**GONDAR UNIVERSITY**

**COLLEGE OF MEDICINE AND HEALTH SCIENCES**

**INSTITUTE OF PUBLIC HEALTH**

**DETERMINANTS OF NONE-ADHERENCE TO ANTIRETROVIRAL THERAPY AMONG HIV INFECTED ADULTS IN AKSUM TOWN, NORTHERN ETHIOPIA**

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**A THESIS PROPOSAL SUBMMITED TO THE INSTITUTE OF PUBLIC HEALTH COLLEGE OF MEDICINE AND HEALTH SCIENCES UNIVERSITY OF GONDAR INPARTIAL FULFILMENT OF THE REQURMENT FOR THE DEGREE OF MASTERS OF PUBLIC HEALTH IN EPIDEMIOLOGY AND BIOSTATISTICS**

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**GONDAR, ETHIOPIA**

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| Full title of the project | Determinants of none-adherence to Antiretroviral Therapy among HIV- infected adults in Aksum town, northern Ethiopia  |
| Duration of the project  | February 2015-june 2015 |
| Study area  | Aksum Tigray Ethiopia |
| Total cost of the project |  |
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# LIST OF ACRONYMS

ART- Antiretroviral Therapy

AIDS -Acquired Immune Deficiency Syndrome

BMI- Body Mass Index

CD4-Cluster Difference 4

CI -Confidence Interval

ETB -Ethiopian Birr

FAO-Food and Agriculture Organization

UNAIDS- United Nations Program on HIV/AIDS

HAART-Highly Active Antiretroviral Therapy

HIV -Human immunodeficiency Virus

NGO- Non Governmental Organization

PLWHA -People Living With HIV/AIDS

WHO -World Health Organization

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# Summary

**Introduction:** Antiretroviral therapy (ART) adherence is a primary determinant of the effectiveness of ART treatment, and is also considered a major predictor of survival among patients living with HIV/AIDS. More than 95% adherence to ART is required in order to prevent the emer­gence of resistant HIV strains, obtain long-term HIV suppression, reduce destruction of CD4 cells, increase survival, and improve quality of life. Adherence is a complex behavior, which is influenced by several determinants belonging to the domains: the patient, the treatment, the disease state, the physician and patient-physician relationship and the health care system. Even though there are studies on adherence to ART in Ethiopia, there is scant information on non-adherence to ART in Tigray region particularly in Aksum.

**Objective**: to identify determinants of none-adherence to antiretroviral therapy among adultPeople Living with HIV/AIDS in Aksum town, northern Ethiopia.

**Methods:** Institution based unmatched case control study design will be conducted to identify determinant factors of non adherence to ART among adultPeople Living with HIV/AIDS. Data will be collected by document review and structured pretested interview based questionnaire. The data will be collected by three diploma nurses working at the health institutions. Descriptive analysis, bivariate and multivariate logistic regression will be used to compute the different rates, proportions and associations (OR, CI) by STATA.

**Work plan**: the project will start in February 2015 and will end in June 2015.The total budget required for the research is ETB 23316.70.

# Introduction

## Statement of the problem

Globally there were 35 million people living with Human immunodeficiency Virus (HIV) in 2013. Almost 12.9 million people were receiving antiretroviral therapy (ART) at the end of 2013. Worldwide, only 38% of adults living with HIV had access to treatment. Three of four people receiving HIV treatment were living in sub-Saharan Africa, where the need is most acute.22 million, or three of five people living with HIV were not accessing ART. There were an estimated 24.7 million [23.5–26.1 million] people living with HIV in sub-Saharan Africa, nearly 71% of the global total([1](#_ENREF_1)).

In Ethiopia HIV adult prevalence was estimated at 1.5% in 2011([2](#_ENREF_2)).In 2013 there were an estimated 793,700(716,300-893,200) people living with HIV/AIDS. Approximately there were 45,200 (36,500-55,200) Acquired Immune Deficiency Syndrome (AIDS) related deaths and about 898,400 (770,700–1,048,500) AIDS orphans in the same year.

ART has played an important role in improving the prognosis and quality of life of HIV/AIDS patients, and in reducing the rate of disease progres­sion and death([3](#_ENREF_3)).

Adherence is defined as a patient’s ability to follow a treatment plan, take medications at prescribed times and frequencies, and follow restrictions regarding food and other medications. Both patients and health care providers face significant challenges with respect to adherence to ART ([4](#_ENREF_4)).

 At least 95% adherence (missing no more than three doses per month) is required for ART regimens to be fully effective and to avoid the emergence of resistant strains of the virus([5](#_ENREF_5)).However, poor ART adherence can create a dangerous public health problem and limit the effectiveness of available HIV treatments ([6](#_ENREF_6)).

Adherence is a complex behavior, which is influenced by several determinants belonging to the domains: the patient, the treatment, the disease state, the physician and patient-physician relationship and the health care system([5](#_ENREF_5)).

In 2012, over 9.7 million people living with HIV in low- and middle-income countries were receiving ART ([7](#_ENREF_7)).However, ensuring adherence to HIV treat­ment remains challenging in all countries. A meta-analysis of patients in North America (*n* = 17 573) and Africa (*n* = 12 116) estimated that only 55% and 77% in these areas, respectively, achieved over 80% adherence([8](#_ENREF_8)).

