ADDIS ABABA UNIVERSITY
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Comparison of antiretroviral treatment outcomes for a general hospital versus that of health centers:
A retrospective cohort study in southern – central Oromia

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Acronyms

AHR……Adjusted Hazard ratio

AIDS……..- Acquired immunodeficiency Syndrome

ART…….. Anti Retroviral Treatment/Therapy

ARV……. Anti Retroviral

AZT…….. Zidovudine

CD4……. Cluster of differentiation four

CI……Confidence Interval

CPT……Cotrimoxazole preventive treatment

d4T……. Stavudine

3TC…….. Lamivudine

EFV…….. Efavirenz

HAART……... Highly Active anti retroviral treatment

HC……. health Centre

HCT…….. HIV Counseling and testing

HIV…….. Human Immunodeficiency Virus

HOP…….. Hospital

HR……. Hazards ratio

IQR…… Inter quartile range

KM……Kilometer

LTFU…… Lost to follow up

ml…… Milliliter

mm^3……..Cubic millimeter

NGO……. Nongovernmental Organization

NNRTI…….. Non Nucleoside reverses Transcriptase Inhibitors

NRTI……. Nucleoside reverse Transcriptase Inhibitors

NVP…….Nevirapin

PLHIV……...People Living with HIV

PMO……. Person-Month of Observation

PMTCT……. Prevention of Mother to child transmission

RNA……. Ribonucleic Acid

RR…….Relative risk

RTI…….. Reverse Transcriptase Inhibitors

TLC…….Total Lymphocyte count

UN……...United Nations

UNAIDS…….....United nations program for HIV/AIDS

USAIDS……United States Agency for International Development Services

WHO……. World Health Organization

Table of Content

List of Tables

List of Figures

Abstract

Background: - Although antiretroviral treatment (ART) services scaling up is being practiced in the country since the last five years, documented evidence that shows the difference in the treatment outcomes between health center and hospital is not available.

Objective: - To compare the survival rate and antiretroviral treatment outcome among ART naïve patients in a general hospital versus that of health centres and to assess determinants affecting the outcome in both settings.

Design: - Retrospective cohort study supported by qualitative approach was conducted using secondary data from medical records of ART naïve patients collected between October 2006 and January 2010. The study compared the treatment outcome between health centers and a general hospital in southern central Oromia regional state. Univariate and multivariate analyses were implemented using Kaplan Meier and Cox proportional hazard models.

Results: - A total of 1,895 (1307 hospital and 588 health center) patient records were followed for 27,990 person-month. During the study period 172 (9.1%) deaths and 235 (12.4%) lost to follow up (LTFU) were recorded. The incidence density of death among ART naïve patients was 6.2 per 100 person-months and incidence of LTFU was 8.4 per 1000 person per month of observation. Risks of death and LTFU from ART treatment were the same between health centre and hospital HIV/AIDS patients. Independent predictors of risk death and LTFU (failure) for both categories of patients include male sex; AHR 1.4 (95%CI 1.1, 1.7), baseline performance scale three/four; adjusted hazard ratio (AHR) 2.4 (95%CI 2.0, 3.0); advanced disease stage; AHR 2.8 (95%CI 2.3, 3.4), baseline WHO stage, AHR 1.3 (95%CI 1.0, 1.6) and fair to poor adherence to ART; AHR 3.4 (95%CI 2.8, 5.2). Other socio-demographic and baseline variables had no associated with risks.

Conclusion and Recommendation: - The ART service scaling up to health centres did not compromise the treatment outcomes in adult ART naïve patients. Important predictors of risk of death and lose to follow up among HIV/AIDS patients on ART were having base line performance scale three/four, being male, having advanced disease and being fair to poor adherent to ART. Therefore, HIV/AIDS patients should be educated and encouraged to start the treatment in either facility as early as possible.

