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Impact of Food and Nutrition Security on Adherence to Anti-Retroviral Therapy (ART) and Treatment Outcomes among Adult PLWHA in Dire Dawa Provisional Administration

By
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A thesis Submitted to the School of Graduate Studies of Addis Ababa University in partial fulfillment of the requirements for the Degree of Masters of Public Health

June 2007
Addis Ababa, Ethiopia

ACKNOWLEDGMENT

My exceptional gratitude goes to my advisors Dr. Fikru Tesfaye and Dr. Solomon Shiferaw for their unreserved help in reviewing my thesis and giving me constructive advice and guidance that helped me materialize this study.

I am grateful to Addis Ababa University, Faculty of Medicine, Department of Community Health for its support in funding my thesis work. My appreciation also extends to Dire Dawa Regional Health Bureau for providing me the necessary information and facilitating conditions while I was carrying out this study. I thank Mr. Mengistab Kidane for his help in developing data capturing format specific for this study. I also thank Dr. Kesetebrhan Delele for his help during the fieldwork and the rest of my friends who devoted their precious time helping me in every aspects of my work. I am indebted to the Mr. Africa Mulugeta who has helped me in selecting interviewers and supervising them strictly till the completion of the filed work. I would also like to thank all the interviewers for their unreserved commitment and careful field work. Data clerks and nurses at Dil Chora hospital ART unit deserve my great acknowledgment. My gratitude goes to all of the study participants for their willingness and participation in the interview.

I would like to express my heart felt gratitude to my families and friends for their moral and material support during my study.

DEDICATION

This paper is dedicated to my elder sister Elsabeth Seifu. My post graduate study is made possible through her unreserved help and ambition. God bless her once more.

ACRONYMS

AACTG	Adult AIDS Clinical Trial Group
AIDS	Acquired Immuno-Deficiency syndrome
ART	Antiretroviral therapy
BMI	Body Mass Index
CD4+	White blood cell types that are the prime targets of HIV
CI	Confidence Interval
DPPA	Disaster Prevention and Preparedness Agency
FAO	Food and Agriculture Organization
FGD	Focus Group Discussion
HAART	Highly Active Antiretroviral Therapy
HAPCO	HIV/AIDS Prevention and Control Office
HH	Household
HIV	Human Immuno-deficiency Virus
HSV	Herpes Simplex Virus
IQR	Inter Quartile Range
MEMSCap	Medication Event Monitoring Systems Caps
N	Number
OR	Odds Ratio
PEPFAR	President's Emergency Plan For AIDS Relief
PLWHA	People Living With HIV/AIDS
PMAQ	Patient Medication Adherence Questionnaire

PMTCT	Prevention of Mother To Child Transmission
SD	Standard Deviation
SPSS	Statistical Package for Social Science
STDs	Sexually Transmitted Diseases
TBMA	Tesfa Bisrat Misikir Association
ART ID No.	ART Identification Number
US	United States
USA	United States of America
USDA	United States Department of Agriculture
VCT	Voluntary HIV counseling and Testing
WHO	World Health Organization

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ABSTRACT

Background: Adherence to Anti-Retroviral Therapy (ART) is critical for optimal virologic suppression and improved CD4+ cell count that in turn determines the survival of People Living with HIV/AIDS (PLWHA) on ART. So far a range of predictors of adherence to ART in many different social and cultural settings have been identified. However, household food and nutrition security as predictor of adherence to ART is less understood.

Objective: The main objective of this research project is to assess the effect of household food and nutrition security on adherence to ART and treatment outcomes.

Method: A cross-sectional study was conducted to assess the effect of household food and nutrition security on adherence to ART and treatment outcomes. Both quantitative and qualitative research methods were applied to triangulate the findings of one with another. Adult PLWHA on ART for at least 3 months were the study participants. Availability of enough food/money to buy one, behavioral and subjective questions, meal frequency, dietary diversity, food aid and BMI were used as indicators to measure the household food and nutrition security situation of PLWHA and self-reported adherence as an indicator to measure adherence to ART. Change in CD4+ cell count, body weight, functional status and frequency of opportunistic infections were used to measure treatment outcomes.

Result: Based on food security assessment core module close to 90% of PLWHA on ART in Dire Dawa were food insecure and 30.1% had at least mild malnutrition. On patient self report of adherence 96.6% of them were adherent to ≥95% of the ART drugs prescribed. The median change in CD4 count after 6 months and the median change in weight after 3 months of ART were 116 (IQR 82-182) and 3kg (IQR 1-6kg) respectively. Reported diarrhea and lung disease among the study participants were 17.9% and 54.1% respectively. Food and nutrition security indicators were associated with treatment

outcomes. Food aid contributed to functional improvement (OR 1.89, 95% CI 1.20-2.97). Dietary diversity and meal frequency were significantly positively correlated with change in weight and change in CD4 count respectively ($p<0.05$). Pre-ART nutritional status was significantly negatively correlated with change in weight after 3 months of ART ($p<0.001$).

Discussion: Food and nutrition insecurity is a serious problem of PLWHA on ART. Overcoming all the odds to adhere to the treatment PLWHA in the present study were adherent to ART more than any documented adherence findings. But food and nutrition insecurity was silent factor that impede treatment outcomes. Food aid, dietary diversity and meal frequency were positively associated with functional improvement, weight gain and CD4 increase. Pre-ART nutritional status was negatively correlated with weight gain indicating better improvement among severely malnourished. Current malnutrition was significantly associated with reported opportunistic infections.

Conclusion and recommendations: The mere success in achieving high level of adherence among PLWHA taking ART should not undermine the impact of food and nutrition security on the treatment outcomes which is the ultimate goal of the program. Lack of food to take with medication is the main reason for those few non-adherents and food ration improved functional status of PLWHA on ART. Food aid as relief together with a sustainable income generating activities need to be included in ART program.

1. INTRODUCTION

The increasingly widespread use of highly active antiretroviral therapy (HAART) since 1996 has substantially improved the prognosis of HIV infected patients who have access to these drugs through decreasing viral load and increasing CD4+ cell counts. (1,2,3) In resource poor settings of Africa, Asia, and South America, where 90% of people with HIV/AIDS live, access to HAART is limited. However, with falling price of proprietary drugs, the increasing availability of generic formulations and launch of initiatives by international agencies, including the World Health Organization's (WHO's) "3 by 5" programme (to get 3 million HIV patients on antiretroviral by 2005), the Global Fund to fight AIDS, Tuberculosis, and Malaria, and the US President's Emergency Plan For AIDS Relief (PEPFAR), this situation is changing. The WHO estimate that on June 2005, about 1 million people were receiving HAART, although this number still only represents 15% of the estimated 6.5 million people in urgent need of antiretroviral therapy in low- and middle-income countries. (2,4) In Ethiopia alone some 245,000 PLWHA were in need of ART in 2003. (5) The promising access to ART in developing countries, including Ethiopia, would be translated into health and psychosocial benefits only when there is nearly perfect adherence to ART.

For optimal virologic suppression and improved CD4+ cell count to happen, however, a high degree of adherence to ART is necessary. (3,6,7,8) Lack of strict adherence to HAART is considered to be one of the key challenges to AIDS care worldwide. Estimates of average rates of nonadherence with ARV therapy range from 50% to 70% in many different social and cultural settings, and the risks associated with nonadherence are extensive at both individual and societal levels. Multiple drug resistance, rapid progression to AIDS and death can happen in PLWHA on ARV therapy with nonadherence. (3,7,9)

On the other hand, the Food and Agriculture Organization (FAO) estimates that 852 million people worldwide, many in Africa, were undernourished in 2004. (10) The situation becomes even worse among households affected and afflicted by HIV/AIDS.

(11,12) In Ethiopia, approximately 49% of the population is without adequate nutrition. (5) According to 2005 DHS, 47% of children under five experience chronic and 24% severe malnutrition. One if four women of reproductive age has chronic energy deficiency and 27% have anemia. (13).

Although there are conflicting hypotheses on the need for increased protein and micronutrient intake the daily recommended levels needs to be assured in HIV-infected adults through consumption of diversified diets, fortified foods and micronutrient supplements as needed. But there is convincing evidence on greater energy need of HIV-infected adults than uninfected adults; extra 10% in asymptomatic HIV infected and 20-30% in adults with more advanced diseases. (12,14)

Interactions between antiretroviral therapy (ART) and food and nutrition can affect medication efficacy, nutritional status, and adherence to drug regimens. Maintaining adequate food consumption and nutrient intake levels and meeting the special nutritional needs the disease and ART generate are critical for PLWHA on ART to achieve the full benefit of such treatment. (4,5,14,15). Food assistance to PLWHA on ART, together with helping PLWHA maximize utilization of existing resources and food production, is advocated as a strategy to improve food security of households of PLWHA in the national guideline for HIV/AIDS and nutrition. Correctly targeted food assistance helps to save household income, fulfill daily nutritional requirement, improve ART adherence and as incentive for vulnerable households. (5)

Evidences documented so far on determinants of adherence to ART and thus treatment outcomes include poor clinician - patient relationship, drug and alcohol use, active mental illness, lack of information, lack of reliable access to ART, side effects, stigma, cost of ART travel/migration, domestic violence and discrimination. (2,3,7,9,16,17) However, the impact of food and nutrition security as determinant of adherence to ART is not well explored. This research is therefore meant to assess the impact of household food and nutrition security on adherence to ART and treatment outcomes. The findings of this research could be used as an input to ART programs at local and/or national levels.

2. LITERATURE REVIEW

Malnutrition and HIV/AIDS work in tandem, creating a vicious cycle. HIV compromises the immune system of infected persons, increasing their susceptibility to other infections, which can negatively affect nutritional status. Conversely, malnutrition increases the severity of the HIV disease by further weakening the immune system, which decreases the body's ability to fight HIV and other infections. (10,12,18)

Food and nutrition security

Food and Agriculture Organization (FAO) estimates that 852 million people worldwide, many in Africa, were undernourished in 2004. (10) The situation becomes even worse among households affected and afflicted by HIV/AIDS. (11,12) In Ethiopia, approximately 49% of the population is without adequate nutrition. (5) According to 2005 DHS, 47% of children under five experience chronic and 24% severe malnutrition. One if four women of reproductive age has chronic energy deficiency and 27% have anemia. (13).

A systematic review of food security and nutrition in Ethiopia found that food availability was severely restricted due to recurrent disasters such as drought, flood, war and a lack of diversity of food items. Food accessibility was limited due to a weak subsistence-agriculture-based economy, depletion of assets, absence of income diversity and a lack of alternative coping mechanisms. Food intake adequacy was rarely achieved due to food shortages, improper diet and poor sanitary conditions. There was a lack of early warning data to monitor food security indicators. Food aid programmes did not meet the requirements for food quantities and composition, and faced major obstacles in logistics and targeting of the vulnerable population. (19)

The premise that high rates of HIV prevalence in Africa are mainly due to high levels of sexual activity has restricted policy interventions. Prevention of HIV is pursued predominantly through initiatives to change behavior, such as ABC ("Abstain, Be

faithful, use a Condom"). Several studies stress the need to look beyond proximal factors of high-risk behavior in HIV transmission. Auvert et al. (20), in a multicenter study, conclude that the differences in efficiency of HIV transmission, as mediated by biological factors, outweigh differences in sexual behavior in explaining the variation in rate of spread of HIV between four cities in Kenya, Zambia, Cameroon, and Benin. Stillwaggon (21), in her pioneering work, found falling calorie and protein consumption and increasing inequality to be strongly correlated with HIV prevalence in 44 sub-Saharan African countries.

Nutrition and immunity in HIV-positive individuals can interact in two ways. First, HIV-induced immune impairment and the heightened risk of subsequent infection that can worsen nutritional status. HIV infection can also lead to nutritional deficiencies through decreased food intake and malabsorption and increased utilization and excretion of nutrients, which in turn hasten the onset of AIDS. Nutritional status modulates the immunological response to HIV infection, affecting the overall clinical outcome. Teasing out the most important pathways is challenging because these relations are deeply intertwined, with many confounders. (13)

Malnutrition weakens the immune system, increasing the risk of ill-health, which in turn can aggravate malnutrition. It is a vicious cycle. Around half of all global preschool child deaths are attributable to the negative synergy of malnutrition and infectious disease, with a majority of deaths complicated by mild to moderate undernutrition (22). Both general (protein and energy) and micronutrient deficiencies are associated with significant defects in cell mediated and humoral immunity, depressed cytokine production, lowered specific antibody production, and decreased phagocyte function (23). Infections are thus longer-lasting and more severe in someone who is malnourished. They may also be more frequent.

Though few studies have investigated whether malnutrition increases the efficacy of horizontal disease transmission between adults, there is some suggestive evidence. In a 24-month nested case-control study of sexually active women in Rwanda, controlling for socioeconomic status, pregnancy, and genetic ulcer disease, weight loss in the first six

months of the study was a significant predictor of eventual seroconversion (24). Malnutrition, particularly vitamin A deficiency, is also associated with an increased risk of STDs, including genital ulcers and cervical herpes simplex virus (HSV) shedding (25), which in turn has been found to increase the risk of HIV transmission. In contrast, in a study among HIV-negative Kenyan men, lower plasma vitamin A levels were associated with a decreased risk of HIV seroconversion (26).