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| A study showed that a pooled estimate of only 77 percent of people taking ART medications in sub-Saharan Africa adhered to the regimen ([9](#_ENREF_9)). People living with HIV and their care providers often face challenges in ensuring good adherence. A 2011 meta-analysis, which pooled ART adherence of 33 199 adults in 84 observational studies, reports that only 62% of individuals took at least 90% of their prescribed ART doses ([10](#_ENREF_10)).Depending on the drug under study, adherence to ARV varies between 37 to 83 percent([11](#_ENREF_11)). In Ethiopia by the end of June 2013 the number of people ever started ART were 439,301 but Only 70.3% of individuals who ever started ART were currently on treatment indicating challenges in patients’ retention. Of the estimated 593,400 adults living with HIV at the end of 2013,298,512 (50%) were on treatment. patient loss to follow-up and ensuring adherence to ART regimens remain major challenges of the ART program([12](#_ENREF_12)).In some Regions of Ethiopia factors associated with non-adherence to ART were studied. However these different studies come out with different findings and there is scant information on factors associated with non adherence to ART in Tigray Region particularly in Aksum. Therefore this study will identify factors associated with non adherence to ART among HIV/AIDS adults in Aksum town and can help as planning interventions and effective strategies for maximizing long-term adherence to ART in the study area. |
| Literature review |  |

Adherence to treatment is critical to obtain full benefits of ART including maximum and durable suppression of viral replication, reduced destruction of CD4 cells, prevention of viral resistance, promotion of immune reconstitution, and slowed disease progression([13](#_ENREF_13)). Successful HIV therapy requires adherence greater than 95%([4](#_ENREF_4)). However in Ethiopia adherence rate were reported below the required level due to different factors associated with non-adherence to ART ([5](#_ENREF_5), [14](#_ENREF_14), [15](#_ENREF_15)).

* + 1. **Factors associated with non-adherence to ART**

**Socio demographic factors**

In Nepal females reported non- adherence were nearly seven times higher than males([16](#_ENREF_16)). Similarly in Zambia females adherence to ART was 3.3 times more higher than males ([17](#_ENREF_17)). study of systematic review in Cameroon showed female gender was found to increase adherence level ([18](#_ENREF_18)). In southern Ethiopia females were 67.8% less likely at risk of non-adherence to ART than male patients ([19](#_ENREF_19)). But In Nigeria and harari eastern Ethiopia sex did not significantly affect adherence to ART([15](#_ENREF_15), [20](#_ENREF_20)).

a study of systematic review in Cameroon showed that age greater than 49 years and higher levels was found to increase adherence level. But In Nigeria and Kenya age, did not significantly affect adherence status ([20](#_ENREF_20), [21](#_ENREF_21)).

Qualitative study in Tanzania explored that religion contributed to a lower adherence motivation among HIV-infected individuals who were on ART ([22](#_ENREF_22)).

In Senegal respondents who were singles tend to complied better adherence than other groups (married and widowed ) ([23](#_ENREF_23)). However in Nepal, Kenya and harari estern Ethiopia, no significant associa­tions was found between marital status and adherence ([15](#_ENREF_15), [21](#_ENREF_21), [24](#_ENREF_24)).

Study conducted in Nepal showed that being illiterate was 4.58 times increased likelihood of non-adherence to ART([16](#_ENREF_16)).Similarly in Lao PDR, those who had educational level at secondary school were 3.7 times more adherent than that of below secondary level of education ([25](#_ENREF_25)).Systematic review in Cameroon also showed that higher levels of education was found to increase adherence level,([18](#_ENREF_18)). However other study in Nepal, Nigeria, Senegal, harari eastern Ethiopia showed that no significant associa­tions was found between education level and adherence ([15](#_ENREF_15), [20](#_ENREF_20), [23](#_ENREF_23), [24](#_ENREF_24)).

 Meta-analysis included 28 studies involved 8743 HIV-infected individuals from each14 developing and developed countries showed that patients with HIV infections who were employed were 27% more likely to adhere to ART than those who were unemployed ([26](#_ENREF_26)).But study in Delhi India and Senegal reported that there was no statistically significant association between employment status and adherence rates([23](#_ENREF_23), [27](#_ENREF_27)).

As study reported in Nepal, those who live far away to treatment centre were less likely to adhere than their counter parts ([16](#_ENREF_16)).But to the reverse, in Kenya respondents who accessed therapy in clinics within a walking distance were about two and a half times more likely non- adherent than patients who refilled in far away clinics ([21](#_ENREF_21)).

**Psychosocial factors**

In Kenya and Nepal social support was not associated with non-adherence to ART([21](#_ENREF_21), [24](#_ENREF_24)). However in southwest and eastern Ethiopia patients who had no family and social support were more likely to be none adherent to ART as compared to those who get materials and financial support from their family, religious and social organizations ([19](#_ENREF_19), [28](#_ENREF_28)).