Introduction

Background:

The human immunodeficiency virus (HIV) has created an enormous challenge worldwide. Since its recognition, HIV has infected close to 70 million people, and more than 30 million have died due to acquired immunodeficiency syndrome (AIDS) [1, 2]. According to the UNAIDS 2008 report, globally, there were an estimated 33 million [30.3 million–36.1 million] people living with HIV in 2007 [2, 3]. Southern Africa continues to bear a disproportionate share of the global burden of HIV: 35% of HIV infections and 38% of AIDS deaths in 2007 occurred in this sub-region. Altogether, sub-Saharan Africa is home to 67% of all people living with HIV and for 75% of AIDS deaths in 2007 [3]. As of December 2007, an estimated 3 million people in low- and middle-income countries were receiving antiretroviral drugs, which represent 31% of those who need the medications, and with 45% increase over 2006 [4].

Ethiopia is the second most populous and one of the seriously affected countries in sub Saharan Africa [1, 2]. According to the single point estimate for prevalence of HIV/AIDS in Ethiopia, done in 2007, urban and rural prevalence was estimated to be 7.7% and 0.9% respectively for year 2009. Prevalence was 1.8% for males and 2.8% for females, and women accounted for 59% of the HIV-positive population. According to the Single Point Estimate, there were an estimated 1,116,216 people living with HIV in 2009, of which 336,160 were eligible for ART. There were an estimated 131,145 new HIV infection (57% Female) and 44,751 AIDS-related deaths (57% Female).There were an estimated 72,945 children less than 15 years old living with HIV, out of which 20,522 needed ART [5, 6]. Adult HIV prevalence in 2009 is currently estimated to be between 1.4% and 2.8%[7].

Antiretroviral treatment drugs (ART) are drugs prescribed to HIV/AIDS patients based on defined criteria, usually, in a combined form with two main objectives: to suppress the viral load and to reconstitute the immune system of the patients. The criteria used to initiate ART in Ethiopia are WHO clinical staging, TLC-count and CD4-count as used in combination or separately. The drugs have multiple categories; Reverse transcriptase inhibiter (RTI) is a major category commonly used in Ethiopia. This category has further sub groups of which Nucleoside Reverse Transcriptase Inhibitors (NRTI) and Non Nucleoside Reverse Transcriptase Inhibitors (NNRTI) are the most commonly used drugs containing 2NRTI + 1NNRTI in a dose [1, 5]. Use of ART drugs in developed countries dates back to mid of 1990s while its initial use in Ethiopia was about a decade later in 2003. In Ethiopia free ARV service was launched in January 2005 and public hospitals started providing free ARV in March 2005. In scaling-up of ART services in the country, health centers have started to deliver HIV care and ART in June 2006. As of March 2007, only about 32% of people living with HIV (PLHIV) in need of ART could be reached. This called for more strengthening and decentralization of the HIV care and ART services to the primary health facilities where low and mid level health workers are given new responsibilities of HIV care and ART services at lower levels [5, 8, 9].

Problem Statement:

Ethiopia, as a UN Member State, joined the international community in the Political Declaration on HIV/AIDS of the UN General Assembly issued on June 2006, which committed all countries to move towards universal access to HIV prevention, treatment, care and support by 2010. As part of this commitment, the rolling out of ART service has reached over 517 sites at the end of 2009 from only four sites in 2003, of which about 70% are health centers and only 10% of the facilities are privates requiring for some payment [7, 10, 11]. Number of HIV/AIDS patient who

accessed ART has also increased from 900 in 2003 to 226,801 in 2009 a quarter of which is receiving the service from public health centers [7, 11].

Over the last four years there is a rapid scaling up of HIV/AIDS prevention and control services including ART service in the country [5]. In Oromia the number of ART sites has reached 165 of which over 76% is health center [12]. In general more than two-third of the site are health centers which have less qualified heath workers & less equipped facilities as compared to hospitals [10]. On the other hand, ART is a drug which needs special precaution while prescribing it to patients in order to avoid risk of drug resistance[13]. ART service decentralization and task shifting from highly qualified to middle level health workers is ever increasing all over the country since 2005 [11]; but scientific evidences that show what is happening to the treatment outcome as task shifting goes on in the country are scarce. Therefore, it was crucial to contribute in filling this gap of evidence by using robust study design & reliable statistical models.