General (protein-energy) malnutrition is associated with adverse clinical outcomes in people living with HIV in both the developed and the developing world. The relation between depletion of body cell mass and survival in adults with AIDS was first observed by Kotler et al. (27), who hypothesized that the degree of malnutrition affected the clinical course and survival of these patients. Suttmann et al. (28) showed that loss of body cell mass independently predicted death. In a U.S. study, weight loss of 5 percent over a period of four months was found to be associated with an increased risk of death and opportunistic infections. (29) In Malawi, a study of people with tuberculosis (80 percent of them HIV-positive) found that a body-mass index (BMI) of less than 17 increased the risk of early death. (30) Losses in weight, fat-free mass, body cell mass, and fat mass were all significant predictors of mortality among HIV-positive persons with wasting syndrome in the Tufts Nutrition for Healthy Living Study in Boston (31). Among HIV-positive Ugandan children, death before the age of 25 months was nearly five times more likely to occur among those with weight-for-age *z*-scores less than –1.5 than among those with higher *z*-scores (32). There are thus convincing data showing a predictive link between malnutrition and adverse clinical outcomes, including death, in people living with HIV. Micronutrient malnutrition, prevalent in many developing countries, may also contribute to a weakening of immune status and thus a worsening of clinical condition among HIV-infected individuals (33).

There is substantial evidence that specific nutritional deficiencies may accelerate disease progression and hasten the onset of AIDS and death. Interactions between immune function and specific nutrient deficiencies in HIV-1 disease have been reported for trace elements (selenium and zinc) and vitamins A, E, B6, and B12. Low levels of serum vitamin E and B12 were shown to prospectively increase disease progression. Higher

intakes of vitamin B (niacin, B1, B2, and B6) and vitamin C were associated with slower progression to AIDS. Selenium deficiency has been demonstrated to be a significant predictor of HIV-related mortality independent of CD4 cell count over time. (34)

No consistent relationship has been shown, however, between vitamin A and zinc deficiencies and HIV/AIDS. Vitamin A deficiency was an independent predictor of mortality among HIV-positive intravenous drug users (35). In a study among HIV-negative Kenyan men, lower plasma vitamin A levels were associated with a decreased risk of HIV seroconversion (26). These investigators also reported dietary zinc intake to increase the rate of disease progression and mortality. In contrast, those who progressed to AIDS in the study had significantly lower serum zinc levels than nonprogressors and HIV-negative subjects.

Reducing food consumption quantity or quality may be a highly erosive "coping" strategy, as nutrient requirements rise following HIV infection. In Côte d'Ivoire, Bechu (36) surveyed 107 households with at least one adult ill with AIDS and with one or more children and interviewed them six times at two-month intervals. These data were compared with the results of a study conducted in Yopougon in May 1992 and based on a sample of 2,064 households. The study found per caput consumption of AIDS-afflicted households to be half that of other households. And in a cross-sectional survey of 119 households in the Rungwe district of Tanzania, found that households that experienced an AIDS death spent substantially less on food than other households. HIV/AIDS related death significantly increased the probability of a household falling below the poverty line. (37)

Analyzing data from emergency food security assessments conducted in Malawi and Zambia (in August and December 2002) and Zimbabwe (in August 2002), a recent study suggests that the impacts of HIV/AIDS on food security during the 2002 food emergency were strong, negative, and complex, demanding a rethinking of future responses (38). Households affected by adult morbidity and mortality and with a high demographic load were significantly more vulnerable to food-security shocks than other households were. They suffered from marked reductions in agricultural production and income, leading to

earlier engagement in distress coping strategies, and, ultimately, a decline in food security. AIDS-affected households will take longer to recover from food crises and in fact may never recover completely. The analysis further demonstrates that different morbidity, mortality, and demographic profiles have different effects on food-security processes and outcomes, with implications for early warning systems.

HIV and resulting opportunistic infections can lead to deterioration in nutritional status by increasing the need for nutrients and energy and by reducing appetite and absorption of nutrients. The effects of HIV on a person's nutritional status can occur early in the course of the disease even when symptoms of the disease are not yet present. Unless the cycle is broken the overall effect is a spiraling deterioration of immune function and clinical status that contributes directly to repeated morbidity and the eventual early death of the infected individual. (12,18,39)

Evidence shows that some nutritional deficiencies can be reversed by timely and adequate nutritional therapy. Nutritional care and support for PLWHA can help manage HIV-related complications, promote response to medical treatment, improve adherence to medication, delay disease progression, and increase the patient's quality of life by maintaining strength, comfort, level of functioning and dignity. (1,13,18,39,40)

Adherence to ART

Adherence to ART is an important determinant of both the degree and duration of virologic suppression. In addition, numerous studies have found an association between poor adherence and virologic failure. In several studies, non-adherence in patients on HAART was the strongest predictor of failure to achieve viral suppression below the level of detection. (3,6,7,8,9,41)

There is substantial evidence documented elsewhere on predictors of poor adherence to ART principally from small-scale studies conducted in different countries. These include poor clinician -patient relationship, drug and alcohol use, active mental illness, lack of information, lack of reliable access to ART, side effects, stigma, cost of ART, travel/migration, domestic violence and discrimination. (2,3,7,9,16,17) However the

impact of food and nutrition security on adherence to ART and ART outcomes is not sufficiently explored. In fact, antiretroviral drugs for the treatment of HIV/AIDS can interact with food and nutrients. They often have to be taken with food to mitigate the side effects such as nausea, vomiting, diarrhea and loss of appetite on the use and utilization of food and adherence to drug regimen. (4,10)

Estimates of average rates of nonadherence with ARV therapy range from 50% to 70% in many different social and cultural settings, and the risks associated with nonadherence are extensive at both individual and societal levels. Multiple drug resistance, rapid progression to AIDS and death can happen in PLWHA on ARV therapy with nonadherence. (3,7,9) A study conducted in Addis Ababa on 431 PLWHA on ART found that 81.2% of patients were ≥95% adherent by self report in the week before the assessment. Being too busy or simply forgot (33.9%) and being away from home (27.5%) were the major reasons for non-adherence. (16) Another study conducted in Botswana enrolling 109 PLWHA on ART found that 54% of patients were adherent by self report, while 56% were adherent by provider assessment. (8) In this study the principal barriers to adherence included financial constraints (44%), stigma (15%), travel/migration (10%), and side effects (9%). In a cross-sectional study among PLWHA on ART at an outpatient clinic in San Jose, Costa Rica it was found that eighty-five percent of patients took 100% of their medications in the last 3 days. (42) Factors that were correlated with nonadherence in this study included difficulty in finding transportation to the clinic, not laying pills out as a management skill, and prescription instructions to take medication on an empty stomach.

ART outcomes

Treatment of HIV-infected patients with antiretroviral therapy (ART) leads to immune reconstitution as shown by increases in CD4 lymphocyte count decreased risk of opportunistic infections and improved survival. (43,44,45,46) A retrospective cohort study of patients attending the national HIV referral center in Singapore found a median increase in CD4 count of 64 (IQR 23-115). (47) Another study in US using marginal structural model to estimate the effect of ART initiation on CD4 cell count showed a weighted estimate of difference in the mean CD4 count at 1 year among participants

continuously treated versus those never treated to be 95cells/mm3. (48) Several reports have described reductions in mortality and in the rate of hospitalization of HIV infected patients after they initiate ART. (49)

Indicators to assess food and nutrition security

The full range of food insecurity and hunger cannot be captured by any single indicator. Instead, a household's level of food insecurity or hunger must be determined by obtaining information on a variety of specific conditions, experiences, and behaviors that serve as indicators of the varying degrees of severity of the condition. Household surveys are used to get this information. (50)

The 18-item core module developed by USDA for the main purpose of assessing the prevalence of food insecurity/hunger at each of its several measurable levels of severity among households, has been shown to be a stable, robust, and reliable measurement tool and can be used in developing countries to easily capture the food security situation of households. (50,51) However, there are a number of issues regarding the potential portability of the US approach to measure household food security in developing countries. One is that food security may be defined differently in developing countries than in the United States, where it is typically much less severe and is a social as well as a biological matter. Another is that experientially based measure should be used to complement rather than replace indirect, since these often describe reasons for food insecurity and increase the use and value of regularly collected statistics. The questions focus on whether the household has enough food or money to meet its basic food needs and on the normal behavioral and subjective responses to that condition, as these have been observed. Other elements of the broad, conceptual definition of food security, such as food safety, nutritional quality of diets, and "social acceptability" of food sources--including the unusual and sometimes ingenious coping behaviors that food-insecure households may undertake to augment their food supply, are not measured by the food security scale. (50)

Meal frequency - the number of daily eating occasions is a proxy indicator for gauging the adequacy of household macronutrients (calories and protein) intake. An advantage in

selecting this as an indicator of household food security is that data are relatively easy and inexpensive to collect. Data on size and composition of meals are not required to calculate the indicator values. (52)

Dietary diversity - the number of different foods and food groups consumed in a household provides a measure of the quality of the diet by reflecting dietary diversity, thus serving as an important complement to the eating occasion indicator. To accurately capture dietary diversity, this indicator should be evaluated in terms of the variety of food groups (meats, milk, fruits, and vegetables) consumed, rather than by simply totaling all types of foods consumed. Increases in dietary diversity are associated with increase in consumption, caloric availability and calories from staples and non-staples. Hence, dietary diversity is a promising proxy indicator of household food security. (52,53,54) The disadvantage of this measure is that the simple form of this measure does not record quantities. (55)

Anthropometric indices - Because anthropometric indices represent the cumulative effect of access to food, health, education and environmental health conditions, the nutritional status is a powerful indicator of nutrition security and well being of an individual and reflects the nutritional and poverty situation of a household. (11,56) Body mass index (BMI), the most commonly used indicator to measure nutritional status in adults and adolescents, is calculated from weight and height measurements using the formula BMI = weight (in kg) divided by height (in m^2) is good indicator of protein and fat reserves, which in turn reflect the functional reserves including the ability to survive nutritional deficit and some diseases. (11,57)

Measuring adherence to ART

The measurement of adherence is imperfect and lacking a gold standard. Clinical estimation of a patient's likelihood of adherence is a poor predictor. Each of several aids to measure adherence, such as pill counts, pharmacy records, smart pill bottles with computer chips recording each opening (i.e. Medication Event Monitoring systems or "MEMSCaps"), and other devices may be of use, though each requires comparison to patient self-reports. In some studies, clinician and patient estimates of the degree of

adherence have been found to exceed measures based on MEMSCaps. Due to its complexity and cost, MEMSCaps technology is best used as an adjunct to adherence research, but is not useful in most clinical settings. (3,6,15,58)

Patient self-report is weakly predictive of the likelihood of adherence; however, an estimate of poor adherence by a patient has a strong predictive value and is closely associated with viral load and should be regarded seriously. (3,59,60,61) Self-report should include a short-term assessment of each dose that was taken over the recent past (the past 1 day, the past 3 days and the past 7 days), and a general inquiry regarding adherence since the last visit with explicit attention to the circumstances of missed doses and possible measures to prevent further missed doses. (3,6,7) In face-to-face interview, questioning about the number of doses missed during the past 7 days can be translated quantitatively into a percentage adherence. However, shorter periods are insufficient to determine whether adherence of >95% is likely. (58) It may be helpful for patients to bring their medications and medication diary to clinic visits. (6)

To measure adherence to ART a structured questionnaire, the Patient Medication Adherence Questionnaire (PMAQ), has been devised. (62) A number of modifications to the PMAQ have been suggested to increase its usefulness. (63) Another tool, Adult AIDS Clinical Trial Group (AACTG) Adherence Instrument, is also developed and tested and used to assess the adherence to ART of PLWHA in developing countries. (7,15)

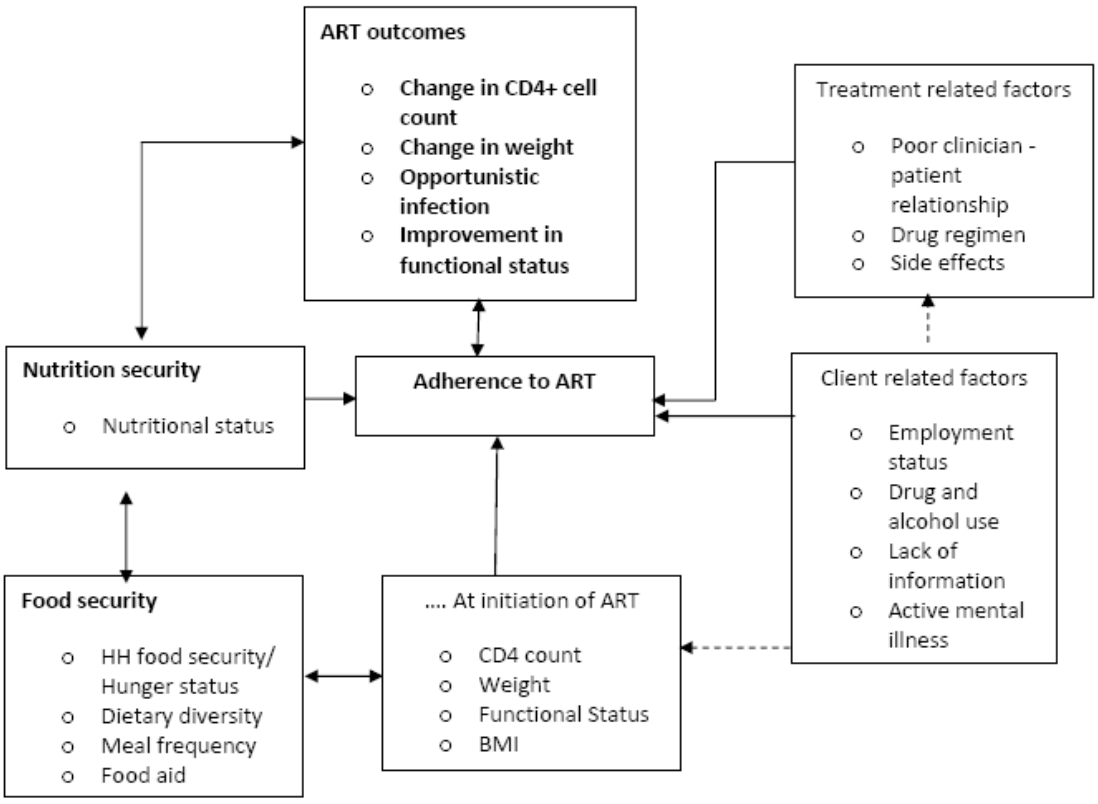

Figure – 1 Conceptual Framework of Impact of Household Food and Nutrition Security on Adherence to ART and treatment outcomes

3. RATIONALE OF THE STUDY

The rate of nonadherence to ART is very high among PLWHA on ART in different settings and remains to be the key challenge of ART programs in many countries of the world. In Ethiopia, although not well documented, some pocket studies conducted in different health institutions depict that the rate of nonadherence to ART is high among PLWHA on ART. Various predictors of nonadherence to ART were studied but the household food and nutrition security as predictor of nonadherence has not been addressed well. Scientific evidence is needed to uncover and support possible associations between household food and nutrition security and adherence to ART and other treatment outcomes. The study on the impact of household food and nutrition security on adherence to ART and treatment outcomes can serve as a significant contribution to answer this question.