Non-disclosure of HIV status to anyone was positively associated with non adherence in Nepal ([16](#_ENREF_16)).As study reported in Togo PLWHA who disclosed their HIV status to their sexual partners were seven times more likely to have good adherence to ART than that of not disclosed their HIV status ([29](#_ENREF_29)). In Ethiopia Debremarkos Hospital, participants who were feel comfort on taking ART drug in front of others were 5.4 more likely adherent to regimens as compared with those who were not feel comfort on taking ART drug in front of others([5](#_ENREF_5)). But in Zambia and Harari eastern Ethiopia no associations was found between self-stigma and non adherence ([15](#_ENREF_15), [17](#_ENREF_17)).

As study reported in Nepal those who drank alcohol were 12.89 times more non adherent to their medication than those who did not drank alcohol ([16](#_ENREF_16)). Study in Hararieastern Ethiopia also reported that alcohol consumers were 5.88 times more likely none adhere to ART as compared to none drinkers ([28](#_ENREF_28)).

**Medication related factors**

Study in Kenya, Lao PDR and south Ethiopia reported that adverse effects did not significantly influence non-adherence ([21](#_ENREF_21), [25](#_ENREF_25), [28](#_ENREF_28)). In the contrary in northwest Ethiopia, those who had ART adverse effects were 1.4 times non adherent than that of without adverse effects of ART ([14](#_ENREF_14)).

In Kenya duration on ART did not significantly influence non-adherence([21](#_ENREF_21)).But in Nepal and Lao PDR those who took ART for a long duration were less adherent than those of who staid short period on ART ([16](#_ENREF_16), [25](#_ENREF_25)). similar results were found in Ethiopia ( Debremarkos and Yirgalem Hospitals) on which the respondents’ adherence rate was inversely proportional to the length of time they had been on ART([5](#_ENREF_5), [19](#_ENREF_19)).

Traditional medicines was negatively associated with non adherence to ART in Nigeria([20](#_ENREF_20)).similarly in Nepal those who had history of illegal drug use were nearly four times non adherent than their counter parts ([24](#_ENREF_24)) .

As study sowed in south Ethiopia Opportunistic infection and WHO stage did not show significant association with none adherence to ART ([28](#_ENREF_28)).

**Nutrition related factors**

In Cape Town, South Africa; food insecurity was significantly associated with non-adherence, and constitutes a threat to adherence for those who were managing optimal adherence. Thirty seven percent of all participants in the study reported not always having food with which to take their ART([30](#_ENREF_30)). study in Zambia also revealed that food insufficiency was positively associated with treatment non adherence([17](#_ENREF_17)).In north Ethiopia inability to get enough and/or quality food and BMI<18.5 Kg/m2) had positive significant association with non-adherence to ART ([31](#_ENREF_31)).Similarly in southern Ethiopia those who had BMI less than18.5 Kg/m2 was 2.83 times more non-adherent to ART than that of who had body mass index(BMI) of greater than or equals to 18.5 ([28](#_ENREF_28)).

**Immunological related factors**

As study identified in India those with higher CD4 counts had significantly lower non adherence rates compared patients having lower CD4 counts <200 cells/mm3 (P = 0.0125).On the contrary study of systematic review in Cameron revealed that lower CD4 count was associated with non-adherence to ART medication ([18](#_ENREF_18)).But as study conducted in Lao PDR,CD4 count did not significantly correlate with non-adherence to ART([25](#_ENREF_25)).

In south and north Ethiopia studies revealed that those who had less CD4 count were more likely none adherent to ART as compared to their counterpart ([28](#_ENREF_28), [31](#_ENREF_31)). But study in Yirgalem Hospital showed patients who had high CD4 counts were 6.125 times more likely at risk of non adherence to ART than those who had less CD4 counts ([19](#_ENREF_19)).

 For factors associated with non-adherence to ART; being busy, forgetfulness, distance to the clinic, running out of medication, having too many pills to take, the taste of the medication, severe side effects, difficulties in maintaining the medication regiment and self-stigma were explained by different scholarliness in different countries ([16](#_ENREF_16), [17](#_ENREF_17), [25](#_ENREF_25), [32](#_ENREF_32)).

### Conceptual framework

Figure I determinant factors on non-adherence to Antiretroviral Therapy among HIV infected adults.

**Nutrition/Feeding related factors**

* BMI
* Food diversity
* Feeding frequency

**Socio-demographic and economical factors**

* Sex
* Age
* Religion
* education
* Employment

**Psychosocial related factors**

* Social support
* Stigma
* Disclosure
* Alcohol use
* Substance use(smoking, chat chewing)

**Immunological factors**

* CD4 count

**Medication related factors**

* Treatment Side effect
* WHO staging
* Duration on ART
* Traditional medication
* Treatment regimen
* Opportunistic infection

## Justification of the study

Human immune deficiency virus poses a unique challenge due to its rapid replication and mutation rates. Successful HIV therapy requires adherence greater than 95% to achieve long term suppression of viral load. But taking ART medicines life-long treatment is one of the biggest challenges and non-adherence remains a major concern due to different factors related to individual characteristics, Social/environmental conditions and Health care delivery systems.