This study envisage determining the difference in ART treatment outcomes between a public hospital and rural health centers and assessing what is happening to the ART service outcomes as task shifting goes on. It would also serve as a bench mark for other researchers who would be interested in the area.

Literature Review

Task shifting in health service delivery system:

Sub-Saharan Africa, in general, is facing a crisis in human health resources due to a critical shortage of health workers. The shortage is compounded by a high burden of infectious diseases; emigration of trained professionals; difficult working conditions and low motivation. In particular, the burden of HIV/AIDS has led to the concept of task shifting being increasingly promoted as a way of rapidly expanding human resource capacity. This refers to the delegation of medical and health service responsibilities from higher to lower cadres of health staff, in some cases to non-professionals [14, 15]. There are different levels of task shifting such as shifting clinical care from physician to clinical officers, to clinical Nurses and to other less trained health workers [16]. This task shifting is believed to entail some opportunities and challenges to the health care. The opportunities include: increasing access to life-saving treatment; improving the workforce skills mix and health-system efficiency; enhancing the role of the community; cost advantages and reducing attrition. The challenges include: problem in maintaining quality and safety; addressing professional and institutional resistance; sustaining motivation and performance and preventing deaths of health workers from HIV/AIDS [14]. On the other hand a study reported that availability of resources alone is not a guarantee for quality of HIV care and treatment [17].

Measurement of ART outcome:

ART treatment out come is measured by gain in body weight/BMI, decrease occurrence and severity of opportunistic infections (OI), increase in total lymphocytes count (TLC) & CD4+ count or decrease in plasma HIV RNA level. Among these, measure of viral load is the best predictor of treatment success [9, 18-20]. Other indicators used to measure ART treatment outcome

include: patient functional status, disease stage as classified by WHO clinical staging, lost to follow up (LTFU) and patient survival [18, 21, 22]. Lost to follow up is calculated differently by different researchers as they may study over various durations of treatment. Total lymphocyte count is used as proxy indicator for CD4 count where the CD4 count technology is unavailable. Total lymphocyte of 1200 cell/ml approximate the cd4 count of about 200cells/ml[23].

Evidences related to ART outcomes from outside side of Africa:

Generally, it is reported that LTFU is lower in developing countries than developed countries as compared to that of the developed countries[20]. Study from Brazil reported that the incidence of LTFU was 3.72 per 100 person-years of follow-up, 95% CI (3.58–3.86) and varied among countries from 0.67 to 13.35. After adjustment for suspected confounders older patients, those with higher CD4 cell counts, and those who had started combination antiretroviral therapy all had lower incidences of LTFU, while injecting drug users had a higher incidence of LTFU [22]. Definite reason for LTFU is unclear; some of the reasons reported include loss of hope in medication, lack of food, mental illness, holy water, lack of money for transport fare, and presence of other illnesses. Taking hard drugs (cocaine, cannabis and IV drugs), excessive alcohol consumption, being bedridden, living outside the town where the patients receive ART and having an HIV negative or unknown HIV status partner were associated with defaulting ART [24]. Introduction of highly active antiretroviral therapy has resulted in a significant reduction in morbidity & mortality and significant changes in the causes of death among HIV/AIDS patients. According to a study which constructed a survival curve based on 597 adult patients notified as AIDS cases between 1997 and 2004, at a Hospital in Brazil, among those patients, 25% progressed to death by December, 2005. These 597 patients had a survival rate of 88% and 86% after one and two years, respectively, and a 75% likelihood of surviving to 1,984

