliance (Sadler *et al.*, 2012; Kedede & Haider, 2014). The sharing was mostly with children because they liked the FBP (Gacheru, 2011). Similar findings have also been observed in this study where those living with children under 5 years were less likely to comply with FBP. Although studies have also reported sharing with HIV positive non-malnourished partners and family members (Sadler *et al.*, 2012). Contrary findings have emerged from this study where those living with an adult are more likely to comply with FBP. This could be because of the support the adult may offer or understanding that he or she may have that the FBP is only meant for the PLHIV. Female are more likely than men to share the FBP (Nagata *et al.*, 2011). Findings on sharing observed in the current study especially among those with children, could possibly explain the high non-compliance observed in the current study where majority of respondents were female.

Low compliance was observed among those with primary education. These are similar to findings from a study by Kedede and Haider (2014) who reported those with a higher level of education comply with prescribed FBP. Indeed it is believed that education influences the choice that a person may take (Villamor et al., 2002). These high levels of education could explain possibly the high compliance among the educated due to the understanding of the benefit of the FBP to their health. However, education level was not associated with compliance in the bivariate analysis. From the findings of this study, a conclusion cannot be made whether education influences compliance or not.

Source of food was associated with compliance to FBP; purchasing food being more compliant than those whose main food source was by farming. This could also be because as from the socio demographic characteristics majority of respondents relied on purchasing food hence those who have the ability to purchase food by spending more than Kshs. 120 a day may be more likely to have food for the family hence may adhere to recommended daily food intake of FBP; unlike their counterparts who spend less, therefore may be more likely to share the FBP with other family members. HIV and AIDS has been shown to impact negatively on food security status of households, reducing the ability of PLHIV to follow optimal food and nutritional recommendations (Castleman *et al.*, 2003). This could explain the low compliance observed in the current study especially among those who spend less than Kshs. 120 per day on food and those who rely on farm as their main source of food and possibly may not have cash to buy any other food in addition to the FBP provided.

Information from the focus group discussions show that lack of compliance in this setting could be attributed to poverty, stigma, opportunistic infections and drug side effects opportunistic infections. The non-compliance, which was due to the hard economic times as a

referred to by one of the respondents as “Ocampo”, which refers to scarcity of food. This is consistent with findings by Gerberg *et al.* (2010) that in periods and locations of severe food insecurity, FBP clients are more likely to depend on the FBP as their primary source of food. Inability to provide food for other family members observed in the current study could have led to situations of enhanced food insecurity, hence noncompliance observed in the current study.

Packaging of the flour was a source of fear of picking the flour and they don’t like being seen carrying the flour since it was associated with HIV, hence the packaging was perceived as an identifier of persons with HIV. This is a manifestation of stigma which featured in both FGD 1 and FGD 2. Stigma deterred some clients from collecting the FBP on schedule. The findings are similar to the study done in Ethiopia by Sadler *et al.* (2012) who found participants had difficulty adhering to FBP because they felt stigmatized as the food is strongly associated with HIV, and people easily identify their sero-positivity. In the event that they did not collect their ration as scheduled, the clients may have been forced to consume less than the recommended daily intake of food by prescription hence the non-compliance.

Respondents were also concerned that the drugs they were taking have strong side effects that in turn affect their compliance to food by prescription. It is worth noting that PLHIV often take other drugs in addition to ARVs to treat opportunistic infections and other common diseases which occur as a result of weakened immune systems (Sadler *et al.*, 2012). Findings from the current study are similar to those by Alumasa (2013) and Kamuzora (2009) where respondents cited the drug side effects such as nausea, metallic taste, making them not able to take the FBP as per the recommendations given at the facility. These side effects may affect food by prescription uptake leading to intake of less than the recommended daily intake.

Opportunistic infections were reported to interfere with compliance to the consumption of the FBP given. Due to the compromised immune system the PLHIV are prone to opportunistic infections. Global evidence suggests that the overall incidence of opportunistic diseases increases with the degree of immune suppression resulting from HIV disease progression (Ghate *et al.*, 2009). The infections encountered in the AIDS patients are of wide variety including bacteria, fungi, viruses and protozoa (Mayer, Karp, Auwaerter, & Mayer, 2007). The opportunistic infections may interfere with intake of the recommended FBP thus leading to non-compliance.

5.3 Nutritional Status of People Living with HIV and AIDs on Food by Prescription

Majority of recipients of FBP had moderate acute malnutrition with few who had severe acute malnutrition and none categorized as having a normal nutritional status based on BMI. This is expected from the study given the program entry criterion which only allows PLHIV with MAM or SAM who are food insecure to be enrolled. In addition as a criterion for the study only clients who have been in the program for at least 2 months and above were included in the study; and clients are expected to be in the program for a period of 3- 6 months, and are discharged from the program if no improvements on nutritional status are observed they are referred for further clinical assessment. Moreover the goal of the program is to boost the nutritional status of malnourished PLHIV in order to improve drug adherence and in turn the quality of life. However, given that none of the participants had a normal nutritional status, this may indicate that the programme had not achieved its aim by the time the study was conducted. However, it is possible that persons with severe malnutrition could have improved to a moderate nutritional status. Although given that the study design was Cross sectional such a conclusion cannot be made.