Adherence is a dynamic process on which adherence status changes over time and is Influenced by multiple factors (no factor stands alone) ([4](#_ENREF_4)). Though there are few studies on adherence to ART in Ethiopia, there is scant information on factors associated with non-adherence to ART in Tigray Region particularly in Aksum town.

Therefore this study will identify determinant factors associated with non adherence to ART among HIV/AIDS infected adults and can help as baseline information for planning interventions and effective strategies for maximizing long-term adherence to ART in the study area and for other scholars doing studies in the issues of ART adherence.

# Objective of the study

To identify determinants of none-adherence to Antiretroviral Therapy among HIV infected adults on ART.

# Methods

## Study design

Institution based unmatched case control study design will be used.

## Study setting and Period

1. The study will be conducted in Aksum town. Aksum town is found in Central Zone of Tigray Northern Ethiopia. Aksum is located 1067 K/m north of Addis Ababa which is the capital City of Ethiopia. In Aksum town there are two health centers and one referral hospital. The hospital serves as a referral for an estimated population of 1.2 million. Currently in Aksum health center 251 and Aksum St.Marry hospital 1330 totally 1581 HIV infected adults are on ART. The study period will be from march20/ 2015 to April 20/2015.

## Source Population

The source population will be HIV/AIDS positive adults who are on ART in Aksum town.

## Study Population

The study population will be HIV/AIDS positive adults who are on ART in Aksum town.

## Sample size calculation

The sample size will be computed by Kelsey formula in Epi Info version7 StatCalc for un-matched case control study. 5% type I error, 80%, power and 1:2 ratio of non-adherent cases to adherent controls will be used to carry out sample size. 12.1%, proportion of exposure among adherent (controls), 21.8 proportion of exposure among non-adherent(cases) and 2.18 odds ratio(OR) will be used ([28](#_ENREF_28)).Then the sample will be 130 for cases and 260 for controls. With 5% adjustment for non response and data incompleteness, the sample size will be 137 for cases and 273 for controls. Therefore the final sample size for the study will be 410.

## Sampling procedure

First baseline assessment will be conducted to identify the number of non adherent (cases) and adherent (controls) clients in Aksum St.Marry hospital and Aksum health center. Cases will be defined as HIV-infected clients who started ART that will report having ingested less than 95% of the total number of the prescribed antiretroviral medication and controls will be having ingested 95% or more of the total number of the prescribed antiretroviral medication in the current visit. Then based on this baseline assessment, proportional sample allocation will be done for Aksum St.Marry Hospital and Aksum Health Center.Participants will be selected by using systematic random sampling method.

## Inclusion and exclusion criteria

### Inclusion criteria

HIV-infected adults greater or equals to18 years old receiving ART at the study site for six month or more will be included in the

### Exclusion criteria

ART clients seriously ill and being hospitalized unable to communicate will be excluded from the study.

## Study variables

Dependent variable: non adherence to ART

Independent variables includes

Socio-demographic and economical factors: - age, sex, religion, marital status, educational status, occupation, income and residence

Psychosocial factors: - social support, disclosure of sero-status, alcohol use and substance use (cigarette smoking and chat chewing).

Medication related factors:- WHO staging, opportunistic infection, duration on ART treatment, side effect of ART, adherence to schedule and illegal drug use

Nutrition/feeding related factors: - BMI, feeding frequency and dietary diversity

Immunological factor: - CD4 count

## Operational definition of variables

Adherence to ART: - is defined as taking one’s medicine as prescribed and agreed between the patient and provider which is 95% or more adherences to ART(95% or more adherence = missing ≤2 doses of 30 doses or ≤3 doses of 60 doses).Over all adherences recorded as the number of drugs taken correctly as a proportion of drugs prescribed ([28](#_ENREF_28), [31](#_ENREF_31)).

Non-adherence to ART: - is the condition of missing doses completely, not following information given by a physician, as well as taking drugs inappropriately(less than 95% adherence = missing >2 doses of 30 doses or >3 doses of 60 doses) ([28](#_ENREF_28), [31](#_ENREF_31)).

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 outside home. It is classified as low < 3 food items, medium 4-6 food items and ≥6 food items as higher based on Food and Agriculture Organization (FAO) recommendation([31](#_ENREF_31)).

Depression: - a score of 1 to 4-No depression, 5 to 9 mild depression, 10 to 14 moderate depression, 15 to 19-moderately severe depression and 20 to 27 severe depression([33](#_ENREF_33)).

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## Data collection procedure

### Data collection instrument

Document review and structured pretested questionnaire developed from different literature will be used to collect data. Data on socio-demographic, Psychosocial, Patient characteristic, and Service provision factors related to none adherence to ART will be collected using interview by tigrigna version questionnaire. The questionnaire will be first developed in English version and translated to the local language tigrigna version and then translated back to English by different interpreters to check for its consistency. Secondary data on HIV related clinical information will be extract from ART registration follow up charts.

### Data quality control

In order to ensure quality of data, by taking 5% of the total sample size, pre testing of the questionnaire will be done on HIV/AIDS clients on ART nearby Health Center a week prior to the actual study and necessary modification will be done for the questionnaire according to the gap identified.