days (66 months). Most of the deaths occurred during the first months after the diagnosis (median, 129 days). Comparing the patients within this group, the characteristics that were associated with lower survival were: male sex, hemoglobin < 10 mg/dl, lymphocytes < 1,000/mm^3, use of fewer therapeutic drugs and antiretroviral regimens and non-introduction of protease inhibitors (25). Another study from the same country which was designed to investigate AIDS survival time per AIDS-case definition and exposure category during the periods 1992 to 1995 and 1998 to 2001 reported the case-fatality rate per AIDS case in the study period to be 37.6% for symptomatic and 9.7% for the asymptomatic CD4 count<350 cells/mm^3 AIDS-case definitions. According to the study, in the multivariate Cox proportional hazards model, the AIDS-case definition (hazard ratio=4.48; 95% CI: 4.53 to 5.16) was strong predictors of survival [(26)]. Another study from Croatia reported that survival following the first AIDS-defining illness markedly improved in the period 1997-2000 compared to the period 1986-1996 (adjusted Hazard Ratio (HR)) for patients surviving more than 6 months: 0.11, (95% CI: 0.04-0.29). A CD4+ cell count of < 100 x 10^6/L was an independent risk factor for patients surviving up to 2 years (adjusted HR = 1.96; 95% CI: 1.1-3.43, p = 0.02). However, despite dramatic survival benefit of combination antiretroviral therapy, mortality at six months following the first AIDS event was similar in the two study periods and the one-year probability of death was still substantial (27.2%) in the period 1997-2000 [(27)].

Evidences related to ART outcomes from sub-Saharan Africa:

Evidence from Lusisiki in South Africa and Thyolo in Malawi showed that the use of nurses and community cadres in the delivery of ART significantly improved overall ART outcomes. That use of task shifting for HIV/AIDS care at two relatively new levels of the health system (health centers and the community) did not compromise quality but, on the contrary, was associated with

significantly better ART outcomes. According to the evidence, from those put on ART in HC and hospital respectively, 81% & 67.2% p. value <0.01 were alive and on ART after 12 months. Lost to follow up were 2.2% & 19.3% for health centre and hospital respectively with p-Value < 0.01. CD4 count ≥ 200cells/mm3 were 87.1% and 75.3% with p-value = 0.08 respectively [14, 28]. Another study witnessed that greater proximity and acceptability of services at the clinic level has led to a faster Uptake of task-shifting in the delivery of HIV services has demonstrated beneficial results; a recent study from South Africa found that, after six months of follow-up, outcomes such as viral suppression, adherence and retention of patients at sites without doctors were similar to those at sites with doctors. Favorable outcomes of the task-shifting approach have also been documented in Rwanda, where a nongovernmental organization, delivers HIV treatment and care services using a model that shifts tasks towards nurses and community health workers; in Haiti, where doctors exclusively perform only 2% of all tasks, the 12-month survival of the people ever started on antiretroviral therapy was comparable to survival outcomes in other resource-limited settings[29]. Study looking specifically at the delivery of HIV services found that the quality of HIV care provided by non-physician clinicians was similar to that provided by medical doctors who were HIV experts, and better than that provided by medical doctors who were not HIV experts[30].