In this study moderate malnutrition appears to be among respondents who are young in age, male, married with high income. Findings on age are in line to those by Nagata *et al.* (2013) who found better nutritional status among the young. However the findings from the current study contradict those by Mitiku *et al.* (2016) which found that under nutrition was higher among clients whose age ranged between 18 to 29 years compared to those aged 45 years and above. Although the younger adults may have unhealthy personality traits they may be more resilient compared to the elderly hence the better nutritional status as it appears in the current study. The elderly who are physically weak or disabled may also have a greater challenge carrying and transporting large amounts of heavy FBP (FANTA-2, 2009). In addition they may have lower success rates due to compromised immunity and reluctance to follow the FBP instructions given at the facility hence may end up with poor nutritional status as observed in the current study. Findings on gender differences are similar to Sadler *et al.* (2012) where compared with men; women had a decreased rate of attaining BMI.20kg/m². However they contradict findings by the NASCOP survey where underweight was more in males compared to females (NASCOP, 2015). Although men on average enrol later into HIV care with more advanced HIV progression and lower BMI than women (Nagata *et al.*, 2014). In which case one would expect to them to have poorer nutritional outcomes. However, women may be more likely to be non-compliant to FBP due to sharing of food at home with other family members (FANTA-2, 2009). They may thus end up denying themselves thereby compromising their nutritional status as might be the case observed in the current study.

Findings of marital status with the widows having severe malnutrition are similar to those by Mitiku *et al.* (2016) where the likelihood of under nutrition was higher among widowed respondents compared to married counter parts. This might be due to the emotion and grief encountered, and loss of spousal support. The risk of mental illness was lower among married

women than widowed (Sherbourne & Hay, 1990). Marital disruption, a stressful life event, elevates the risk of psychological distress thereby contributing to poor dietary habit and health outcomes which adversely affects their nutritional status (Loue & Sajatovic, 2004). The married would have better nutritional status unlike the widowed and this could probably be due to the support they receive from their spouses. Although it is logical that people who are married would be able to get support from their wives especially in preparation of the FBF as a possible explanation for a better nutritional status, the study design does not allow conclusions on the direction of the relationship to be made. This therefore should be explored in a study with a more appropriate design although the current study results indicate that it is possible to have better nutritional status. Income plays a key role in the food choices made; poor households have limited choices for food with adequate nutritional values (Ivers *et al.*, 2009). They usually adapt to this situation by cutting down the number of basic meals or reducing the amount in each meal (Anema *et al.*, 2009).

In such households with low income levels, there is a likelihood of succumbing to various forms of under nutrition, (Saloojee *et al.*, 2007). However, the opposite is expected for households with high income as observed in the current study hence the likelihood of better nutritional status among respondent. Respondents with secondary education had poor nutritional status. It is believed that education influences the choice and quality of diet (Villamor *et al.*, 2002). These findings are also in line with the findings of Ogutibeju *et al.* (2007) where among the various education levels, the proportion of those malnourished decreased with increasing levels of education. Indeed, a higher educational level could potentially be related to improved nutrition and, in turn, improved immune function through mechanisms such as enhanced hygienic practices; better knowledge about food and food preparation; earlier identification and treatment of infections and better management of

household resources (Islam *et al.*,1994). According to Baqui *et al.* (1994), HIV-infected individuals with a higher level of education consume more food and appear healthier than those HIV-infected individuals with a low level of education. Although it is logical that those with higher education will have better nutritional status may be due to the high income they may have but the study design may not allow conclusions to be made to that effect but only suggest the possibility.

Information from the focus group discussion shows that the flour is perceived to have helped the recipients gain weight. This is similar to findings of a study by Gerberg *et al.* (2010) where recipients also appreciated the flour helped them gain weight. Although the weight gain may not be notably greater among respondents receiving the FBP as demonstrated in the study in Uganda from then community based organisation (Kadiyala & Rawat, 2013). This could be due to non-compliance which is reflected in the findings of the current study on respondents that are not compliant. However these cannot be concluded from this study since BMI measurements were only taken once given that it was a cross sectional and not a longitudinal study that could be able to compare the BMI measurements over a period of time.

5.4 Drug Adherence by People Living with HIV and AIDs on Food by Prescription

A majority of recipients of FBP from low resource settings adhere to the drug regimen. The drug adherence level is high in this population. Similarly high levels of adherence were observed in a study done in Pumwani Hospital by Karanja (2013) where 91% of the respondents showed perfect adherence levels between 95 and 100%. However a study in Embu by Mugo *et al.* (2016) drug adherence was reported at 48.2 %. Similar findings of low level adherence were made among HIV patients attending Moi Teaching and Referral Hospital where it was reported that the overall adherence levels was low for all respondents

43.2% Talam *et al.* (2008). This high adherence according to the PLHIV can be attributed to the counselling they had been given on importance of the drugs, so they tried at all times to adhere to what they were told. Although they may not take their medication on time, sometimes, they ensured that they took it. Medication adherence needs to be 95% in order to obtain optimal suppression of HIV and AIDS (Bangsberg, 2006; Maggiolo *et al.*, 2005; Shuter *et al.*, 2007; Talam *et al.*, 2008). Despite worries that the scale-up of ART provision in developing countries would be dogged by inadequate adherence, people living with HIV/AIDS in sub-Saharan Africa generally take more than 85% of their prescribed doses of ART (Fogarty *et al.*, 2002). This is consistent with the findings of the current study where drug adherence was high.