Two day training will be given to data collectors and supervisors on how to approach the clients and how to collect data from ART registration charts. Interview of participants will be carried out in private room. Data collection process will be strictly followed day to day by the supervisor and principal investigator and the collected data will be checked for completeness and consistency every day by supervisor and principal investigator.

### Data management and analysis

Data will be coded and entered into epinfo version 7.0 and will be exported to STATA Version 12 for analysis. Descriptive analysis will be conducted to describe the study participants in relation to relevant variables. Bivariate analysis will be used to assess the presence and degree of association between dependent and independent variables.

Finally factors that show association in bivariate analysis and which has P-value less than 0.2 will be entered in to multiple logistic regression models for controlling confounding factors and to identify significant factors of non-adherence to ART among HIV infected adults. At the end adjusted OR with 95% CI and P-value <0.05 Will be considered as significant.

# Ethical consideration

Ethical clearance will be obtained from Review Board of institute of public health, collage of Medicine and Health Science, University of Gondar. An official permission letter will be obtained from Aksum St.Marry hospital and Aksum health center medical directors and administrators to get formal permission. During data collection written consent will be obtained from each participant after they are introduced the purpose and importance of the study. They will be informed about their rights to interrupt the interview at any time. To ensure confidentiality, all of the study participant will be assured that the data will be anonymous, name or any other personal identifiers will not be recorded.

# Dissemination and utilization of results

The result of this study will be presented and communicated to university of Gondar, college of medicine and health science institute of public health as part of MPH in Epidemiology and Biostatistics. The findings will be also communicated to Aksum St.Marry hospital and Aksum health center medical directors and administrators, district health offices and Tigray Regional health bureau. Publication in Scientific journal and online dissemination will be considered.

# Work plan

GANTT chart showing a work plan to identify determinant factors of non adherence to ART among HIV infected adults in Aksum town, Tigray, Northern Ethiopia, 2015.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| S.N | Activity | Responsible person | February  | March  | April  | May | June  |
| 1 | Development of the research proposal and 1st draft submission | PI and Advisors |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Proposal defense | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Approaching funding agencies  | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Final proposal submission | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 | Securing Ethical clearance | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 | Arranging study site and administration  | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7 | Recruiting and training of supervisors and data collectors | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 | Pre-testing questionnaire and Data collection | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 9 | Data coding, entry and clearing  | PI, sup & DC |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 10 | Data analysis and interpretation | PI and advisor |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 11 | Thesis write up and submission of first draft | PI and advisor |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 12 | Second draft submission | PI and advisor |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 13 | Mock defense  | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 14 | Thesis defense |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 15 | Final report submission | PI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**PI**- principal investigator, **Sup** –supervisor, **DC**-data collecton

# Budget breakdown

Budget breakdown for undertaking a post graduate research on determinants of non adherence to ART among HIV infected adults in Aksum town; Northern Ethiopia, 2015

|  |
| --- |
| **Budget category** |
| **Part I. personal cost** |
| S.N | Title  | Qualification  | Activity  | Unit cost | No.of days | Total ETB |
| 1 | Principal investigator | 1 BSC | Pre-test, training and data collection | 200 | 15 | 3000 |
| 2 | Data collector | 3 Diploma nurse | training and Pre test | 200 | 2 | 1200 |
| 3 | Data collector | 3 Diploma nurse | data collection | 15 birr per questionnaire | 13 | 4035 |
| 4 | Supervisor  | 2 BSC nurse/Health Officer | Pre test, training and data collection | 200 | 15 | 6000 |
| Sub total  | 14235 |
| **Part II. Stationery and supplies** |
|  | Type | qualification | Unit cost | Quantity  | Total/ ETB | Activity  |
| 1 | Pen | Bic | 5 | 10 | 50 | For training and supervision |
| 2 | Pencil  | Dot pencil | 2 | 10 | 20 | For training and supervision |
| 3 | Eraser  | Each  | 2 | 5 | 10 | For training and supervision |
| 4 | Note pad | SINARLINE | 15 | 5 | 75 | For training and supervision |
| 5 | CD-RW | Sony | 25 | 5 | 125 | For submission of the document in soft copy |
| 6 | Flash disc | Each | 200 | 1 | 200 | To keep documents |
| 7 | Paper | Pack | 150 | 1 | 150 | For training and supervision |
| 8 | Duplicating questionnaire  | Copy | 1 | 2860 | 2152 | For pretest and data collection  |
| 9 | Printing the final proposal | Print | 3 | 2x3x55 | 330 | For submission of the document in hard copy |
| 10 | Printing the final thesis report | Print | 3 | 3x70x2 | 420 | For submission of the document in hard copy |
|  | Sub total  | 3532 |  |
| **Part III:Transport**  |
|  |  | Rate | Duration | Number  | Total  |
| 1 | Investigator  | 12birr/day | 15 | 1 | 180 |
| 2 | Supervisor  | 12birr/day | 15 | 2 | 360 |
| 3 | Data collector | 12birr/day | 15 | 3 | 540 |
|  | Sub total | 1080 |
|  | **Part IV:Other** |
| 1 | Refreshment  | 100birr/day | 2 | 6 | 1200 |
| 2 | House rent | 200 | 2 | 1 | 400 |
| 3 | Mobile | 50 | 15 | 1 | 750 |
|  | Sub total | 2350 |