Further, understanding the impact of household food and nutrition security on adherence to ART and treatment outcomes in a population where poverty and food insecurity are cross cutting problems could help to rethink on our ART program and mobilize resources to integrate programs like safety net in HIV/AIDS prevention and control effort.

The study can also help to support the consistency of research findings on the predictors of adherence to ART evidenced locally in other areas and elsewhere in the world. Additional significance which can be gained by conducting this study is knowledge of the adherence rate to ART, treatment outcomes and the household food and nutrition security of PLWHA on ART which enable to lay the base for other similar studies that may be conducted in the future.

4. OBJECTIVES

4.1 General Objective:

To assess the impact of household food and nutrition security on adherence to ART and treatment outcomes among adult PLWHA on ART

4.2 Specific objectives:

1. To assess the food and nutrition security status of households with adult PLWHA on ART
2. To determine adherence to ART among adult PLWHA on ART
3. To assess treatment outcomes of ART among adult PLWHA on ART
4. To determine the effect of household food and nutrition security on adherence to ART and treatment outcomes

5. METHODS

5.1 Study area

The present study is conducted at Dire Dawa Provisional Administration. Dire Dawa Provisional Administration is located 515 km east of Addis Ababa with a total area of 1288.02 km^2. The area is dominated by dry, windy and hot climatic condition. According to the projections made based on the 1994 Census and the 2000 Demographic and Health Survey the total population of the Provisional Administration is 383,529 of which 283,773 (74%) live in urban city and 99,756 (26%) live in the rural areas. (63,64)

Dire Dawa Provisional Administration is among the areas with better health service coverage in the country. Close to 83.5% of the people of the area are within 10km of the 3 hospitals, the 6 health centers or the 22 health posts that are found in the Provisional Administration. In the Administration there are 6 VCT centers (4 governmental and 2 non-governmental), 2 PMTCT centers and 1 hospital, Dil Chora Hospital, with ART unit. At the time of the survey, according to the ART unit record, more than 1,300 PLWHA were enrolled in ART program in the ART unit from an estimated total of 3,306 PLWHA in need of ART.

Although the food and nutrition security conditions of PLWHA on ART is not assessed in the Provisional administration according to the 2006 humanitarian appeal for Ethiopia by DPPA a total of 31,160 people are in need of emergency food assistance only in 2006 in the Provisional Administration (65).

5.2 Study design

A cross-sectional institution based study design is used to conduct the present study. Use of population (community) based study would clearly figure out the adherence status and treatment outcomes of PLWHA on ART but for logistic and time factors it was not possible to trace the study participants and interview them from within the general community. To obtain sufficient power for internal comparison the sample size of the

present study was calculated by cross-sectional comparative design which later was combined.

5.3 Study population

The study population of this research was all adult PLWHA on ART in Dire Dawa Provisional Administration at Dil Chora Hospital ART unit.

5.4 Sampling unit

All PLWHA above 18 years of age and who have been on ART for at least 3 moths in Dire Dawa Provisional Administration at Dil Chora Hospital ART unit

5.5 Inclusion and exclusion criteria

Eligible PLWHA on ART were those above 18 years of age and who have been treated with ART for at least 3 moths. They were excluded from participation in the study if they were less than 18 years of age, have been on ART for less than 3 moths, pregnant and refused to participate in the study.

5.6 Study unit

Randomly selected PLWHA above 18 years of age and who have been on ART for at least 3 moths in Dire Dawa Provisional Administration at Dil Chora Hospital ART unit.

5.7 Sample size

To determine the sample size for the quantitative part of the cross-sectional survey the following assumptions were taken into account. Because the impact of household food and nutrition security on adherence to ART and ART outcomes (or proportion) in the area is not known 18% prevalence of non-adherence among PLWHA on ART was taken from a local study in Addis Ababa (14) to calculate the size of the study population in the two groups. The calculation of the sample size in the two groups was with the assumption of detecting 12% variation in non-adherence to ART of PLWHA in food and nutrition insecure households compared to the non-adherence in food and nutrition secure households. Hence, 18% of non-adherence to ART was assumed among PLWHA on

ART within food and nutrition secure households and 30% non-adherence among PLWHA on ART within food and nutrition insecure households.

Using the formula (66)

$$n_1 = \frac{\{u\sqrt{[Л_1(1-Л_1) + Л_2(1-Л_2)]} + v\sqrt{[2Л(1-Л)]}\}^2}{(Л_2-Л_1)^2}$$

Where n_1 = Food and nutrition secured households with adult PLWHA on ART

n_2 = Non- Food and nutrition secured households with adult PLWHA on ART

$Л_1$ = prevalence of non-adherence among adult PLWHA on ART within households with food and nutrition security =0.18

$Л_2$ = prevalence of non-adherence among adult PLWHA on ART within households with food and nutrition insecurity =0.30

v =Value of the standard normal distribution curve corresponding to level of significance α 0.05 = 1.96

Power = u =Value of the standard normal distribution curve corresponding to power of 90% = 1.28

$$Л \text{ (average proportion)} = \frac{Л_1 + Л_2}{2} = \frac{0.18 + 0.30}{2} = 0.24$$

Considering 10% non-response rate: n= 214 x 2= 428 x 10% non-response rate N=472 (n_1= 236, n_2= 236).

The assumption behind calculating the sample size using a comparative study design was to have sufficient power in order to compare the primary outcome variable (Adherence to ART) between households (with PLWHA on ART) with food and nutrition security and without food and nutrition security.

5.8 Variables

Table – 1 Dependent, independent and background variables of the present study

No	Factors	Variables	Indicators	Method of assessment
1		***Dependent variable***		
	Adherence to ART	Level of adherence	Adherence rate	Questionnaire
	ART outcomes	Change in CD4+ cell count,	CD4+ count at initiation of ART & Current	Record review Questionnaire
		Change in weight	Weight at initiation of ART & Current	
		Opportunistic infection	Frequency of opportunistic infection	
		Change in functional status	Bed ridden, ambulatory, working ART client	
2		***Independent variables***		
	Household food security	HH food security/Hunger status	Availability of food/money, behavioral & subjective responses	Questionnaire
		Dietary diversity	Number of different foods/food groups consumed by HH members	
		Meal frequency	Number of daily eating occasions by HH members	
		Food aid	Type and size of food received	
	Nutrition security	Nutritional status	Body mass index (BMI)	Anthropometry
		Opportunistic infection	Frequency of opportunistic infection	Questionnaire
3		***Background variables***		
	Socio-demographic factors	Age, sex, marital status, employment status, Level of education, housing condition, religion, ethnicity, disclosure	*Reported* date of birth, sex, marital status, employment status, completed level of education, religion, ethnicity, disclosure status	Questionnaire
4	**Adherence related factors**	***Confounding variables***		
		CD4+ cell count, body weight at initiation of ART, functional status at the initiation of ART, ART duration	CD4+ cell count, body weight at initiation of ART, r*eported* functional status at the initiation of ART, duration on ART	Questionnaire

8.9 Sampling procedures

At the time of this study there was a single public Hospital providing ART for all PLWHA in need in Dire Dawa. To recruit study participants for the present study the unique ID ART number of the PLWHA on ART is used to randomly select every other PLWHA on ART who is eligible to participate in the study by systematic random sampling technique.

8.10 Data collection instrument

A pre-tested structured questionnaire was used to assess the household food security status of PLWHA on ART. It consisted of 18 questions in the core module to assess food security and questions to assess dietary diversity and meal frequency situation of households. The optional first question was used as part of the first-stage screener in the core module proper, and/or for its additional information content. It and its follow-ups were not used in forming the food security scale. The core module proper (Q2-Q16, plus three skip-pattern follow-up questions) provides the smallest set of indicators that will allow implementation of the full range of the food security scale. The instrument also contains questions related to background variables, adherence to ART and treatment outcomes.

8.11 Data collection procedures

Six high-school graduate data collectors and 1 health officer supervisor were trained for 3 days with the objective of standardizing the date collection instrument among the data collectors and providing them with basic skill of communicating with the study participants and taking height and weight measurement of the study participants. Before the actual data collection pursued a pre-test of the instrument and the procedure was conducted and corrective measures were taken.

A structured pre-tested questionnaire was used to collect data on the variables through face-to-face interviews in Dil Chora Hospital from 5 January 2007 to 22 February 2007. The language of questionnaire was translated from English into Local language (Amharic) and translated back to English to keep for the consistency of the translation.

To assess the nutritional status of PLWHA on ART measuring instruments including weighing scale and height measuring board were used.

A total of 4 focus group discussions, two for each sex group and 5 in-depth interviews were conducted with the key informants from 12 April 2007 to 23 May 2007. Each FGD consisted of 6-12 participants recruited considering criteria including their willingness to participate in the discussion, their sex, their duration on ART and their participation in the quantitative study. Open ended focus group discussion guide and in-depth interview guide were prepared to probe discussions and interviews. Discussion points including food and nutrition security, adherence to ART and treatments outcomes were raised and members of the focus group discussion and in-depth interview key informants reflected their views and concern. Rough notes were taken during the discussions and in-depth interviews. In addition, all sessions of the discussions and interviews were tape-recorded.

8.13 Data quality assurance

To ensure data quality a pre-tested standard questionnaire and height and weight measuring instruments were used. Training was given for the data collectors and supervision and on spot checking of the data collection procedure was made. Every day, at the end of the data collection discussion was made with the data collectors and problems encountered were discussed and timely solutions were worked out from experiences. The completeness of the questionnaire was checked before data entry. Data capturing format with highly controlled skipping pattern and missing values was prepared by computer programmer using Microsoft Access Program and data cleaning was made after data were entered into the computer. Because food consumption pattern is affected by seasonal factors including fasting for religious reasons both the regular and main fasting among Orthodox Christians were given due attention during data collection. In the regular fasting those Orthodox Christian respondents that were interviewed on Thursday and Saturday were asked about their fasting status and if reported yes were asked about their dietary history in the day before the fasting day instead of the immediate day before the interview date. For the main fasting in which 13.8% of the data were collected they were asked for their fasting status. The fact that they were counseled about nutrition in the ART unit made fasting uncommon among the Orthodox Christian study participants.

8.14 Data Analysis procedures

Data collected through a structured self-administered questionnaire were entered into a specially prepared data capturing software using Microsoft Access Program and transported into and analyzed by SPSS version 13. In this research, the primary outcome variable is adherence to ART and any skipping of doses in the previous day, in the previous three days, in the previous seven days and in the previous year was assessed and the last was used for comparison.

To measure food security status of households number of affirmative answers given by study participants to the 18 questions in the core module were added and depending on the presence of children in the households (in the absence of children maximum possible affirmative answer would be 10 because 8 questions were not applicable in households without children) the households were classified as food secure (0-2 affirmative answers), food insecure without hunger (3-7 affirmative answers in households with children and 3-5 in households without children), food insecure with moderate hunger (8-12 affirmative answers in households with children and 6-8 in households without children) and food insecure with severe hunger (13-18 affirmative answers in households with children and 9-10 in households without children). The first and the last two categories were combined throughout the analysis with the assumption that hunger is important in population where food insecurity is a common phenomenon as in the participants of this study. Seven meal occasions and 12 food groups were asked to assess the food frequency and dietary diversity situation of households and those households with more than the median score of the meal frequency and dietary diversity scores were classified as high meal frequency and high dietary diversity households.

Analysis of variables was made using descriptive statistics (basic summaries of the client characteristics), univariate binary logistic analysis to look into the association between household food and nutrition security and adherence to ART & treatment outcomes and multivariate logistic regression analysis to adjust values of the dependent variables for the influence of the likelihood of the confounding or intervening variables. Chi-square test,

paired t-test & correlation regression analysis and their p-value < 0.05 at 95% CI is used to define statistical associations between variables. Odds Ratios (OR) and their 95% CI are used to look into the association between the dependent and independent variables.

6. ETHICAL CONSIDERATIONS

To conduct this research project ethical approval was secured from Addis Ababa University, Faculty Research and Publication Committee (FRPC) permission from Dire Dawa Health Bureau and Dil Chora Hospital was obtained. In addition, letter of support from Tesfa Bisrat Misikir Association (TBMA – An association of PLWHA in Dire Dawa Provisional Administration that works on the rights and well-being of member PLWHA) was taken before commencing the data collection process.