Adherence was observed among those who earn above Ksh 20,000, not living with children <5years, those who do not share FBP. Findings on income are similar to those reported by Karanja (2013) for Pumwani CCCs where respondents earning an income of 20,000 Kenyan shillings adhered to ART more than those earning less. However they are contrary to findings at Embu Hospital in Kenya by Mugo *et al.* (2016) who reported that respondents earning less had better adherence as compared to higher income earners. The adherence among those earning more than Ksh.20, 000 could be attributed to the ability to meet expenses such as transport to the clinic, food and shelter leading to a better way of dealing with economic problems that can negatively affect adherence. On the other hand those with little income may have challenges meeting some of the expenses leading to non-adherence to their medication. So far little is documented on adherence among those living with children less than 5 years and drug adherence. However lower adherence could be possibly because children may not offer the social support which may boost drug adherence. Findings are contrary to those reported by Mugo *et al.* (2016) where those that

had disclosed the status to children had good ART adherence. This could imply that they could be using the children to remind them to take the medication hence good adherence to the medication. However the study did not specify whether the children that provided support were < 5 years or above. Indeed social support is a significant predictor of adherence to treatment and PLHIV are encouraged to share the HIV status to ensure drug adherence (Ministry of Medical Services, 2011). In case of non-disclosure clients on ART resort to hiding pills, occasionally skipping medications and failure to keep clinic appointments for refills or review while disclosure on the other hand allow for support which plays a vital role in encouraging good adherence (Karanja, 2013). Findings of this study provide important information on distribution of drug adherence among households with children < 5 years and those not although based on study design direction cannot be made towards either direction on whether they influence drug adherence or not.

Respondents who reported that they did not share the FBP appear to have had drug adherence. Studies by Byron *et al.* (2008) and Gerberg *et al.* (2010) indicate that FBP improve drug adherence. This could be explained by the fact that food lessens the drug side effects such as nausea, vomiting and metallic taste (Ministry of Health, 2014). Although FBP is intended only for the individual client, there may be differences in how persons at different stages of life share and allocate their FBP based on food insecurity situation in different households (Sadler *et al.*, 2012). Moreover, sharing the FBP and perceived food adequacy were associated with reduced drug adherence. Those who shared FBP were less likely to adhere to drugs than those who did not share FBP. Those who perceived food to be adequate were less likely to adhere to drugs than those who perceived food as not being adequate. Food insecurity is emerging as an important barrier to ART adherence, especially in resource-limited settings (Bukusa *et al.*, 2007). Findings point to an association between food

insecurity where the client is forced to share FBP and poor drug adherence but cannot infer causation. Majority of respondents who were divorced appeared to have lower drug adherence to ARV. Similar findings were reported by Talam *et al.* (2008) in Moi Teaching and Referral hospital where those who were divorced, widowed or separated had lower drug adherence. This might be due to the emotion and grief encountered, and loss of spousal support. The risk of mental illness was lower among married women than the widowed (Sherbourne & Hays, 1990). However, findings to the contrary were shown in Ethiopia where the married were found to have the least adherence to ART (Alemayehu *et al.*, 2008). Indeed the support given by a spouse is very important and those who are divorced may miss out on this which seems to help in drug adherence.

5.5 Association between Compliance and Nutritional Status of People Living with HIV and AIDs on Food by Prescription

The findings of this study indicate an association between compliance to food by prescription and nutritional status. Those with a better nutritional status had better compliance. This possibility is supported by results a study where participants reported that they looked healthier and were able to engage in social events and other activities (Gerber *et al.*, 2010) ; Panagides *et al.*, 2007). It implies they could have had a better nutritional status as a result of consuming the FBP provided and following instructions given to them. This suggests that indeed there is good potential to achieve aim of FBP if additional efforts are put in place by health care workers and donors to improve client compliance. However, although it is logical that good compliance would improve nutritional status, the study design does not allow conclusions on the direction of the relationship to be made, because it is also plausible that persons with severe malnutrition are less able to comply with the instructed regimen (Sadler *et al.*, 2012).

So far, little has been done to examine relationships on compliance to intake of FBF and nutritional status especially in resource limited settings hence the need for more research to examine this. Findings that could be obtained from literature to compare with findings of this study only focused on uptake of the FBF/supplementary food among the HIV positive malnourished and nutrition status without its association with compliance to the food being considered, given that nutrition interventions are increasingly being advocated to prevent malnutrition and restore good nutritional status of malnourished PLHIV with a view to maintaining their productivity and immune function capacities. It is good to look into compliance to the FBP and its association to provide more studies to compare and make conclusions.

5.6 Association between Compliance to Food by Prescription and Drug Adherence in PLHIV on Food by Prescription

Findings from the current study indicate that compliance is not associated with drug adherence in PLHIV. This indicates that, in this population, drug adherence is independent of compliance. PLHIV follow instructions on drug regimens even when they do not comply with instructions on taking the FBP. These findings contradict those reported in a study by AMPATH program in western Kenya, where FBP facilitated ARV adherence. In the study 78 % of clients reported that access of food lessened side effects of ARVS including increased appetite, dizziness and vomiting which are ARV side effects (Byron *et al.*, 2008). Moreover in a study in Zambia, food supplementation program in Lusaka for patients on ARV reported improved drug adherence compared to controls without supplementation but the effects were not noticeable during the first 6 months (Cantrell *et al.*, 2008).

Although there was no association between compliance and drug adherence focus group discussion results indicated that clients appreciated how the FBF helped them regain strength,

appetite, weight and energy as well as supported adherence to ART (some reported drinking FBP when swallowing their medicines). They reported to have experienced improved response to ARVs and reduced side effects (such as nausea). These were almost the same sentiments that clients reported during an assessment that was done by Gerber *et al.* (2010) as it was reported by a client during the FGD that:

“I had diarrhea, I was very weak, I also suffered from short breaths. When I was put on mogo [flour], I regained my strength and could walk without losing my breath.”