**Budget summary**

|  |  |  |
| --- | --- | --- |
| S.N | Category  | Cost in ETB |
| 1 | personal cost | 14235 |
| 2 | Stationery cost | 3532 |
| 3 | Transport cost | 1080 |
| 4 | Other cost | 2350 |
| 5 | Total | 21197 |
| 6 | 10%contigencey  | 2119.7 |
|  | **Grand total** | **23316.70** |

**Budget justification:** since data collection is primary and secondary, longer time will be given for data collection and majority of the budget (17665ETB) will be for data collection

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# Annexes

## Annex one: Dummy tables

**Table-1:** Socio-demographic characteristics of the study participants on ART in Aksum town northern Ethiopia, 2015

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable  | Non adherence to ART | Adherent to ATR | frequency | % |
| Sex: 1,Male 2,Female  |  |  |  |  |
| Age  |  |  |  |  |
| Residence: 1,Rural 2,urban |  |  |  |  |
| Religion: 1,Orthodox 2,Muslim 3,Other |  |  |  |  |
| Education level: 1,No education 2,Read and write 3,1-8 grade 4,9-12 grade 5,Higher education  |  |  |  |  |
| Occupation: 1,No occupation 2,Government employed 3,Busnes /self employed 4,Daily laborer  |  |  |  |  |
| Income  |  |  |  |  |

**Table-2:** Bivariate and multivariate analysis between explanatory variables and none adherence to ART among HIV/AIDS on ART in Aksum town northern Ethiopia, 2015

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Explanatory Variable |  Adherence statues | Crude OR (95% CI) | CORP-value | Adjusted OR (95% CI) | AORP-value |
| Non adherent (%) | Adherence (%) |
| Sex: Male  Female |  |  |  |  |  |  |
| Residence : Urban  Rural  |  |  |  |  |  |  |
| CD4 count: ≥500 201-499 ≤ 200 |  |  |  |  |  |  |
| WHO stage I II III  IV |  |  |  |  |  |  |
| Side effect of drugs : Yes No  |  |  |  |  |  |  |
| Opportunistic infection: yes No |  |  |  |  |  |  |
| Family support: yes No |  |  |  |  |  |  |
| Dietary diversity:  ≤ 3 food groups 4-5 food groups ≥6 food groups  |  |  |  |  |  |  |

## Annex two: Consent form in English language

Institute of Public Health Department of Epidemiology and Biostatistics, collage of Medicine and Health Science, University of Gondar study questionnaire on the determinants of none-adherence to Antiretroviral Therapy among HIV infected adults in Aksum town, North Ethiopia, 2015.

**Dear madam/sir good morning /good afternoon**

My name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.I am working as data collector in research project, which is conducted by University of Gondar. The aim of this study is to identify determinants of none-adherence to antiretroviral therapy among adultPeople Living with HIV/AIDS in Aksum town, Northern Ethiopia. Identifying these factors will help to design and implement an intervention to improve treatment adherence of ART clients to their medication.

Since you are taking ART, I would like to ask you some questions concerning this study. The information you will be giving me will be used only for study purpose and your name, identification number and address are not required. All your personal information will be confidentially treated.

To fill this questionnaire it will take from 15-20 minutes. You have all the right to refuse to answer to any of the questions and withdraw at any time.

If you are interested to participate, will you sign here please?

1. Yes, (if say yes thanks and continue with her)

2. No, (if say no thanks and skip her)

Participant’s signature ----------------------------------

## Annex three: Information sheet in English language

**Title of the Research Project**: To identify determinants of none-adherence to antiretroviral therapy among adultPeople Living with HIV/AIDS in Aksum town, Northern Ethiopia, 2015

**Name of Principal Investigator:** Berhe Beyene

**Name of the Organization:** University of Gondar College of Medicine and Health Sciences, institute of Public Health Department of Epidemiology and Biostatistics

Information sheet and consent form prepared for persons who are going to participate in this research project.

 **Introduction**

This information sheet and consent form is prepared with the aim of identifying determinants of none-adherence to antiretroviral therapy among adultPeople Living with HIV/AIDS. The research group includes the principal investigator, three data collectors, two supervisors, and two advisors from University of Gondar.

**Purpose of the Research Project**

The aim of this study is to identify determinants of none-adherence to antiretroviral therapy among adultPeople Living with HIV/AIDS in Aksum town, Northern Ethiopia, 2015 which is essential to formulate a better new policy strategies and intervention measures. The results of this study will be used to design appropriate intervention programs to address the none-adherence to antiretroviral therapy among adultPeople Living with HIV/AIDS during their medication.

**Procedure**

This study involves adult people on ART. You are randomly selected to be one of the study participants if you are willing to take part in this study; we kindly invite you to take part in our project. If you are willing to participate, we are so happy and we need you to clearly understand the aim of this study and to sign the consent form. Finally you are kindly requested to give your genuine response in the interview questionnaire. You do not need to tell your name to the data collector and all your responses and the results obtained will be kept confidentially by using coding system whereby no one will have access to your responses.