During data collection process the data collectors informed each study participant about the purpose and anticipated benefits of the research project and the study participants were also informed on their full right to refuse, withdraw or completely reject part or all of their part in the study and they were assured that their treatment and other benefits they gain from the hospital and/or other organizations will not be influenced by their participation in the study. Finally, they were asked for their informed written consent to participate or not to participate in the study and for their willingness on use of their files and records for the study. Interviews and measurements were conducted in a quite, ventilated, lighted room to respect the study participants' anonymity and boost their confidence on the study.

During the interview and measurements study participants were provided with general information by interviewers on the means of improving their household food and nutrition security status and on the mechanisms to promote their health and maximize their adherence to ART.

7. OPERATIONAL DEFINITIONS

Household food security – the ability of household members to have the type of food they need at the time they need it sufficiently to meet their dietary needs and food preferences for an active and healthy life. It is assessed by asking whether the household has enough food or money to meet its basic food needs and on the normal behavioral and subjective responses to that condition, as these have been observed.

Nutrition security – adequate nutritional status in terms of protein, energy, vitamins, and minerals for all household members at all times throughout the year. In this study, it is assessed through anthropometric measurement (BMI).

Adherence – ART clients are considered adherent when they stick to (take) medication prescribed (ART drugs) for greater than 95% of the time which corresponds to missing no more than 1 dose in a 10-day period (in a 2 times a day dosing regimen) or 1 dose in a 7 days (in a 3 times a day dosing regimen).

100% adherence – sticking to 100% of the prescribed ART drugs since the initiation of ART

Treatment outcomes – Important outcomes of ART in this study include improvement in general health status, CD4+ cell count change, weight change, frequency of opportunistic infections, and improvement in functional status.

Meal frequency – is the number of reported daily eating occasions by household members in a household experienced with in a day. This does not include eating occasions by the household members experienced outside home.

Dietary diversity – is the number of reported different foods and food groups consumed in a household over a 24-hour period. This does not include food group consumed by the household members outside home.

8. RESULT

8.1 Quantitative result

8.1.1 Socio-demographic characteristics of study participants

A total of 472 PLWHA on ART were approached and 442 consented to participate in the present study giving a response rate of 93.6% of which 170 (38.5%) were males and 272 (61.5%) were females on ART for at least three months prior to the survey. The mean age of the study participants was 35.1 ± 9.7 years with 63.3% of them belonging to the age group 30 – 49 years.

Of the 442 interviews 61 (13.8%) were conducted during the Orthodox Christians main fast season of which 9 (2%) were fasting. Because we could not identify major difference in the type and frequency of food they consumed in the 24 hours preceding the survey in this group in the quick analysis we did on we included them in the analysis part.

Among the 442 study participants interviewed 29.0% were married while 25.3% were never married. The majority of the study participants belonged to Amhara Ethnic group and Orthodox Christian religion, 70.6% and 58.4%, respectively. Assessment of educational status of the study participants showed that 70.8% of them attended elementary school or higher education.

Assessment of the average monthly income that the households in which the study participants are living showed that 63.3% of the study participants had monthly income below 262 birr with the median monthly income of 150 birr. Majority of the study participants had no job at all (64.3%), live with their families (56.1%) and got food ration on a monthly basis (57.9%) from Save USA Dire Dawa Branch/WFP and some of them from OSSA Dire Dawa Branch. About 90.7% study participants claimed that they have disclosed their HIV serum status to at least one person other than their counselor/doctor (see Table 2).

Table – 2 Socio-demographic variables of study participants, Dire Dawa, Ethiopia, May 2007

Variables	*Frequency*	*Percent*	*Variables*	*Frequency*	*Percent*
Sex of study participant			**Food aid**		
Male	170	38.5	**Present**	256	57.9
Female	272	61.5	**Absent**	186	42.1
Age			**Living with**		
<30	124	28.1	**Family**	248	56.1
30 – 39	202	45.7	**Alone**	150	33.9
40 – 49	78	17.6	**Friend**	44	10.0
50+	38	8.6			
Marital status			**Working situation**		
Married	128	29.0	**Employed**	158	35.7
Unmarried	112	25.3	**Unemployed**	284	64.3
Divorced	38	8.6			
Separated	73	16.5			
Widowed	91	20.6			
Education			**Monthly income (Birr)**		
Illiterate	86	19.5	**≤ 105**	56	12.7
Read & write	43	9.7	**106 - 150**	66	14.9
Elementary	201	45.5	**151 - 262**	158	35.7
High school+	112	25.3	**≥ 263**	71	16.1
			DNK/R	91	20.6
Religion			**Ethnicity**		
Orthodox	312	70.6	**Amhara**	258	58.4
Catholic	6	1.4	**Oromo**	114	25.8
Protestants	34	7.7	**Guraghe**	31	7.0
Muslim	90	20.4	**Tigre**	20	4.5
			Somali	7	1.6
			Others	12	2.7

DNK/R – Do not know/ refused

8.1.2 Clinical condition before and after initiation of ART

Close to 80% of the study participants were on ART for a year or less with a median ART duration of 8 months. About 32.6% of respondents were bed-ridden before they started ART and 0.5% of them were bed-ridden at the time of interview. Morbidity report of the study participants indicated that 17.9% and 54.1% of the study participants had self reported diarrhea and lung diseases, respectively. Up on review of PLWHA record 95% of the 420 PLWHA on ART with pre-ART CD4 record started the treatment with CD4 count of less than or equal to 250 with a median CD4 count of 139 and after 6 months of ART, 57.2% of the 187 PLWHA with CD4 record had counts above 250 with a median count of 249.

8.1.3 Food & nutrition security

The study also sought food security situation of households of PLWHA and it was found that 72.4% of the households were food insecure with moderate or severe hunger and majority of them (any member of the households they are living in) eat less than the mean meal frequency (63.6%) and less than the mean dietary diversity (47.1%) in the preceding 24 hours of the survey. Assessment of nutritional status of study participants indicated that 35.3% of them started the treatment with moderate to severe malnutrition and 20.6% with mild malnutrition with mean BMI of 18.2±3.1 kg/m2, and after 3 months of ART 4.8% of them had moderate to severe malnutrition with a mean BMI of 19.6±3.1 kg/m2. The observed nutritional status showed that 15.8% had mild malnutrition and 14.3% of the PLWHA had moderate to severe malnutrition (see Table 3).

Table – 3 Clinical, food and nutrition security situation of study participants, Dire Dawa, Ethiopia, May 2007.

Variables	***N (%)***	
Treatment duration (months)		
3-6	166 (37.6)	
7-12	184 (41.6)	
13+	92 (20.9)	
Food security situation		
Secure	45 (10.2)	
Insecure without hunger	77 (17.4)	
Insecure with moderate huger	203 (45.9)	
Insecure with severe hunger	117 (26.5)	
Meal frequency		
High	161 (36.4)	
Low	281 (63.6)	
Dietary diversity		
Low	208 (47.1)	
High	234 (52.9)	
Current BMI of PLWHA on ART		
>25	39 (8.8)	
18.5 – 25	270 (61.1)	
17 – 18.4	70 (15.8)	
<17	63 (14.3)	
	Before ART	***After ART****
Functional status	**N (%)**	**N (%)**
Working	124 (28.1)	340 (76.9)
Ambulatory	174 (39.4)	100 (22.6)
Bed ridden	144 (32.6)	2 (0.5)
CD4 count	**Median (IQR)**	**Median (IQR)**
	139 (84, 200)	249 (183, 345)
BMI	**Mean ±SD**	**Mean ±SD**
	18.22±3.08	19.57±3.13

**After ART = after 3 months of ART for BMI, after 6 months of ART for CD4 count and after total treatment duration for functional status*

Study participants were asked about their self description of the food consumed in the past twelve months. Of the total interviewed 43.2% and 40.5% described the food consumed in their household in the last twelve months of the survey as some times not enough and often not enough respectively (Figure 2).

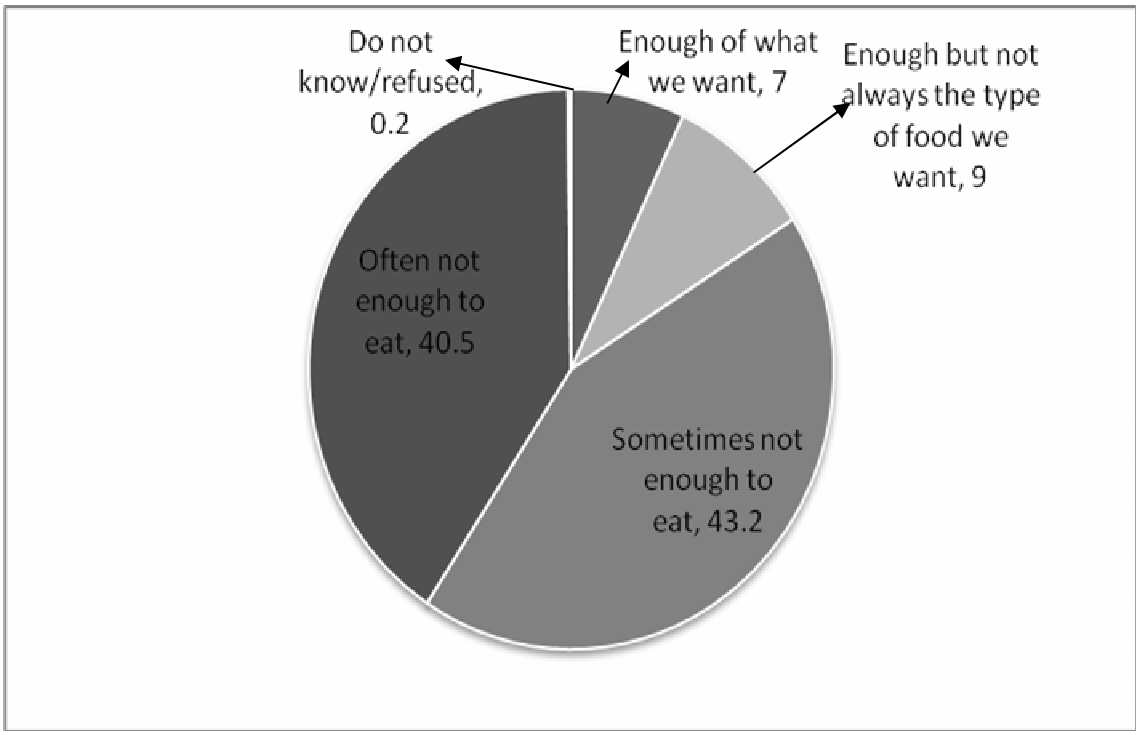

Figure – 2 Self description of the food consumed in the households of PLWHA on ART in the 12 months preceding the survey, Dire Dawa, Ethiopia, June 2007

The study also assessed dietary diversity score of PLWHA on ART which was measured by the total number of food groups that PLWHA on ART (any member of the household in which the PLWHA on ART live) consumed during 24 hour period preceding the survey. The finding showed that close to 90% of the study participants consumed five or more food groups in the preceding 24 hours with median food group consumption of 7.

The food types frequently consumed during 24 hours preceding the survey by the study participants were cereals (99.3%), oil/fats (96.4%) and condiments/coffee/tea (88%). Fish/sea foods (2.7%) and eggs (21.7%) were least consumed food groups by members of PLWHA households (Table 4).

Table – 4 Food groups consumed in the 24 hours preceding the survey in the households of PLWHA on ART, Dire Dawa, Ethiopia, June 2007

Food groups consumed	*Frequency**	*Percent*
Cereals	439	99.3
Oil/fats	426	96.4
Miscellaneous	389	88.0
Honey/sugar	387	87.6
Pulses/legumes	344	77.8
Roots/tubers	264	59.7
Fruits	181	41.0
Vegetables	150	33.9
Meat	140	31.7
Milk/milk product	135	30.5
Eggs	96	21.7
Fish/sea food	12	2.7

Multiple food groups possible

Analysis of the frequency of meals consumed in the preceding 24 hours of the survey in the households of PLWHA showed that 3% of the households of PLWHA consumed 1 – 2 times, 60.8% 3 times and 36.4% 4 – 7 times in the preceding 24 hours.

8.1.4 Nutrition security situation

The nutrition security of PLWHA on ART as measured by the BMI of the study participants was significantly affected by sex, functional status before ART, reported diarrhea, treatment duration and nutritional status before ART. Females had better BMI than their male counterparts ($p<0.05$). Those PLWHA who were ambulatory and working before they initiate ART had poor current nutritional status compared to bed-ridden PLWHA at the initiation of ART (<0.05). Those PLWHA who were complaining diarrhea had poor current nutritional status compared to those without diarrhea ($p<0.05$). PLWHA 100% adherent to ART had poor nutritional status compared to those who were not adherent ($p<0.05$). The analysis also found that a month increase in ART duration was associated with 0.057 kg/m2 increase in BMI ($p<0.05$). It was also found that for a kg/m2 increase in BMI before ART the current BMI increased by 0.772 kg/m2 ($p<0.001$) (Table 5).