There is inadequate literature that focuses on compliance to FBP and drug adherence. The findings that could be obtained from literature to compare with findings of this study only focused on uptake of the FBF among PLHIV who are malnourished and drug adherence without compliance to the FBF being considered. The aim of improving adherence to drugs by providing FBP is therefore achievable. However, much higher adherence to the drug regimen than compliance to FBP indicates that regardless of the FBP, PLHIV in this setting will comply with their drug regimen especially because drugs are less likely to be shared than food.

CHAPTER SIX

SUMMARY OF THE FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

6.1 Summary of Findings

Out of the 300 sampled patients, over 76% were below 35 years with a mean age of 29.3 ± 9.7 years. 18% said they had adequate food for the family. The main source of food was purchasing. About 26% were compliant to the FBP. Compliance appeared to be found mainly among respondents who did not share the FBP, male, respondents aged 46 years and above and married. Male respondents were more likely to comply with FBP than their female counterparts. Similarly, purchasing food and not having under-fives was associated with compliance with FBP. Those who purchased food were more likely to comply with the FBP than those whose main food source was by farming; while those who lived with children aged less than 5 years were less likely to comply than those who did not live with children in this age group. Sharing of the FBP, stigma, poverty, opportunistic infections and drug side effects were some of the reasons for non-compliance that were reported from the focused group discussion.

None of the participants achieved normal nutritional status, which is the aim of the programme. Most respondents had moderate malnutrition with 23% having severe acute malnutrition. Better nutritional status appears to be among the young aged (26-35), male, married and with high income while poor nutritional status appear to be among those aged above 46 years of, divorced and with secondary education. Being married was the only factor associated with nutritional status in this study. Poverty was the perceived reason for no change in weight after commencement on the FBP program because it led to sharing of the flour and eventually stock outs before the refill dates.

Most of the PLHIV adhered to their drugs. Drug adherence was much higher than adherence to FBP. Compliance to FBP was associated with nutritional status with those who were compliant having a better nutritional status than those who were not compliant. However compliance to FBP was not associated to drug adherence.

6.2 Conclusions

From findings of this study, compliance to food by prescription among PLHIV was low. The observed low level of compliance to the Food by Prescription to FBP in this population occurs among those who do not share the FBP, male respondents aged 46 years and above and those who are married. The low compliance from FGD findings could be attributable to poverty, stigma, opportunistic infections and drug side effects.

None of the PLHIV who were on FBP had achieved normal nutritional status. Majority of respondents are moderately malnourished with close to a quarter having severe acute malnutrition. Better nutritional status occurs among the young aged 26-35 years, males, married persons and persons with high income; while poor nutritional status occurs among those aged above 46 years of age, the divorced and those with secondary education. Being married is associated with better nutritional status than that of those who are not married. PLHIV on FBP perceive poverty, which results in sharing, as the reason for no change in nutritional status after commencement of FBP program.

Drug adherence is high among respondents who do not share the FBP, those who do not stay with children less than 5 years and earn Ksh. 20,000 and above. However, it is low among respondents that are divorced, those who earn between Ksh.5000 to 19,000 and those who share FBP.

From the current study findings, it emerged that there is an association between compliance to food by prescription and nutrition status. PLHIV who are compliant to FBP have a better nutritional status than those who do not comply.

Findings indicate there is no association between compliance to FBP and drug adherence. This indicates that, in this population drug adherence is independent of compliance. PLHIV follow instructions on drug regimens even when they do not comply with instructions on taking the FBP.

6.3 Recommendations

The following are recommendations based on findings from the current study;

1. Non-compliance to prescribed FBP due to sharing could undermine the success of the program. Health care providers need to involve family members during enrolment of the client to FBP. This will help them understand importance of compliance to FBP.
2. Respondents who have been in the program for at least 2 months were still moderately malnourished indicate that the objective of the program to improve nutritional status is unlikely to be achieved. However the possibility of achieving the objective of improving the nutritional status may be improved if compliance to FBP is achieved in a large proportion of persons in the programme. The government/program donors needs to provide support to those aged 46 years and above either by considering a higher caloric content of FBP for a longer duration so that they may improve their nutritional status.
3. The drug adherence level is good. However, there is need for health care workers to establish ways in which the 14% who do not adhere to the prescribed drug regimen can be encouraged to do so with a focus on improving level of income since those

who earn little income and share FBP show lower drug adherence. This can be achieved through linking them up to support groups where they can start income generating activities to boost their income level.

4. Since compliance to food by prescription is associated with better nutritional status, efforts to promote compliance to FBP should be integrated in the program, given the low level of compliance observed. This could be achieved by the government integrating activities that address poverty and stigma; and improved access to FBP for PLHIV who are too sick to leave their homes due to opportunistic infections.

6.4 Suggestions for Further Research

1. Factors influencing lower compliance to FBP among females should be explored in order to improve adherence in this group.
2. Factors contributing to poor nutritional status among those on FBP aged 46 years and above.
3. A study to determine factors associated with achievement of normal nutritional status in PLHIV
4. A study assessing whether compliance to FBP would lead to better drug adherence and quality of life in a study sample that takes into account low compliance to FBP.