**Benefits,**

By participating in this research project you may feel some discomfort in wasting your time (a maximum of 20minutes) .However, your participation is definitely important to the level ART utilization and its associated factors so as to design appropriate strategy and intervention to enhance adherence to ART. The result will be disseminated to University of Gondar College of Medicine and Health Science, institute of public health, Tigray Regional Health Bureau, Aksum St Marry hospital and Aksum health center

**Risk and /or Discomfort**; there is no risk or direct benefit in participating in this research project.

 **Incentives/Payments for Participating**

You will not be provided any incentives or payment to take part in this project.

**Confidentiality**

The information collected from you will be kept confidential and stored in a file, without your name by assigning a code number to it. And it will not be revealed to anyone except the principal investigator and will be kept locked with key

**Right to Refusal or Withdraw**

Participating and not participation is the full right participants and they can stop participating in the study at any time. They can also skip any question which they want to respond. They can ask any question which is not clear for them.

**Person to contact**

This research project will be reviewed and approved by the ethical committee of the University of Gondar. If you have any question you can contact any of the following individuals and you may ask at any time you want.

 a) Name: Berhe Beyene: Telephone: +2519 10893579

b) Professor Yigzaw Kebede (MD, MPH, Telephone +**251 913 99 79 33**

 c) Mr.Yalemzewod Assefa (MPH): Telephone +**251**911568477

## Annex- four. Assent form

I have been informed that the purpose of this study is to identify determinant factors of non adherence to ART among adultPeople Living with HIV/AIDS.I have understood that participation in this study is entirely voluntarily. I have been told that my answers to the questions will not be given to anyone else and no reports of this study ever identify me in any way. I have also been informed that my participation or non-participation or my refusal to answer questions will have no effect on me. I understood that participation in this study does not involve risks.

Respondent’s signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If no, skip to the next participant

Date of interview: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time started: \_\_\_\_\_\_\_ Time finished: \_\_\_\_\_\_\_\_\_

Interviewer Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_

Supervisor’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ signature \_\_\_\_\_\_\_\_

## Annex – five: Structuré English version questionnaire

University of Gondar College of Medicine and Health Science, Institute of Public Health questionnaire on determinant factors of non adherence to ART among adultPeople Living with HIV/AIDS in Aksum town, Northern Ethiopia, 2015