Table 5: Determinants of current nutritional status of PLWHA on ART, multiple linear regression, Dire Dawa, Ethiopia, June 2007

Variables	*β- coefficient*	*p-value (2-tailed)*
Being female	0.786	0.001*
Being employed	0.152	0.553
Disclosing sero-status	0.177	0.649
Receiving food ration	-0.148	0.550
Functional status before ART		
(Bed-ridden, Ambulatory, Working)	-0.425	0.006*
Diarrhea	-0.849	0.007*
Lung disease	-0.154	0.515
100% Adherence to ART	-0.264	0.042*
Age	0.015	0.238
Duration of ART	0.057	0.002*
CD4 before ART	-0.001	0.238
BMI at the initiation of ART	0.772	0.000**
Dietary diversity score	0.055	0.386
Meal frequency score	0.150	0.348
Food Security Score	0.022	0.416

* Significant correlation ** highly significant correlation

8.1.5 Adherence to ART

Out of the total PLWHA interviewed 96.6% of them reported having complied to ≥95% of their drugs prescribed in the past 7 days. The assessment of 100% adherence to the ART pills prescribed indicated that 13.6% of the PLWHA on ART have missed a dose or more in the last 12 months. Among those who have ever missed a dose or more in the past 12 months 61.7% ascribed lack of food to take with medicines as their reason for missing pills followed by forgetting to take pills (36.7%) and running out of pills to take (20.0%) (Table 6).

Table – 6 Reported reasons of missing ART pills among study participants, Dire Dawa, Ethiopia, May 2007

	Reasons for missing pills(N=60)	*Frequency*†	*Percent**
1	**No food to take with medication**	37	61.7
2	**Simply forgot**	22	36.7
3	**Run out of pills**	12	20.0
4	**Away from home**	6	10.0
5	**Busy with other things**	6	10.0
6	**Had a change in daily routine**	6	10.0
7	**Had problems taking pills at specified times**	6	10.0
8	**Slept through dose time**	4	6.7
9	**Had alcohol at specified times**	4	6.7

†Reasons with ≤3 frequency not displayed
*Multiple answers possible

Analysis done to look for factors contributing for adherence to ART of PLWHA showed that sex of the study participants was significantly associated with their adherence to ART. Females adhere more than males (OR 2.85, 95% CI 1.19-6.87). Apparently, living with family or friend was related with adhering better to the ART pills prescribed than living alone (OR 1.86, 95% CI 1.13-3.68) but the association disappeared when adjusted for other variables.

The food and nutrition security indicators analysis against 100% adherence status of PLWHA on ART showed that there was no statistically significant association between food security, meal frequency or dietary diversity of households and 100% adherence status of PLWHA on ART living in the respective households. BMI score of PLWHA on ART was also found to have no statistically significant association with 100% adherence status of PLWHA on ART (data not shown).

8.1.6 Treatment outcomes of ART

8.1.6.1 Change in functional status of PLWHA on ART

Multiple logistic regression analysis was made to control for any potential confounders that determine improvement in functional status. The result showed that age, occupation, food ration, dietary diversity, CD4 count and BMI at the initiation of ART were significantly associated with improvement in functional status of PLWHA on ART. Older PLWHA improved better than the younger PLWHA, ≥50 years age group improved more than three times higher than <30 years age group (OR 3.44, 95% CI 1.39-8.57). Compared to the unemployed the employed PLWHA on ART had poor improvement in their functional status (OR 0.59, 95% CI 0.39-0.89). However, this association disappeared when adjusted for other socio-clinical variables.

The analysis also showed that food ration was associated with improvement in functional status of PLWHA on ART. PLWHA who were not receiving any food aid had poor improvement in their functional status than those who received food aid (OR 1.89, 95% CI 1.20-2.97). Similarly those PLWHA in higher dietary diversity score households had

better improvement in functional status compared to PLWHA in low dietary diversity score households (OR 2.19, 95% CI 1.42-3.39). Even though, living in food secure and with high meal frequency score households was associated with better improvement in functional status of PLWHA on ART the association was not statistically significant. PLWHA with BMI ≥18.5kg/m2 and CD4 count of 140-754 per micro liter at the initiation of ART had poor improvement in functional status (OR 0.58, 95% CI 0.35-0.96 and OR 0.57, 95% CI 0.36-0.92 respectively). Other socio-clinical variables had no significant association with improvement in functional status of PLWHA on ART (Table 7).

Table – 7 Perceived Improvement in functional status of PLWHA on ART against socio-demographic variables of the study participants, Dire Dawa, Ethiopia, May 2007

Variables	***Improvement in functional status*:**		*Crude OR (95%CI)*	*Adjusted OR (95%CI)***
	Yes (N=271)	*No (N=171)*		
Sex of study participant				
Female	171 (62.9)	101 (37.1)	1.00	1.00
Male	100 (58.8)	70 (41.2)	0.84 (0.56, 1.27)	0.79 (0.50, 1.23)
Age of the study participants				
<30	70 (56.5)	54 (43.5)	1.00	1.00
30-49	172 (61.4)	108 (38.6)	1.23 (0.78, 1.93)	1.42 (0.88, 2.30)
> or =50	29 (76.3)	9 (23.7)	2.49 (1.02, 6.20)*	3.44 (1.39, 8.57)*
Working situation				
Unemployed	187 (65.8)	97 (34.2)	1.00	1.00
Employed	84 (53.2)	74 (46.8)	0.59 (0.39, 0.89)*	0.69 (0.43, 1.09)
Living with				
Alone	95 (63.3)	55 (36.7)	1.00	1.00
Family/Friend	176 (60.3)	116 (39.7)	0.88 (0.57, 1.35)	1.03 (0.66, 1.60)
Treatment duration (Months)				
<12	211 (60.3)	139 (39.7)	1.00	1.00
≥12	60 (65.2)	32 (34.2)	1.24 (0.75, 2.05)	1.04 (0.60, 1.79)
Food aid				
Absent	98 (52.7)	88 (47.3)	1.00	1.00
Present	173 (67.6)	83 (32.4)	1.87 (1,24, 2.82)*	1.89 (1.20, 2.97)*
Food security situation				
Insecure	72 (59.0)	50 (41.0)	1.00	1.00
Secure	199 (62.2)	121 (37.8)	1.14 (0.73, 1.79)	1.06 (0.65, 1.73)
Meal frequency				
High	100 (62.1)	61 (37.9)	1.00	1.00
Low	171 (60.9)	110 (39.1)	0.95 (0.62, 1.44)	0.75 (0.47, 1.19)
Dietary diversity				
Low	114 (54.8)	94 (45.2)	1.00	1.00
High	157 (67.1)	77 (32.9)	1.68 (1.12, 2.52)*	2.19 (1.42, 3.39)*
CD4 count at initiation of ART				
No record	142 (72.8)	53 (27.2)	1.00	1.00
10 – 139	75 (65.8)	39 (34.2)	0.72 (0.42, 1.22)	1.10 (0.65, 1.85)
140 – 754	67 (53.2)	59 (46.8)	0.42 (0.26, 0.70)*	0.58 (0.35, 0.96)*
BMI at the initiation of ART				
<18.5	264 (66.4)	83 (33.6)	1.00	1.00
≥18.5	101 (54.3)	85 (45.7)	0.37 (0.25, 0.56)*	0.57 (0.36, 0.92)*
No record	6 (66.7)	3 (33.3)	0.63 (0.14, 3.25)	1.10 (0.23, 5.26)
Current BMI of study participants				
≥18.5	183 (59.2)	126 (40.8)	1.00	1.00
<18.5	88 (66.2)	45 (33.8)	1.35 (0.86, 2.11)	1.19 (0.71, 2.00)

*Significant association **Adjusted for socio-demographic variables, **:**Improvement in functional status is transferring from bed-ridded to ambulatory or from ambulatory to working functional status

8.1.6.2 Change in CD4 count and weight

The median increase in CD4 count for the total 187 PLWHA whose paired CD4 count was recorded was 116 (IQR of 82-182) in 6 months of ART. Paired t-test result showed that the CD4 increase after 6 months of ART was highly statistically significant ($p<0.001$). Weight at 3 months of PLWHA on ART had also changed significantly compared to the weight at the initiation of the treatment for the 423 PLWHA whose paired weights were identified. The median increase in weight after 3 months of ART was 3kg (IQR 1kg-6kg). The paired t-test had shown highly significant change in weight after 3 months of ART ($p<0.001$).

To examine for any relation between the change in weight and food and nutrition security variables partial correlation regression analysis was done. The pre-ART nutritional status of the study participants was significantly negatively correlated with change in weight of PLWHA ($p<0.001$). Those with higher BMI at the initiation of the treatment had less change in weight after 3 months of ART than those with lower BMI at the initiation of the treatment. On the other hand, PLWHA with high dietary diversity had better change in weight compared to those with lower dietary diversity ($p<0.05$).

It was found that meal frequency score of households of the study participants was significantly positively correlated with change in weight after 6months of ART ($p<0.05$). However, neither food security module score of households of PLWHA nor pre-ART nutritional status of PLWHA had significant correlation with change in CD4 after 6 moths of ART.

8.1.6.3 Opportunistic infections

PLWHA who stayed for shorter period on treatment had less chance of being free from diarrhea compared to those who stayed longer on the treatment. The association between shorter period treatment and diarrhea compliant was statistically significant in independent analysis (OR 0.37, 95% CI 0.16-0.84) but the statistical significance disappeared on adjustment for other socio-clinical variables. PLWHA on ART in household with low meal frequency score had high rate of reported diarrhea compliant (20.6%) compared to PLWHA on ART in households with high meal frequency score (13.0%). However this association was not statistically significant. The analysis also indicated that PLWHA on ART with BMI of ≥18.5kg/m2 had high chance of being free from diarrhea compliant (85.8%) compared to those with BMI of <18.5kg/m2 (73.7%). The association between BMI and being free from diarrhea was statistically significant (OR 2.27, 95% CI 1.20-4.30) (data not shown).

Apparently, shorter duration of stay on treatment was associated with higher chance of being free from lung disease compliant (OR 1.69, 95% CI 1.02, 2.79) but on adjustment to other socio-clinical variables this apparent association disappeared. PLWHA in the age group 30-49 years had higher chance of being free form lung disease compliant compared to those <30 years age group (OR 1.82, 95% CI 1.13, 2.89). The study also examined that PLWHA in households with high dietary diversity score had higher report of being free from lung disease (51.4%) compared to those in households with lower dietary diversity score (41.0%). The association was statistically significant in bivariate analysis (OR 1.52, 95% CI 1.03, 2.26) but disappeared when adjusted for socio-clinical variables (data not shown).

8.2 Qualitative result

Qualitative data are collected to triangulate the finding of quantitative study and to look at issues that are found deepened among the study participants and people working in the area of food, nutrition and ART. Focus group discussion among PLWHA on ART of different categories and in-depth interviews with key informants representing different bodies including Head of regional HAPCO, President of Association of PLWHA, Dil Chora Hospital ART coordinator, Save the Children Dire Dawa Branch/WFP coordinator and DPPA Dire Dawa Office Director were conducted.

Participants for the focus group discussion were recruited by their sex category and four focus group discussions, two for each sex groups were conducted. Members of the FGDs represent different groups including young, old, males, females, married, currently unmarried, Orthodox Christian, Muslim, Protestant, employed, unemployed, homeless, with home, urban dwellers and rural dwellers. The following common themes around the issue of food security, adherence to ART and treatment outcomes emerged from discussions with all the focus group discussion groups.

8.2.1 Focus group discussions

8.2.1.1 Food security situation of PLWHA on ART

The household food security problem of PLWHA on ART which is critical according to the quantitative assessment was also repeated in the qualitative assessment. Most of the FGD participants were emotional when they talk about the food security situation of their households. One of the female FGD participants said *"Live alone with the disease and the limited capacity we have now a day it is difficult to survive even for one Diploma graduate Ethiopian with his monthly income. Living is getting expensive"*. Another female participant said *"I need to eat 6 times per day. The drug needs that much. But in*

most of the cases I couldn't even afford to eat three times per day. Sometimes I feel shame when I visit my friends and eat any food they give me without any hesitation".

The participants also mentioned that the food ration/support they are getting, if at all, are very small in amount and inconsistent to cover their dietary need. The discussants mentioned that the problem of eating enough of what one likes is not confined to PLWHA on ART. But when there is increased need to eat and the community denies the chance of accessing food through stigma and discrimination things become worst for PLWHA on ART. One females FGD participant is quoted saying "*The government should support us. We couldn't even sell something in our door front. People buy from others passing you; they think as if you put your blood in the goods you are selling".*

The study participants also reported to use some coping strategy to respond to the food crises they are facing. Reducing the portion of the food they are consuming, passing part or whole of meals of the day, selling fixed asset they have, borrowing money from relatives & friends and sending their children to their relatives were some of the coping mechanisms they mentioned. In addition, participants mentioned some dangerous coping strategies that could even fuel the existing increasing prevalence of the pandemic. One female FGD participant said "*Had it not been for God help……you know when you fail to find any food to eat you are obliged to do anything…..anything including changing sex for money".*

Most of the FGD participants were repeatedly commenting the food ration as a strategy for sustainable alleviation of the food insecurity problem of PLWHA on ART. All of the four FGD participants were mentioning some sort of income generating activities and creating job opportunity for PLWHA on ART as the state-of-the-art food security strategy to sustainably respond to the increasing support need of PLWHA on ART. A male participant of FDG said *"ART took us far away from illness and death. But to keep this promising outcome longer and to start thinking more about our health we need to have access to job. When we work we support ourselves and our country. When we work we can feed ourselves. I don't want any food ration if I have a job to do".*

8.2.1.2 Adherence to ART

Concerning adherence to the ART medication prescribed the finding of all the FGDs confirmed that PLWHA are taking their ART medication according to their physicians' recommendation. FGD participants were confident enough when they report that no reasons have made them miss the pills if not delaying them 5-10 minutes late than their regular time. They claimed that they are curious on their ART. Majority of the discussion participants who reported passed days without food to eat were repeatedly mentioning that they didn't miss doses of their ART for they said it is their life. One of the female FGD participants who reported passed 2 days without food said *"The issue of ART is serious. You can argue about food after you took your pills but you can not say anything about any issue by discontinuing your pills because this is a life issue. Sometimes you need to take the pills without food if conditions didn't allow you to access food"*. Another male participant said *"I take the pills 2 O'clock in the morning and 2 O'clock at night. If I found no food to take with the drugs I take them without food and will search for any food then…… I took my pills without food before days for example"*. Another male FGD participant also said *"We know what changes the treatment brought to our life. How can you stop drugs that let you live? We took them whether we eat or not"*.