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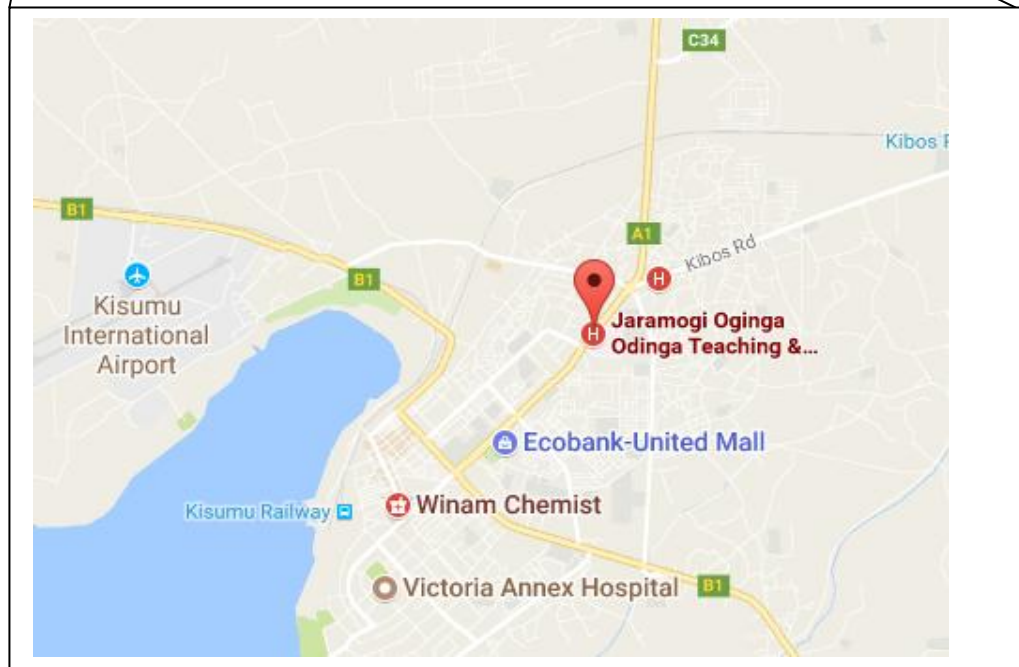
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APPENDICES

Appendix I: Kenyan Map Showing the Study Area



Appendix II: Introduction Letter from Maseno University to National Council



MASENO UNIVERSITY

SCHOOL OF GRADUATE STUDIES

Office of the Director

P.O. Box Private Bag Maseno

Tel: 057, 351468

Our Ref: MSU/SGS/57

Date: 17th March, 2011

Executive Secretary,
National Council for Science and Technology,
Po Box 30623 -00100
NAIROBI.

RE: MWANDO WANYONA RAEAL - PG/MSC/0023//07

The above named person is a student pursuing a Master of Science in Community Nutrition and Development, in the School of Public Health and Community Development (ESPUDEC), Maseno University.

She would like to undertake a research study entitled *"Impact of Compliance to Food by Prescription on Nutrition Status and Drug Adherence among People Living With HIV/AIDS Attending the New Nyanza Provincial Hospital, Kenya."* During her research, she will need to visit various places to collect data which will help her to write a thesis. We kindly request that she be given a research permit to allow her carry out research without any hindrance.

Any assistance accorded to her will be highly appreciated by the Maseno



Appendix III: Approval from JOOTRH Ethics Review Committee

MINISTRY OF MEDICAL SERVICES

Telegrams: "MEDICAL", Kisumu
Telephone: 057-2020801/2020803/2020321
Fax: 057-2024337
E-mail: medsupt@africaonline.co.ke
When replying please quote

NYANZA PROVINCIAL GENERAL HOSPITAL
P.O. BOX 849
KISUMU

Ref. No: NPGH-ERC 2/11/10

Date 30th November 2010

Dear Rael Mwando,

Impact of Compliance To Food By Prescription Program on Drug Adherence and Nutrition Status
Among People Living With HIV/AIDS Attending Nyanza Provincial General Hospital, Kenya.

Following an ethics review committee meeting held on the 24th of November 2010, your proposal was discussed and **approved** for the duration commencing on 25th November 2010 to 24th November 2011.

You will be required to seek approval for extension beyond this period by re- applying to NPGH-ERC.

The NPGH-ERC wishes you the best as you carry out the study and kindly requests that you share a summary of the findings at the end of the trial. This will ensure that a study of a similar nature is not duplicated in the future.

Signed: .....

Dr. G.W. Mwangi

Secretary-NPGH-ERC.

Appendix IV: Authorization letter from National Council for Science and Technology

REPUBLIC OF KENYA



NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Telegrams: "SCIENCETECH", Nairobi
Telephone: 254-020-241349, 2213102
254-020-310571, 2213123.
Fax: 254-020-2213215, 318245, 318249
When replying, please quote

NCST/RR1/12/1/MED-011/34/4

P.O. Box 30623-00100
NAIROBI-KENYA
Website: www.ncst.go.ke

1st April, 2011

Date:

Our Ref:

Rael Wanyona Mwando
Maseno University
P. O. Box Private Bag
MASENO

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on **"Impact of compliance to food by prescription programme on nutrition status and drug adherence among people living with HIV/AIDS attending the New Nyanza Provincial Hospital Kenya"** I am pleased to inform you that you have been authorized to undertake research in **Kisumu East District** for a period ending **30th June, 2011**.

You are advised to report to **the Provincial Director of Medical Services, New Nyanza Provincial Hospital** before embarking on the research project.

On completion of the research, you are expected to submit **one hard copy and one soft copy** of the research report/thesis to our office.


A handwritten signature in black ink, appearing to read 'P. N. Nyakundi'.