|  |
| --- |
| **Section I: questions on socio-demographic and economical factors** |
| No,  | Questions  | Coding categories | Code |
| 101 | Sex  | 1,male2,female |  |
| 102 | Age in years | --------------- |  |
| 103 | Religion | 1,Orthodox2,Muslim3,Other specify------------- |  |
| 104 | Ethnicity  | 1,Tigray2,Amhara3,Oromo4, Other specify------------ |  |
| 105 | Residence | 1,Urban2,Rural |  |
| 106 | Marital status | 1,single2,Married3,Widowed4,Divorced5,separated |  |
| 107 | Educational status | -------- |  |
| 108 | Distance from health facility in K/m | ---------- |  |
|  | Occupation type | 1,no occupation2,government employed3,busnes/self employed4,Daily laborer |  |
| 109 | Monthly income in ETB | --------- |  |
|  | **Section II: Questions on nutrition related factors** |
| 110 | During the previous 24 hours period (yesterday and night)did you consume the following?(mark all that you apply) |
|  | * Any bread, rice noodles, biscuits, or any other foods made from millet, sorghum, maize, rice, etc?
* Enjera made from whole grains like wheat, sorghum, teff, corn etc?
* Any vegetables, any meat like beef, chicken, liver, kidney, heart, or other organ?
* Any eggs?
* Any fresh or dried fish or shellfish?
* Any foods made from beans, peas, lentil, or nuts, any cheese, yogurt, milk, or other milk products?
* Ay foods made with oil, fat, or butter?
* Any sugar or honey?
* Any other foods, such as condiments coffee, or tea?
 |  |
| 111 | Daily eating pattern of last 12 months1, Three meals & above2,Two meals & eating between meals2,Two meals or less |  |
|  | **Section III: Questions on medication related factors** |
| 112 | For how long have you been on ART? | 1,6-12 months2,13-24 months3,>=24 months |  |
| 113 | How many times did you take your medication per day | 1,Once2,Twice3,Three times4,Four times 5,Do not know |  |
| 114 | Are there are any other medications that you are taking? if no skip to question 116 | 1,Yes2,No |  |
| 115 | If yes to question 114, what types of medications are taking? | 1,traditional2,modern |  |
| 116 | Have you ever faced drug side effects | 1,yes2,no |  |
| 117 | We appreciate how difficult it can be to take pill on daily basis. In the last one month, while you feel better/worse, did you sometimes take a break from your medication? | 1,yes2,no |  |
| 118 | Thinking about the last three days how many doses did you ever forget to take your ART medicine? | 1,One dose2,Two dose3,Three dose and more |  |
| 119 | Thinking about the last seven days how many doses did you ever forget to take your ART medicine? | 1,One dose2,Two dose3,Three dose and more |  |
| 120 | Thinking about the last month how many doses did you ever forget to take your ART medicine? | One dose2,Two dose3,Three dose and more |  |
| 121 | Some people find that they forget to take their pills on the weekend days. On the last month how often did you miss any of your anti-HIV medications(Saturday or Sunday) | 1,Always2,Usually3,Seldom4,Never  |  |
| 122 | Reasons for missing doses | Toxicity-Side effectShared with othersSimply forgetFelt betterToo illPoor interaction with health care providerDrug out of stock(health facility)Patient run out of stock/lost themDo not know doseAlcohol FastingStart other treatmentAway from homeToo many pills Long waiting time Missed appointment Stigma/discriminationOthers specify------------- |  |
| **Section IV: Questions on psychosocial factors** |  |
| 123 | Do you have history of active substance use?If no skip to question124 | 1,yes2,no |  |
|  | If yes to question 123 which substance do you use? | 1,chat2,cigarette3,alcohl4,IVdrug5,Others specify---------- |  |
| 124 | Whit him do you live? | 1,Live alone2,With my parents3,Unstable4,Other specify----------- |  |
| 125 | Do you disclose your HIV status to your partner? | 1,Yes2,Ne3,don’t know |  |
| 126 | Do you disclose your HIV status to others? | 1,Yes2,No3,don’t know |  |
| 127 | Do you have any emotional and practical support? If no skip to128 | 1,yes2,no  |  |
|  | If yes to question 127, who supports you**?** | 1,Family2,friends/peers3,homebased care providers / community4,health care providers5,others specify------ |  |
| 128 | Do you have any emotional and practical support? | 1,yes2,no  |  |
| 129 | What type of support do you get from your supporters**?** | 1,material/financial2,information/advice3,social/moral4,others specify |  |
| 130 | Do you feel you are excluded from any social gathering (weeding, funeral, party and community association group)? | 1,Yes2,No3,Do not know |  |
| 131 | Over the last two weeks how often have you been bothered by any of the following problems?(CIRCLE ONE NUMBER ON EACH LINE)  | Not at all | Several days | More than half the days | Nearly everyday |  |
| 1.Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |  |
| 2.Feeling down, depressed or hopeless | 0 | 1 | 2 | 3 |  |
| 3.Trouble falling or staying asleep or sleeping too much  | 0 | 1 | 2 | 3 |  |
|  | 4.Feeling tired, or having little energy  | 0 | 1 | 2 | 3 |  |
| 5.Poor appetite or overeating | 0 | 1 | 2 | 3 |  |
| 6.Trouble concentrating on things | 0 | 1 | 2 | 3 |  |
| 7.Feeling bad about myself | 0 | 1 | 2 | 3 |  |
| 8.Moving or speaking so slowly that other people could have noticed | 0 | 1 | 2 | 3 |  |
| 9.Thoughts that I would be better off dead ,or of hurting myself | 0 | 1 | 2 | 3 |  |

**THANK YOU!** I have finished my interview if you have any question on ART?

## Annex – six: Structuré Tigrigna version questionnaire

Annex-seven: determinant factors of non adherence to ART from ART follow up charts among adultPeople Living with HIV/AIDS in Aksum town, Northern Ethiopia, 2015

|  |  |  |
| --- | --- | --- |
| S.N | Factors included in ART follow up form | Recent  |
|  | Adherence level/missed doses |  |
|  | Side effect/write all that apply | 1,2,3,4, |
|   | symptom screen/ write all that apply | 1,2 |
|  | Opportunistic infection/ symptom | 1,2, |
|  | Symptom screen/write all that apply | 1,2, |
|  | Dispense dose/regimen | 1,adult first line regimen2,adult second line regimen |
|  | WHO staging |  |
|  | Therapeutic /supplementary feeding | 1,yes2,no |
|  | BMI(kg/m2 |  |
|  | HGB(mg/dl) |  |
|  | WBC | 1,Neutrophill2,lymphocytes |
|  | Platelet |  |
|  | CD4 count |  |
|  | Evaluators impression about mental condition |  |

## Annex-eight: Assurance of investigator

The undersigned senior MPH Epidemiology and Biostatistics student agrees to accept responsibility for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as pre terms and conditions of the research and publications office of the University of Gondar.

Name of the student: Berhe Beyene

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ signature\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval of the advisor(s)

Advisors

 Name Signature Date

1. Professor Yigzaw Kebede (MD,MPHprofessor) \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_
2. Mr. Yalemzewod Assefa (MPH) \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_

## Annex-nine: Declaration

I the undersigned senior MPH Epidemiology and Biostatistics student declared that this thesis proposal is my original work in partial fulfillment of the requirement for the degree of Masters of Public Health.

Name: Berhe Beyene

signature\_\_\_\_\_\_\_\_\_\_\_\_\_

Place of submission Institute of Public Health, College of Medicine and Health Science, University of Gondar.

Date of submission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This thesis work has been submitted for examination with my/our approval as university of advisor(s).

Advisors

 Name Signature Date

1. Professor Yigzaw Kebede (MD,MPH,professor) \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_
2. Mr. Yalemzewod Assefa (MPH) \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_