FGD participants were also asked for any reasons they know some PLWHA on ART could discontinue ART or miss pills. Stigma and discrimination by relatives, poor counseling, lack of home-based care service, being away form home, religious reasons (wholly water), simply forgetting the pills and lack of food especially among PLWHA in the early period of ART are mentioned as reasons for poor adherence to ART. One FGD participant said *"I know a PLWHA who discontinued ART. He came to Hospital long after he stopped taking his drugs. I asked him why he did that. He said his families were stigmatizing him a lot. They thought as if the ART drugs transmit HIV. They took his medicine away from places he put and discard them. Now he is gone"*.

8.2.1.3 Outcomes of ART

The FGD participants also reflected their perception and experiences in terms of the outcome they gained from ART. Among the outcomes they have reported to have gained from the treatment are improved general health status, decreased frequency of different infection, improved appetite, pleasure, enhanced psychological confidence, hope to live indefinitely, weight gain and increased CD4 count. One of the female FGD participants is coated saying *"When I started the treatment my CD4 count was only 1(per micro liter). Now it is more than 600 (per micro liter). My weight was also 40kg and now I weigh 60kg. But this improvement is not merely due to the food I am eating. It is also due to the psychological stability, pleasure and care that I am getting from people I am working with and from the Doctors who are taking care of us".* Another participant reinforced this by saying *"I was 90kg before the disease and my weight lowered to around 40 kg when I give birth to a newborn that shortly passed away. I and my husband started the medicine together. His CD4 increased from 400 to more than 700 and mine from 149 to more than 600. His weight increased from about 50kg to 70kg and mine from around 40kg to 79.5kg. So the treatment has benefit in this way".* The improvement in weight, CD4 count and other health indicators among PLWHA on ART were positive according to their perception and experiences mentioned in the discussions.

But the FGD participant PLWHA on ART were consistently mentioning the full blown benefit they would have gained from the treatment if they had enough of the type food they want and the type of food their physicians are counseling them to eat. They perceive that lack of food to take with the ART has impact on the level of the benefits they are gaining from the treatment if not on the level of adherence to the treatment. One female FGD participant coated saying *"The difference in the effectiveness of the treatment is a matter of access to the food you want at the time and amount you need it. Those reporting better improvement are those with enough food to eat".* Another male FGD participant said *"The improvement that I have gained in terms of weight and CD4 count would have been better than this if I had enough of the type of food I want to eat. I even believe the disease could be eliminated from the face of the world if PLWHA on ART could access the required food needed for the drug".*

8.2.2 In-depth interviews

8.2.2.1 Food security situation

The result of in-depth interview clearly indicated that there is food security problem in Dire Dawa Provisional Administration in general and among PLWHA in particular. HIV/AIDS accentuates the prevailing poverty in the region and people become infected usually for common reasons that impoverished them. HIV infected people are further subjected to poverty making a vicious circle. The regional DPPA officer said *"In the early times unemployment was the main reason for food insecurity problem in urban settings. Now a day HIV/AIDS becomes the front sited reason to erode the asset and production capacity of people and families infected and affected by the disease"*. Most of the low income inhabitants of Dire Dawa and the city in general were known for contraband business. Due to the ban and binding control system instituted by the government currently there is almost no marketing of smuggled goods in the area and people who had their bread from this sector become food insecure, some even with unusual response for the food crises they are confronting.

Save the Children USA Dire Dawa Branch's Coordinator said *"The food insecurity situation in the area is showing us its worst scenario. We support poor PLWHA with food ration. But what we saw in the process is some people appeal for the ration and when they are screened for HIV and turned negative they cry for they fail to fulfill one of the criteria to receive the food ration"*. On the other hand attitude of people towards the food types they are accessible to is another challenge for food security situation of PLWHA on ART. Dire Dawa HAPCO's head said *"As any part of the country there are many people who live under poverty line and those who can't eat once per day in the region. But the other challenge here with PLWHA on ART is their attitude towards the food type one should eat. They consider only meat and butter as food groups that should be taken with the drugs. Eating vegetables and legumes is considered as a sign of poverty. We are trying to change this attitude through mobilization of the PLWHA community"*.

8.2.2.2 Adherence to ART

The in-depth interview with different key informants consistently assure that adherence to ART among PLWHA in Dire Dawa Provisional Administration is good. In the region there are different efforts made by governmental and non-governmental organizations that are targeted to increase the patients' compliance to the drugs prescribed to them. To mention them there are more than 100 trained voluntary home-based care providers for the total 1350 PLWHA on ART and around 1500 PLWHA on pre-ART list. They report for Kebele HIV/AIDS facilitators who are assigned by the regional HIV/AIDS Prevention and Control Office in all of the 9 Kebeles. Along with other responsibilities they are assigned to execute these home-based care providers periodically visit PLWHA at home and assist them to take their medication. They also trace defaulters and new cases in the community and refer to the ART unit in the Hospital. In addition, at the time of the survey there were PLWHA trained in peer counseling and assigned in the ART unit and other department of Dil Chora Hospital with the responsibility of counseling PLWHA on ART or those listed on pre-ART file. On top of this, there is one missionary charity rehabilitation center in the region that admits and provides food, shelter and other cares for certain period of times for destitute PLWHA that started ART.

At the time of this survey there was also broadcasting of a weekly one hour local radio (FM) program which openly discuss with audiences on the issues and concerns of PLWHA, VCT, ART and related issues by inviting health professional, PLWHA and other people working in the area. Furthermore, there are social gathering sessions in each Kebeles that are facilitated by the Kebele HIV/AIDS facilitators on a monthly basis that discuss on issues related to ART adherence and related concerns of PLWHA. The association of PLWHA named as Tesfa Bisrat Misikir Mahiber also contributed its part for the better adherence to ART the PLWHA scored.

This study focuses on those PLWHA for at least three months on ART to assess the contribution of food and nutrition security to adherence to ART and on the gains of the treatment. According to the Dil Chora Hospital ART coordinator the problem of non-adherence is a challenge particularly in the first month of the start of the treatment. Out of

the total PLWHA ever enrolled in the ART program nearly 300 PLWHA discontinued the treatment with more than 90% of them in the first month of their treatment. Close to 50% of all the defaulters discontinue their treatment due to death, about 10% of the defaulters were traced and returned to the program but the fate of 40% of all the defaulters is not known because they could not be traced and asked for their reasons to discontinue the treatment. They gave wrong contact address and some live in other geographic area. Adherence rate of the PLWHA sticking to their appointment is good but that could not show us the real picture of the adherence to ART situation of the PLWHA community.

8.2.2.3 ART outcomes

Concerning the outcomes of ART that PLWHA are benefiting from the result of in-depth interview showed that although food insecurity can shadow the contribution of the treatment the outcomes still observed with the short lived experience of the program in the area are promising and encouraging for people working in the area of care and treatment. According to the Save the Children USA Dire Dawa Branch's Coordinator *"Our record shows that previously more than 500 PLWHA were bed-ridden but now their number decreased to less than 50. This is how we can appreciate the outcomes of the treatment "*. The next challenge to the program people in the region is creating job opportunity for the potential working group that are flooding intothe prevailing unemployed population of the region after PLWHA are treated with ART. Their chance of getting employed is influenced by their competency beyond the stigma and discrimination prevailing in the area as in most of the cases PLWHA on ART have little or no qualification and skill in the pre-ART period of their life. Most of them come to the program from the disadvantaged and marginalized part of the community.

Food security situation of PLWHA on ART is impacting adherence to ART and treatment outcomes. The Dil Chora Hospital ART coordinator said *"Among those PLWHA who are traced as defaulters by peer counselors some report lack of food as their reason for abandoning their medication. We usually take too much time on nutrition counseling to persuade them take their drugs with any food they have. Food security is an*

emerging issue in the program". Participants of the in-depth interviews agreed that food security is an issue that is overlooked by the program and a challenge to the successful implementation of the program. *"For lack of awareness or real reasons we are facing the fact that food security is challenging the adherence and treatment outcomes of ART. We are at our utmost effort to convince people to stick to their ART medications through food ration and awareness raising sessions. But if PLWHA continue to withdraw from their treatment due to lack of food and new strain of the virus resistant for the drug in the country appears in the community that would be failure of the whole program"*.

9. DISCUSSION

The present study found that food and nutrition insecurity were serious problems of PLWHA on ART. Adherence to ART was very high and apparently was found not to be affected by food and nutrition security variables. Food and nutrition security variables were associated with treatment outcomes of ART.

Food security situation indicators of PLWHA on ART clearly uncovered the magnitude of food insecurity prevailing in the study area. According to the food security assessment module used to assess household food security status of PLWHA on ART close to 90% were food-insecure with or without hunger. Even using hunger as a criterion to classify the households of the PLWHA 72.4% of the households remained food insecure with moderate to severe hunger. The proxy indicators of food security used in this study to support the core module also showed that significant number of PLWHA on ART consumed less than the mean meal frequency and dietary diversity score in the area. This might be due to the impact of the disease on the household food security situation of PLWHA as it was found in a study conducted in Cote de Vore where per caput consumption of AIDS-afflicted households to be half that of other households. (36) A cross-sectional survey in Tanzania, also found that households that experienced an AIDS death spent substantially less on food than other households. HIV/AIDS related death significantly increased the probability of a household falling below the poverty line. (37) The food security problem of PLWHA on ART in Dire Dawa is also a felt challenge for people working in the ART program as it was clearly reflected on the qualitative part of the study.

A well established indicator of malnutrition (nutrition security) used in this study further revealed that 30.1% of the study participants had evidence of at least mild malnutrition which is comparable with a study done in Singapore. (47) Multiple regression analysis showed that female PLWHA had good nutritional status than male PLWHA. Compared to PLWHA who were bed-ridden at the initiation of ART PLWHA who were ambulatory

and working at the initiation of ART had poor BMI. PLWHA for longer period of time on ART had good nutritional status compared to those for shorter period on the treatment. This might be due to the outcome of the treatment they had received. Those PLWHA who were 100% adherent to ART had poor nutritional status than those who were non-adherents. The perceived improvement in weight might be the reason for missing drugs among those with better current nutritional status. However, additional study may be needed to explain the reason why PLWHA with better nutritional status miss drugs. The analysis further found that reported diarrhea was significantly associated with poor nutritional status. This might be due to increased resting energy expenditure and sharply decreased energy intake in HIV-positive patients with active secondary infection that leads to wasting (68). The pre ART nutritional status of PLWHA was significantly associated with the current nutritional status. For an increase in a kg/m2 of BMI before ART the current MBI increased 0.772kg/m2. Because the current nutritional status is the outcome of the pre ART nutritional status and the change in weight due to ART the pre ART nutritional status definitely determines the current nutritional status of PLWHA.

Adherence to ART which is defined as taking ≥95% of the prescribed doses over the previous year in this study was 96.6%. This is more than the 81.2% adherence documented locally by a study done in Addis Ababa (16) and 54% adherence in a study done in Botswana. (7) Similarly adherence to 100% of the doses prescribed in the last year (86.4%) is comparable with a study in Costa Rica (85%) with 100% pills compliance in the last 3 days. (42) In both ways of measuring adherence to ART PLWHA on ART in this study adhere more than the adherence rate documented locally, in other developing countries or in developed countries. (9,16,42) This could partially be explained by the coordinated and multifaceted local efforts going on in the study area where organized system is instituted by governmental and non-governmental organizations towards improving adherence as figured out in qualitative study. The other reason for good adherence might be due to the method applied to assess adherence in this study and other similar studies. (7, 16) Institution based evaluation of adherence to ART could hardly capture the non-adherence problem of PLWHA on ART as many of the defaulters of the treatment could not be traced by such a method. Defaulters of ART treatment usually disappear from the health system for the same reasons they interrupt

their treatment and they could not be reached by institution based study like this as reflected by in-depth interview. However, this study can evaluate the adherence situation of those coming to the health facility at the time of the survey.

Among PLWHA ever missed a dose or more of the ART pills prescribed in the last one year the chief barriers to adherence mentioned were lack of food to take with the drugs (61.7%), forgetting to take pills (36.7) and running out of pills (20.0%). This finding is different from the study done in Addis Ababa that found being too busy or simply forget (33.9%) and being away from home (27.5%) as major barriers to adherence. (16) As the ART drugs in Ethiopia are for free this study did not find cost of medication as barrier to adherence which was found to be the leading predictor of adherence to ART in Botswana. (7) The study in Costa Rica on the other hand found difficulty in finding transportation (54%) as major reason to non-adherence. (45) Lack of food to take with the drugs as a major cause for non-adherence in this study is in agreement with a finding of focus group discussion conducted in Nairobi. (69) Although lack of food to take with medication is not a factor for missing pills among those who adhere to their medication it was a primary reason for missing ART drugs among those who were non-adherent to their medication in the last one year. The in-depth interviews also identified food insecurity as barrier to adherence to ART and as a threat for the universal access of the program in the region.