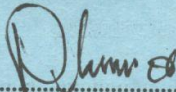
P. N. NYAKUNDI
FOR: SECRETARY/CEO

Copy to:

The Provincial Director of Medical Services
New Nyanza Provincial Hospital
KISUMU

Appendix V: Research Clearance permit

<p style="text-align: center;">CONDITIONS</p> <ol style="list-style-type: none"> 1. You must report to the District Commissioner and the District Education Officer of the area before embarking on your research. Failure to do that may lead to the cancellation of your permit 2. Government Officers will not be interviewed without prior appointment. 3. No questionnaire will be used unless it has been approved. 4. Excavation, filming and collection of biological specimens are subject to further permission from the relevant Government Ministries. 5. You are required to submit at least two(2)/four(4) bound copies of your final report for Kenyans and non-Kenyans respectively. 6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice <p style="text-align: center;"><u>GPK6055t3mt10/2009</u></p>	 <p>REPUBLIC OF KENYA RESEARCH CLEARANCE PERMIT</p> <p>(CONDITIONS— see back page)</p>
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<p style="text-align: center;">PAGE 2</p> <p>THIS IS TO CERTIFY THAT:</p> <p>Prof./Dr./Mr./Mrs./Miss Rael Wanyona Mwando</p> <p>.....</p> <p>of (Address) Maseno University Box Private Bag Maseno</p> <p>.....</p> <p>has been permitted to conduct research in</p> <p>.....Location, Kisumu East District, Nyanza Province,</p> <p>on the topic "Impact of compliance to food by prescription programme on nutrition status and drug adherence among people living with HIV/AIDS attending the New Nyanza Prov. Hospital Kenya" 11</p> <p>for a period ending 30th June 2011</p>	<p style="text-align: center;">PAGE 3</p> <p>NCST/RRI/12/1/MED-011/34 Research Permit No...... 1/4/2011 Date of issue..... Kshs. 1000 Fee received.....</p> <div style="text-align: center;">  </div> <p>..... Applicant's Signature</p> <p style="text-align: right;">  Secretary National Council for Science and Technology </p>
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Appendix VI : Information Sheet and Consent Form

(A) Information sheet

The following information is to enable you to give voluntary, informed consent to participate in this study. Please read the information carefully before signing the consent form (part B). (This was verbally read for those who were not able to read.)

Study title: Influence of compliance to food by prescription program on nutritional status and drug adherence among people living with HIV/AIDS attending Jaramogi Teaching and Referral Hospital.

Investigators Names: Rael Wanyona Mwando

Address P. O. Box 721-40100

Kisumu.

Tel: 0721848 526

Aim and Significance of the study

The aim of this study is to assess the influence of compliance to food by prescription program on nutritional status and drug adherence among people living with HIV/AIDS in Jaramogi Teaching and Referral Hospital. This study will provide information to the ministry of health and other government organizations on whether to modify interventions. Compliance to food by prescription is expected to improve the nutrition status that will in turn improve drug adherence as well as improve quality of life.

What participation will involve

Upon enrolment in the study you will be participants were given questionnaire on demographic data and socioeconomic activities which they will be required to fill. After which you will be asked questions on compliance to food by prescription and drug adherence. This information will be recorded onto forms. In addition a you will asked questions concerning your diet and your weight and height will be measured. The participants will not get any benefits by participating in this study.

Data Security

All information you provide us will remain confidential. Only the study team will have this information and will be treated with confidentiality unless your express permission is obtained.

You may withdraw from participating in this study at any time without giving reasons. This will not affect services you are receiving.

(B) Consent Form

Please read the previous information sheet (or have the information read to you) carefully before completing and signing this consent form. Should you have any questions about the study please feel free to ask the investigator prior to signing your consent

Consent Form for the Study

Influence of compliance to Food by Prescription program on nutrition status and drug adherence among people living with HIV/AIDS in Nyanza provincial general hospital.

Investigators name: Rael Wanyona Mwando
Provincial Hospital Kisumu
P.O. Box 849-40100,
Kisumu
Tel: 0721 848 526

FOR COMPLETION BY PARTICIPANTS

I have read the following sheet concerning this study and I understand what will be required of me if I take part in the study.

Any questions regarding this study have been answered by

.....

I understand that at any time I may withdraw from the study without giving a reason and this will not affect the care am receiving at the patient support centre.

I also understand that there are no benefits that I will gain by participating in this study.

I AGREE TO TAKE PART IN THE STUDY:

Name of participant:.....

Signed..... (Or thumb print)

Date:.....

Name of interviewer.....

Signed.....

Date.....

Appendix VII : Questionnaires and Interview Guide

**INFLUENCE OF COMPLIANCE TO FOOD BY PRESCRIPTION PROGRAM ON
NUTRITIONAL STATUS AND DRUG ADHERENCE AMONG PEOPLE LIVING
WITH HIV/AIDS IN NEW NYANZA PROVINCIAL GENERAL HOSPITAL
KISUMU, KENYA**

SECTION 1: SOCIO DEMOGRAPHIC DATA QUESTIONNAIRE

INSTRUCTIONS

Write the correct response in the space provided

1 Basic information

- 1.1 Questionnaire code
- 1.2 Date of interview dd/mm/yy

2.0 Demographic data

- 2.0 Sex/Gender of participant (1) male (2) female

2.1 Age of the respondent

- 1 18-25 years
- 2 26- 35 years
- 3 36-45 years
- 4 46 and above years

2.2 Marital status of the respondent

- 1 Married
- 2 Single
- 3 Divorced
- 4 widow /widower
- 5 Cohabiting (living with partner but not married)
- 6 Other (specify.....)

2.3 Level of education of the respondent

- 1 Primary education (1-4 years)
- 2 Primary education (5-8 years)
- 3 Secondary education (1-3 years)
- 4 completed Secondary education
- 5 Colleges
- 6 None

3.0 socio- economic information

3.1 In the last one month what was your income?

- 1 less than 1000
- 2 1000-2999
- 3 3000-4999
- 5 5000-6999
- 6 7000- 19,999
- 7 above 20,000

3.2 Currently who are you living with?

- 1 Alone
- 2 Parents
- 3 Spouse
- 4 Children
- 5 Friends
- 6 Others (specify.....)

3.3 Do you live with children less than 5 years in your household

- (1) Yes
- (2) No

3.4 Do you live with an adult >18 years in your household

- (1) Yes
- (2) No

3.5 Excluding yourself on average how many people eat at your house in a day?

3.6 Is the food enough for all the people?

- (1) Yes
- (2) No

3.7 (a) what is the main source of food in your house?

- 1 Purchase
- 2 House hold garden
- 3 Relatives and friends support
- 4 NGO support
- 5 Others (Specify.....)

3.8 If not enough how do you cope with the deficit?

- 1.....
- 2.....
- 3.....
- 4.....

3.9 How much money in Kenyan shillings do you spend, on average, in buying food for one day in your household?

**SECTION 2: COMPLIANCE TO FBP INTERVIEW GUIDE
INSTRUCTIONS**

Now, I want to ask you questions on how you have been taking your food by prescription (flour you are given at the clinic) in the past one month. Be assured that this information will not change the way you receive your food by prescription

2.1 Did you consume the food supplement yesterday?

- (1) Yes (2) No

2.2 If no when was the last time you used the food supplement?

2.3 How many days have you used the food supplement in the past 1 week?

2.4 How many times did you use the supplement last month?

2.5 When was your last visit to the clinic? (dd/mm/yy.....)

2.6 How many bags of food supplement did you receive?.....

2.7 How many bags/sachets are remaining as of today?bags/sachets

2.8 How do you normally prepare the porridge? Water.....cups. Flour.....

2.9 Did you share the supplement with anyone in or outside the family?

- (1) Yes
(2) No

3.0 If yes, with whom did you share the supplement?

- 1 Spouse
2 Own children
3 Friend
4 Neighbours
5 Other family members specify.....
6 Any other specify.....

3.1 How much did you consume on the day the supplement was shared.....

3.2 How much did the person you shared with consume?

3.3 How many times in the past month have you missed taking the supplement?

- 1 Once
2 Twice
3 Severally
4 Can't remember
5 None

If the response to the above question is option 5, skip question 6.3

3.4 What were the reasons for not taking the supplement?

- 1 Forgot to take the food
- 2 Fear of side effects/Toxicities
- 3 Shared with others
- 4 Did not like the taste
- 5 Felt better
- 6 Too ill to prepare the supplement
- 7 Stock was finished
- 8 Run out of cooking oil/water to make the food
- 9 Had travelled
- 10 Other specify

3.5 Did you have any other family member who supported/helped you to prepare or take the supplement?

3.6 Did the health personnel at the clinic explain to you the importance of taking the food supplement correctly as explained?

- 1 yes
- 2 No

3.7 What do you think would happen if you don't adhere to the instructions given?

- 1 my health will deteriorate
- 2 I will not gain weight
- 3 Nothing will happen
- 4 Don't know
- 5 Other specify

3.8 Is there any difference in your weight or health status from the time you started the supplement to now?

- 1 Yes
- 2 No

If the answer to question 7.7 is no skip to question 7.9

3.9 If there's a difference what have you put in place to ensure that your weight/health does not deteriorate when food provision of the supplement is stopped

- 1.....
- 2.....
- 3.....

4.0(a) If no why do you think there's no difference?

- 1.....
- 2.....
- 3.....

4. O (b) in your own opinion what are the challenges to maintaining compliance to the supplement

- 1.....
- 2.....
- 3.....

**SECTION 3: DRUG ADHERENCE INTERVIEW GUIDE
INSTRUCTIONS**

Now, I want to ask you questions on how you have been taking your medication in the past one month. Please be aware that everyone misses doses some of the time. Be assured that this information will not change the way you receive your medications.

1.0 Which drugs are you currently taking?

- 1.....
- 2.....
- 3.....
- 4.....
- 5.....
- 6.....

1.1(a) everyone misses medication doses some of the time, Have you ever missed taking your medication as required?

- 1 Yes
- 2 No

If the response is no, skip to question 5.3, if response is yes go to 5.2b

1.2 (b) which drug, specify with the number of doses missed

(Note: A dose constitutes a measured portion or amount of medicine taken at any one time e.g. two doses are considered if they are to be taken at 8am and 8 pm respectively).

Name of Drug	No of dose missed the past day	No of dose missed past two days	No of dose missed past week	No of dose missed past month
1.				
2.				
3.				
4.				

1.3 What were the reasons for missing the drugs?

- 1 Forgot to take the drug
- 2 Experienced side effects
- 3 Had travelled
- 4 Felt better
- 5 was too ill
- 6 Did not have food
- 7 Too many pills
- 7 Other's specifying.....

1.4 In your own opinion has the food supplement assisted you?

1 Yes

2 No

1.5 If yes, how has it assisted you in adhering to your medication?

.....
.....

SECTION 4: NUTRITIONAL STATUS ASSESSMENT GUIDE

INSTRUCTIONS

I would like to take some of your body measurements to see how you are fairing on with both the medication and the food supplement. However the information obtained will not affect the services you are receiving.

1.1 Weight(Kg) Wt 1 Wt 2..... Average.....

1. Height (M) Ht 1 Ht 2..... Average.....

1.3 BMI(Kg/M²)

Classification.....

Comments-

.....
.....