Multiple logistic regression analysis found that females were adhering more to their prescribed doses than their male counterparts. Females experience in taking pills for longer period of time such as contraceptives could partially explain the difference. Looking for any association between household food and nutrition security and adherence to ART was the principal interest of this study. However, there was no significant association between adherence to ART and belonging to households with food security, high meal frequency and high dietary diversity score. Adherence to ART is not also affected by nutritional status of PLWHA on ART. The high level of adherence to ART among PWLHA might be due to the benefit they are gaining from the treatment as they were consistently mentioning in the focus group discussions conducted. Taking ART

drugs in an empty stomach is not uncommon among participants of the focus group discussions.

Although the household food and nutrition security did not affect the level of adherence to ART pills it had affected the treatment outcomes. Food ration had significant impact on the functional improvement of PLWHA on ART. Better functional improvement reported by PLWHA with food ration may be due to the relative contribution of food aid in postponing HIV/AIDS related illness and prolonging life. (70) Although not specific to HIV infection a randomized control trial of energy and protein supplementation in patients with wasting associated with tuberculosis initiated at the time of commencing antituberculous drugs demonstrated significant early improvements in lean body mass and associated improvement in physical function which is in agreement with the finding in the present study. (71) Household dietary diversity also affected the functional improvement of PLWHA on ART. Increases in dietary diversity are associated with increase in consumption, caloric availability and calories from staples and non-staples (52,53,54) the more food groups PLWHA on ART consumed the more will be their energy that in turn leads to better functional status improvement.

Belonging to good nutritional status and high CD4 count at the initiation of ART was associated with poor improvement in functional status. This could be explained by the fact that PLWHA on ART with good nutritional status and high CD4 count at the initiation of ART probably had better functional status at the start of ART and their progress from their pre-ART functional status upon treatment would be horizontal that could hardly be noticed by the method used to assess improvement in functional status.

Change in weight was one of the indicators used to measure the treatment outcome of ART. The median change in weight observed after 3 months of ART was significantly high. On correlation regression analysis it was found significantly positively correlated with dietary diversity of households of PLWHA. Although the current dietary diversity is not efficient enough to explain the changes observed in the 3 months of initiation of treatment assuming it will not change over the median treatment duration we can admit its contribution to the weight gain PLWHA have scored. However, the mere implication

of this association is those PLWHA in households with better dietary diversity had better change in weight. It could not tell us the consumption of which dietary group brought better weight change.

In adults, ART is associated with a sustained weight gain and increased BMI. (72) The pre-ART nutritional status of PLWHA was significantly negatively correlated with weight change. Those with lower BMI at the start of treatment had better improvement in weight. It is possible that food aid, employed as adjunct at the time of the start of ART could accelerate or augment the recovery of body weight among those with severe wasting at the start of ART. Weight recovery among wasted at the start of ART is inconsistent in other studies. (73) Other possible explanation could be those with poor pre-ART nutritional status could be admitted in health facilities and rehabilitation centers and cared for nutritionally and psychologically. Most of those with low BMI at the start of ART had lost their weight severely before the initiation of the treatment and the effect of the treatment might be more visible on these groups than on those with high BMI at the start of ART.

The median change in CD4 count observed after 6 months of ART [116 (IQR of 82-182)] was promisingly high for the study participants with great odds treatment outcomes. It is more than a study findings in Singapore and US that found a median increase in CD4 count of 64 (IQR of 23-115) after 6 months of ART (47) and a weighted estimate of difference in the mean CD4 count at 1 year among participants continuously treated versus those never treated to be 95 (48), respectively. Feeding frequently was significantly positively correlated with CD4 count change after 6 months of ART. Although we do not have sufficient ground to explain the change in CD4 count which happened after 6 months of the start of the treatment by the current meal frequency of households of PLWHA the correlation might be due to consumption of extra food that helped to boost their immunity.

In the present study it was found that PLWHA with malnutrition had higher risk of diarrhea and lung disease compared to those with good nutrition. This is in agreement with the established evidence that there is strong synergistic relationship between the

health status and the nutritional status of PLWAH as around half of all global preschool child deaths are attributable to the negative synergy of malnutrition and infectious disease, with a majority of deaths complicated by mild to moderate undernutrition (22). Another explanation for the finding could be due to the association of both general (protein and energy) and micronutrient deficiencies with significant defects in cell mediated and humoral immunity, depressed cytokine production, lowered specific antibody production, and decreased phagocyte function (23). Infections are thus longer-lasting and more severe in someone who is malnourished. They may also be more frequent. This becomes very important especially among PLWHA on ART because frequency of opportunistic infections is an important indicator of the effectiveness of the treatment. In addition, according to FGD participants their maximum compliance to ART prescribed were attributable to the changes they have observed by the treatment including being free from frequent illnesses.

10. STRENGTHS AND WEAKNESSES OF THE PRESENT STUDY

10.1 Strengths

In the present study both qualitative and quantitative methods were used. Qualitative method used to triangulate the findings of the quantitative method and explore some issues overlooked by the quantitative instrument. The issue examined in this research is hardly investigated, if at all, elsewhere in Ethiopia as to the investigator's knowledge putting this finding as a breakthrough to document the household food and nutrition security of PLWHA and their interaction with adherence to ART and treatment outcomes. The sample size of the study was fair enough to represent the study targets. Use of multiple treatment outcome indicators helped to evaluate the impact of the independent variables on the dependent variables. Attempt was made to include many of the factors suspected to potentially influence adherence to ART and treatment outcomes. Logistic regression analysis was used to control for the effect of possible confounders.

10.2 Limitations

Although maximum effort was made to assess the household food security situation of PLWHA on ART through combining the food security assessment module with proxy indicators (dietary diversity and meal frequency) determining the availability dimension of food security, which partially determines the access dimension, is beyond the scope of this research. Excluding PLWHA for less than 3 months on ART in this study challenged its power to find out the real picture of non-adherence to ART which is major problem in the first month of the treatment. Although use of patient self-report to measure adherence is reliably associated with both objective measure of adherence and viral load patients tend to overestimate adherence. CD4 count and weight records were incomplete and inconsistent in the health facility. The food and nutrition security situation of pediatric PLWHA on ART and their interaction with adherence was not assessed in this study limiting the generalization of the findings only to adult PLWHA.

11. CONCLUSION

The study found that food and nutrition insecurities were serious problems of PLWHA on ART. Adherence to ART by self report was very high (96.6%) compared to findings of other studies confirming the success of the program in resource poor settings. Lack of food was the leading reason (61.7%) for missing drugs among those who had ever missed. However, adherence was not statistically significantly associated with the indicators used to assess food and nutrition security. Among those who have ever missed their ART pills lack of food was the primary reason for missing pills.

Adherence to ART is not the ultimate goal of ART program. Instead, treatment outcomes for the patients receiving therapy should be the ultimate goal of the program. Food and nutrition security had significantly affected indicators of treatment outcomes. Food aid and dietary diversity were positively associated with functional improvement. High dietary diversity and high meal frequency were significantly correlated with increased weight gain and CD4 count among PLWHA on ART, respectively. However, pre-ART nutritional status was negatively correlated with weight gain suggesting that the velocity of weight gain among PLWHA with severe malnutrition is more than among those with mild malnutrition or normal nutrition. The window of hope for saving the lives of even severely affected PLWHA using ART might be evidenced by this.

Good nutrition helped keep PLWHA on ART well and healthy. Malnutrition among study participants was associated with self reported opportunistic infections such us diarrhea and lung disease.

12. RECOMMENDATIONS

Patient self report adherence was promisingly high in this study. Improving food and nutrition security could further prevent missing of drugs. Nutrition counseling, nutrition intervention and treatment of opportunistic infections might help to improve the adherence level of PLWHA on ART.

Food aid should be considered both as nutritional supplement and transitory strategy towards sustainable income generating self-help activities. Because food aid can enable marginalized population (including PLWHA) take advantage of development opportunities inclusion of food assistance as a safety net in the ART program is recommended. Sustainable income generating schemes should, however, be the long term strategy to respond for the food problems related to the life time epidemic (HIV/AIDS).

There is need for provision of IEC/BCC on ART, nutrition, adherence and treatment outcomes to the public in general and to the PLWHA community in particular. IEC/BCC tailored to the context of PLWHA and the public could improve the attitude towards ART, nutrition, care and prevention.

While keeping the multifaceted effort that resulted in increased adherence to ART in the region by different stakeholders it is better to repeat it on sustainably alleviating the food and nutrition security problems of PLWHA on ART.

It is recommended that the present study is repeated in pediatric PLWHA on ART. Further study, methodologically follow up design, is also recommended on PLWHA community to pick the real picture of adherence among PLWHA on ART and to observe the impact of food and nutrition security on treatment outcomes.

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ANNEXES

Annex 1 – ENGLISH VERSION QUESTIONNAIRE TO ASSESS THE IMPACT OF FOOD AND NUTRITION SECURITY ON ADHERENCE TO ART AND TREATMENT OUTCOMES AMONG PLWHA ON ART IN DIRE DAWA

CONSENT INFORMATION SHEET

Good morning/good afternoon. My name is _____. We came from Addis Ababa University Medical Faculty. We are working for an investigator doing his thesis for the partial fulfillment of master's degree in public health. We would like to ask you few questions about your household food security situation, antiretroviral treatments and related factors affecting its adherence. This will help us to identify some of the barriers to good adherence to antiretroviral drugs and treatment outcomes based on your answer to our questions.

We will also take some measurements including weight and height from you. If you are interested we can tell you your weight and height measurements. You have full right to refuse, withdraw or completely reject part or all of your participation in the study. But we encourage your full participation as the answers you give on this form and your participation in taking your measurements are very important to this study and to plan ways to help other people who must take pills on a difficult situation. We need also to take some information from your files and records archieved in the ART Unit of Dil Chora Hospital.

We would like to assure you that all of your responses to our questions will be kept confidential throughout the study process. Any of your information you provide will be used only by the research team and will, by no means, be revealed to a third party. We will ask you questions and take measurements in a place where other people or conditions couldn't interfere. We would like to assure you that your participation on this research will not affect any of your treatment and other benefit that you get from any organization.

We would be thankful if you spend sometime with us answering questions related to the issues described above and cooperating in taking some measurements from you. The questions and measurements will take 30-45 minutes. May I get your permission to continue my interview?

Yes ☐ 1

No ☐ 2→ Stop

If yes, Study participant's Unique ART ID No. _____

Signature _____

Date_____

Data collector's
Name _____
Signature _____

Supervisor's
Name _____
Signature _____

1. SOCIO-DEMOGRAPHIC CHARACTERISTICS

No	*QUESTIONS AND FILTERS*	*CODING CATEGORIES*	*CODE*
Q101	Age of the study participant	☐☐ years	
Q102	Date of birth of the study participant	| |	
Q103	Sex of study participant	Male ☐ 1 Female ☐ 2	
Q104a	Religion	☐☐	
Q104b	Ethnic group	Amhara ☐ 1 Oromo ☐ 2 Somali ☐ 3 Tigre ☐ 4 Garage ☐ 5 Other (S)_____ 6	
Q105	Marital status	Married ☐ 1 Unmarried ☐ 2 Divorced ☐ 3 Separated ☐ 4 Widowed ☐ 5	
Q106	Education	Illiterate ☐ 1 Read & write ☐ 2 Elementary ☐ 3 High school ☐ 4 Diploma + ☐ 5	
Q107	Monthly income (Birr)	☐☐ Birr	
Q108	Working situation	Employed ☐ 1 Unemployed ☐ 2	
Q109	Whom do you live with?	Alone ☐ 1 My family ☐ 2 My parents ☐ 3 Others (specify)_____ No answer ☐ 99	
Q110	Treatment duration (months)	☐☐ Month	
Q111	Housing condition		
	Number of rooms	☐☐ room	

	Number of people in the household	☐	
	Running water	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	Electricity	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q112	Does anyone else know about your HIV status?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q113	If yes who?	Wife/husband ☐1 Own child (ren) ☐2 Parents ☐3 Brothers/sisters ☐4 Relatives ☐5 Friends ☐6 Others (Specify)_____	
Q114	(IF FEMALE ASK)Are you pregnant?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q115	(IF YES TO Q114) When was the last time you see your menustrial bleeding?	☐	
Q116	(IF FEMALE ASK)Are you currently breastfeeding?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q117	(IF YES TO Q116) For how long?	☐ Mths	
Q118	Are you receiving any food ration from any organization?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q118a	If yes, from where? (THE ORGANIZATION THAT AIDS YOU)	☐ ☐	
Q118b	If yes, what is the type of food you are receiving?	☐ ☐ ☐	

2. DIETARY DIVERSITY AND MEAL FREQUENCY

No	*QUESTIONS AND FILTERS*	*CODING CATEGORIES*	*CODE*
Q201	*During the previous 24-hours period (yesterday day and night), did you or anyone in your household consume?*		
201A	Any bread, rice noodles, biscuits, or any other foods made from millet, sorghum, maize, rice, wheat, or [INSERT ANY OTHER LOCALLY AVAILABLE GRAIN]?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201B	Any potatoes, yams, manioc, cassava or any other foods made from roots or tubers?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201C	Any vegetables?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201D	Any fruits?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201E	Any beef, pork, lamb, goat, rabbit wild game, chicken, duck, or other birds, liver, kidney, heart, or other organ meats?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201F	Any eggs?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201G	Any fresh or dried fish or shellfish?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201H	Any foods made from beans, peas, lentil, or nuts?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201I	Any cheese, yogurt, milk or other milk products?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201J	Any foods made with oil, fat, or butter?	Yes ☐ 1	

		No ☐ 2 Don't Know ☐ 99	
201K	Any sugar or honey?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
201L	Any other foods, such as condiments, coffee, or tea?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q202	*During the previous 24-hours period (yesterday day and night), did you or anyone in your household consume*		
202A	Any food before a morning meal	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
202B	A morning meal	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
202C	Any food between morning and midday meals	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
202D	A midday meal	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
202E	Any food between midday and evening meal	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
202F	Any evening meal	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
202G	Any food after the evening meal	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	

3. HOUSEHOLD FOOD-SECURITY/HUNGER SURVEY MODULE

NO	*QUESTIONS AND FILTERS*	*CODING CATEGORY*	*CODE*
Q301	Which of these statements best describes the food eaten in your household in the last 12 months:	Enough of the kinds of food we want to eat [SKIP 1a and 1b]---------- ☐ 1 Enough but not always the kinds of food we want [SKIP 1a; ask 1b]---------- ☐ 2 Sometimes not enough to eat [Ask 1a; SKIP 1b]--------- ☐ 3 Often not enough [Ask 1a; SKIP 1b]---------- ☐ 4 DK or Refused (SKIP 1a and 1b)---------- ☐ 99	
301a	*[IF OPTION 3 OR 4 SELECTED, ASK] Here are some reasons why people don't always have enough to eat. For each one, please tell me if that is a reason why YOU don't always have enough to eat. [READ LIST. MARK ALL THAT APPLY.]*		
	Not enough money for food	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	Not enough time for shopping or cooking	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	Too hard to get to the store	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	On a diet	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	No working stove available	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	

	Not able to cook or eat because of health problems	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
301b	*[IF OPTION 2 SELECTED, ASK] Here are some reasons why people don't always have the quality or variety of food they want. For each one, please tell me if that is a reason why YOU don't always have the kinds of food you want to eat. [READ LIST. MARK ALL THAT APPLY.]*		
	Not enough money for food	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	Kinds of food (I/we) want not available	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	Not enough time for shopping or cooking	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	Too hard to get to the store	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	On a special diet	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Now I'm going to read you several statements that people have made about their food situation. For these statements, please tell me whether the statement was often true, sometimes true, or never true for (you/your household) in the last 12 months, that is, since last (name of current month).			
Q302	"(I/We) worried whether (my/our) food would run out before (I/we) got money to buy more." Was that often true, sometimes true, or never true for (you/your household) in the last 12 months?	Often true ☐ 1 Sometimes true ☐ 2 Never true ☐ 3 DK or Refused ☐ 99	
Q303	"The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true ☐ 1 Sometimes true ☐ 2 Never true ☐ 3 DK or Refused ☐ 99	

Q304	"(I/we) couldn't afford to eat balanced meals." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true ☐ 1 Sometimes true ☐ 2 Never true ☐ 3 DK or Refused ☐ 99	
[IF CHILDREN UNDER 18 IN HOUSEHOLD, ASK Q5 - 7; OTHERWISE SKIP TO Q8]			
Q305	"(I/we) relied on only a few kinds of low-cost food to feed (my/our) child/the children) because (I was/we were) running out of money to buy food." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true ☐ 1 Sometimes true ☐ 2 Never true ☐ 3 DK or Refused ☐ 99	
Q306	"(I/We) couldn't feed (my/our) child/the children) a balanced meal, because (I/we) couldn't afford that." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true ☐ 1 Sometimes true ☐ 2 Never true ☐ 3 DK or Refused ☐ 99	
Q307	"(My/Our child was/The children were) not eating enough because (I/we) just couldn't afford enough food." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true ☐ 1 Sometimes true ☐ 2 Never true ☐ 3 DK or Refused ☐ 99	
Q308	In the last 12 months, since last (name of current month), did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food?	Yes ☐ 1 No (SKIP TO 8a) ☐ 2 DK (SKIP TO 8a) ☐ 99	
308a	[IF YES ABOVE, ASK] How often did this happen---almost every month, some months but not every month, or in only 1 or 2 months?	Almost every month-- ☐ 1 Some months but not every month---------- ☐ 2 Only 1 or 2 months--- ☐ 3 DK or R---------- ☐ 99	
Q309	In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q310	In the last 12 months, were you every hungry	Yes ☐ 1	

	but didn't eat because you couldn't afford enough food?	No ☐ 2 Don't Know ☐ 99	
Q311	In the last 12 months, did you lose weight because you didn't have enough money for food?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q312	In the last 12 months, did (you/you or other adults in your household) ever not eat for a whole day because there wasn't enough money for food?	Yes ☐ 1 No (SKIP TO 12a) ☐ 2 DK (SKIP TO 12a) ☐ 99	
Q312a	[IF YES ABOVE, ASK] How often did this happen---almost every month, some months but not every month, or in only 1 or 2 months?	Almost every month-- ☐ 1 Some months but not every month---------- ☐ 2 Only 1 or 2 months--- ☐ 3 DK or R---------- ☐ 99	
[IF CHILDREN UNDER 18 IN HOUSEHOLD ASK 13-16; OTHERWISE SKIP TO END.]			
Q313	The next questions are about children living in the household who are under 18 years old. In the last 12 months, since (current month) of last year, did you ever cut the size of (your child's/any of the children's) meals because there wasn't enough money for food?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q314	In the last 12 months, did (CHILD'S NAME/any of the children) ever skip meals because there wasn't enough money for food?	Yes ☐ 1 No (SKIP TO 14a) ☐ 2 DK (SKIP TO 14a) ☐ 99	
Q314a	[IF YES ABOVE ASK] How often did this happen---almost every month, some months but not every month, or in only 1 or 2 months?	Almost every month-- ☐ 1 Some months but not every month---------- ☐ 2 Only 1 or 2 months--- ☐ 3 DK or R---------- ☐ 99	
Q315	In the last 12 months, (was your child/ were the children) ever hungry but you just couldn't afford more food?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	

Q316	In the last 12 months, did (your child/any of the children) ever not eat for a whole day because there wasn't enough money for food?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	

4. ART ADHERENCE SITUATION

Q401. YOU ARE CURRENTLY TAKING THE FOLLOWING DRUGS AT THE FREQUENCY AND DOSES LISTED.

Study Drug Name/Dose	***# Pills Each Time (Pills Each Dose)***	***# Times Per Day (Doses Per Day)***

NO	***QUESTIONS AND FILTERS***	***CODING CATEGORIES***	***CODE***
Q402	Did you miss taking any of your ART drugs:		
	Yesterday?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	In the last 3 days?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
	In the last 7 days?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q403	A. How many doses did you missed taking:		
	Yesterday?	☐	
	In the last 3 days?	☐	
	In the last 7 days?	☐	

	B. During the past 7 days, on how many days have you missed taking all your doses?	None ☐ 1 One day ☐ 2 Two days ☐ 3 Three days ☐ 4 Four days ☐ 5 Five days ☐ 6 Six days ☐ 7 Seven days ☐ 8	
Q404	Most anti-HIV medications need to be taken on a schedule, such as "2 times a day" or "3 times a day" or "every 8 hours." How closely did you follow your specific schedule over the last four days?	Never ☐ 1 Some of the time ☐ 2 About Half the time ☐ 3 Most of the time ☐ 4 All of the time ☐ 5	
Q405	Does any of your anti-HIV medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids?"	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q406	If Yes, how often did you follow those special instructions over the last four days?	Never ☐ 1 Some of the time ☐ 2 About Half the time ☐ 3 Most of the time ☐ 4 All of the time ☐ 5	
Q407	Some people find that they forget to take their pills on the weekend days. Did you miss any of your anti-HIV medications last weekend—last Saturday or Sunday?	Yes ☐ 1 No ☐ 2 Don't Know ☐ 99	
Q408	When was the last time you missed any of your medications? Check one.	1-2 weeks ago ☐ 1 2-4 weeks ago ☐ 2 1-3 months ago ☐ 3 4-12 months ago ☐ 4 > 12 months ☐ 5 Never/not applicable ☐ 6	

5. REASONS FOR SKIPPING THE DOSES

NO	*QUESTIONS AND FILTERS*	*CODING CAT.*	*CODE*
Q501	What caused you to miss dosage of ARV medications?		
Q501	Had no food to take with medication?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q502	Were away from home?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q503	Were busy with other things?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q504	Simply forgot?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q505	Had too many pills to take?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q506	Wanted to avoid side effects?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q507	Did not want others to notice you taking medication?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q508	Had a change in daily routine?	Never ☐ 1 Rarely ☐ 2	

		Sometimes ☐ 3 Often ☐ 4	
Q509	Felt like the drug was toxic/harmful?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q510	Fell asleep/slept through dose time?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q511	Felt sick or ill?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q512	Felt depressed/overwhelmed?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q513	Had problems taking pills at specified times (with meals, on empty stomach, etc.)?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q514	Ran out of pills?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q515	Felt good?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	
Q516	Had alcohol at specified times?	Never ☐ 1 Rarely ☐ 2 Sometimes ☐ 3 Often ☐ 4	

6. ART TREATMENT OUTCOMES

NO	*QUESTIONS AND FILTERS*	*CODING CAT*	*CODE*
Q601	Before you start taking ART		
	How much was your body weight?	☐☐☐	
	What was your functional status?	Working ☐ 1 Ambulatory ☐ 2 Bed-ridden ☐ 3	
	How much was your CD4+ cell count?	☐☐☐☐	
Q602	What is your current		
	Body weight	☐☐☐	
	Functional status	☐☐☐	
	CD4+ cell count	☐☐☐☐	
Q603	In the past 4 weeks do you have any diarrhea?	Yes ☐ 1 No ☐ 2 Don't Know ☐☐ 99	
Q604	In the past 4 weeks do you have any lung diseases?	Yes ☐ 1 No ☐ 2 Don't Know ☐☐ 99	
[FOR THE DATA COLLECTOR] NEXT ARE SOME STATEMENTS THAT YOU ARE EXPECTED TO GENUINELY TREAT BEFORE YOU COMPLETED YOUR INQUIRY			
	TAKE THE STUDY PARTICIPANT'S WEIGHT (KG)	☐☐☐	
	TAKE THE STUDY PARTICIPANT'S HEIGHT (CM)	☐☐☐	
	CHECK FROM THE RECORD THE STUDY PARTICIPANT'S CD4+ CELL COUNTS BEFORE (S)HE STARTS ART	☐☐☐☐	
	CHECK FROM THE RECORD THE STUDY PARTICIPANT'S LAST CD4+ CELL COUNTS 6 MONTHS AFTER (S)HE STARTS ART	☐☐☐☐	
	THE OVERALL HEALTH CONDITION OF THE STUDY PARTICIPANT IS	Excellent ☐ 1 Very good ☐ 2 Good ☐ 3 Fair ☐ 4 Bad ☐ 5	

We would like to express our respect and gratitude to you for your interest and motive to participate in this study.

Annex 2 - **GUIDELINE FOR FOCUS GROUP DISCUSSION**

1. During the previous 24-hours period (yesterday day and night), which groups of food did you or anyone in your household consume? *(LIST THE FOOD GROUPS IF NECESSARY)*
    a. Which food groups are frequently consumed? Why?
    b. Which food groups are less frequently consumed? Why?
    c. What should be done to encourage PLWHA on ART feed on diversified food groups?
2. During the previous 24-hours period (yesterday day and night), how frequent did you or anyone in your household consume meals? *(LIST THE MEAL TYPES IF NECESSARY)*
    a. Which meal types are frequently consumed? Why?
    b. Which meal types are less frequently consumed? Why?
    c. What should be done to encourage PLWHA on ART to increase their meal frequency?
3. How do you best describe the food eaten in your household in the last 12 months?
    a. Do you eat enough of the kinds of food you want to eat? How?
    b. Do you eat enough but not always the kinds of food you want? Why?
    c. Do you sometimes eat not enough? Why?
    d. Do you often eat not enough? Why?
4. In the last 12 months did you worry about your food security situation? Why?
    a. In the last 12 months did you worry about your food security situation in terms of feeding your child/children? Why?
    b. In the last 12 months did you ever cut the size of (your/your child/any of the children) meals or skip meals because there wasn't enough money for food? How often did this happen?
    c. In the last 12 months, did (you/your child/any of the children) ever not eat for a whole day because there wasn't enough money for food? How often did this happen?
5. How common/rare is missing ART drugs among PLWHA on ART?
    a. What are the reasons for missing ART drugs?
    b. What should be done to encourage adherence to ART among PLWHA on ART?
    c. What ART outcomes did you get? How beneficial they are?
6. Do you have any additional general comment on household food and nutrition security of PLWHA in relation with ART?

Annex 3 - **GUIDELINE FOR IN-DEPTH INTERVIEW**

1. Is there problem of eating less diverse food groups in this area? Is that problem of PLWHA (on ART)? Why? What should be done to improve this?
2. Is there problem of eating less frequent meals in this area? Is that problem of PLWHA (on ART)? Why? What should be done to improve this?
3. Are PLWHA (on ART) in this area secure with adequate household food and nutrition? Why?
4. Did PLWHA (on ART) worry about their household food and nutrition security situation? How often? Why?
5. How do you describe the food and nutrition security situation of PLWHA (on ART)?
6. How common/rare is missing ART drugs among PLWHA on ART in this area? Why? What should be done to improve adherence to ART in this area?
7. Do you think the household food and nutrition security situation of PLWHA on ART affects their adherence to ART? How?
8. Do you have any additional comment on household food and nutrition security situation of PLWHA and their adherence to ART?

DECLARATION

I the undersigned, declare that this is my original work and has not been presented for a degree in this or any other university and all sources of materials used for this thesis have been acknowledged.

Name ***Abiy Seifu***

Signature _____

Place Addis Ababa

Date of submission July 1 2007

This thesis has been submitted with my approval as University advisor.

Name ***Dr. Fikru Tesfaye***

Signature _____