Thank you for accepting to participate in the study

Appendix VIII : Focused Group Discussion Guide

1. What factors affect compliance to the food supplement?
2. In your own opinion what are the benefits of compliance to the supplement.
3. What is your recommendation for the program?

Appendix IX : Details and Nutritional Value of Fortified Blended Flour

CSB and WSB are by far the most widely used FBF. They contain cornmeal or wheat flour, soybeans, and a mineral-vitamin mix. CSB consists of; 80% maize and 20% soy, and WSB consists of; 75% wheat and 25% soy. In Kenya, CSB is most widely used product.

There are three branded nutrient dense CSB products recommended as part of the intervention for FBP. These products are manufactured by Insta products (EPZ) Ltd a wholly owned Kenyan company. They include, First Food, Foundation Plus, and Advantage manufactured under the brand name “Insta Health Builder”

Insta Health Builder first food is a precooked, nutritious, complimentary weaning porridge suitable for older infants (over 6 months of age) and for older growing children and young adults. Adults of all ages will also enjoy and benefit from eating First food. It is shelf stable, dry extruded, porridge flour made from whole maize, millet, sorghum, and soybeans. With added energy and a compliment of crucial micronutrient fortification, First food is formulated as a nutritionally dense (435Kcal/100g) complimentary weaning food to ensure infants grow into strong healthy children. In the context of FBP, First food is recommended for moderately malnourished children; for easy distribution it is packaged in 3kg bags which contain ten 300g sachets. Children aged 6 – 23 months require 100g per day which translates into one bag per month, while 24 – 59 month old children require 200g per day (i.e. 870 kcal) which translates to two 3kg bags.

Insta Health Builder foundation plus is dry extruded flour, convenient to prepare with water to be eaten as a nutritious boiled porridge. Insta Products has confirmed its shelf life, ease of preparation and palatability through years of successful use in food assistance programs. It is manufactured as a shelf stable dry-extruded (precooked) porridge flour made from whole maize and soy. With added energy in the form of vegetable oil, sugar and with a

full complement of 20 micronutrients, Foundation plus+ is formulated as a nutritionally dense supplemental food with additional energy (450 kcal per 100 grams). It is effective nutrition for all ages where increased nutrition density in energy, protein, and micronutrients is critical. In the context of FBP, Foundation Plus is packed in 300g X 15 sachets packaged in a 4.5kg bag for ease of use and dispensability. It is prescribed to adolescents 11 – 17 years, and adults 18 years and above. A daily prescription of 300g of Foundation Plus delivers 1,350kcal.

Insta Health Builder advantage was developed for pregnant and nursing mothers. Advantage should be consumed during pregnancy to contribute to the baby's birth weight and maintain the nutrition of the mother. The porridge also provides mothers with energy and nutrients while they are nursing their new born babies. A comprehensive range of vitamins and minerals have been added to contribute both the mother and child's nutrition during this critical stage in the child's development. Advantage is dry extruded flour, convenient to prepare with water to be eaten as a nutritious boiled porridge. It consists of the following ingredients: Precooked whole maize, soy beans, with cane sugar, salt, vegetable oil, and fortified with vitamins and minerals

Appendix X: Nutritional Value of Foundation Plus

Nutrient per 100 kcal	Unit	Minimum	Maximum
Protein	g	20	43
Fat	g	25	65
Minerals			
Sodium (Na)	mg	-	500
Potassium (K)	mg	1500	2200
Magnesium (Mg)	mg	280	420
Phosphorus (P) ^d	mg	850	1400
Zinc (Zn) mg	mg	20	35
Calcium (Ca)	mg	1000	1400
Copper (Cu)	mg	1	3.5
Iron (Fe) ^e	mg	18	30
Iodine (I)	ug	150	350
Selenium (Se) ^f	ug	35	90
Manganese (Mn)	mg	1	2g
Vitamins Water soluble			
Thiamin (B1)	mg	>1	-
Riboflavin (B2)	mg	>4	-
Pyridoxine (B6)	mg	>2	-
Cobalamine (B12)	ug	>5	-
Folate (dietaryfolate equivalent)	ug	> 400 ^h	-
Niacin	mg	>25	-
Ascorbate (vitamin C)	mg	>150	-
Pantothenic acid	mg	>5	-
Biotin	ug	>20	-
Vitamins, fat soluble			
Retinol (vitamin A)	ug	2000	3000
Cholecalciferol (vitamin D)	ug	20	60
Vitamin E (dl- α tocopherol acetate)	mg	>30	-
Phytomenadione (vitamin K)	ug	>50	-
Fatty acids			
ω -6 fatty acid	% energy	>4.5	<10
ω -3 fatty acid	% energy	>0.5	<3
Trans-fatty acids	% energy	3	
Ratios of nutrients (based on weight)			
Ca/P ratio		1.0	1.5
Zn/Cu ratio		5	20
Zn/Fe ratio		0.8	3.5

Vitamin C/Fe		3	16
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Appendix XI : FBP Eligibility and Exit Criteria Protocol

Client Category	Eligibility criteria	Exit criteria
Adult PLHIV (18 years and above)	BMI <18.5 kg/m ²	BMI ≥ 20 kg/m ²
Pregnant or postpartum women (P/PP)	MUAC between 22-24cm	BMI ≥ 20 kg/m ²
OVC (6 months-5 years)	Weight for height (WHZ) <-2 z-score	WHZ ≥ -1.0 z-score
OVC (6-9 years)	BMI for age <-2 z-score	BMI for age ≥ -1.0 z-score
OVC (10-17 years)	BMI for age <-2 z-score	BMI for age ≥ -1.0 z-score

Source: MOH, (2006b)