Evidences from Ethiopia

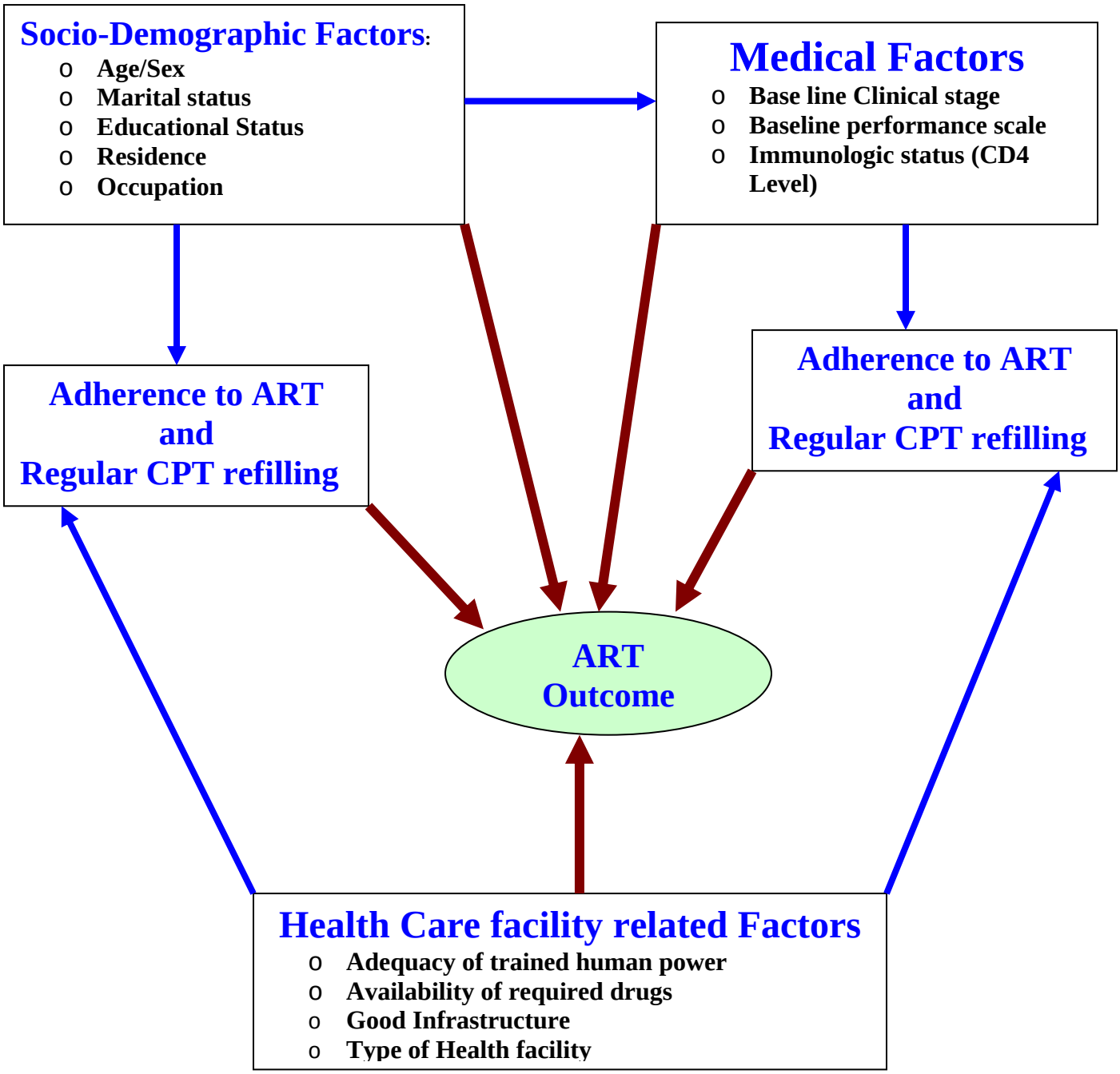
In the country, it was reported that a quarter of the AIDS patients put on ART during the period between 2005 and 2007 were lost to follow up. Among the these patients 55% were reported as drop (discontinued treatment for more than three months), 34% dead, 10% lost (discontinued treatment for less than three months), 0.8% stopped taking the treatment while the status of the remaining 0.2% was not known. The minimum survival of the ART cohort was also reported to

be 78.6% (n=89,451), 72.5% (n=62,659, and 64.6% (n=18,999) at 6, 12 and 24 months, respectively. Patients alive and on treatment significantly (R^2=0.91, p-value=0.0031) declined as duration of treatment increased. Patients treated at health center has shown the highest (n=13593, 82%) minimum survival as compared to those treated in hospitals (72%) (11). In the same national ART cohort study, it was revealed that high attrition from ART treatment is associated with being young (under 24 years of age), divorced, less educated and unemployed [(11)]. It was reported in study conducted in Arbaminch hospital that death rate among patients on HAART was 16.7%[(31)] .

Rationale and Significance of the Study:

Ethiopia is committed to move towards universal access to HIV prevention, treatment, care and support by 2010. In line with this commitment, the country started to expand the ART service to health centers from hospitals with related task shifting from medical doctors to heath officer and Nurses. Various evidences show that the ART up take is increasing with service decentralization, yet no evidence is available regarding the effect of this scaling up on the treatment outcomes. This service decentralization and task shifting to less qualified health workers may threaten the ART service quality; and this in turn endangers the overall HIV prevention interventions in the country. Understanding what is happening to the ART outcome has paramount advantages. Hence, it is very important to know what is happening to the treatment outcomes as the service scaling up goes on. Therefore, this study tried to shed light mostly on the difference on treatment outcome between hospital (former set up) and the health center (the new set up). It also looked up to the major factors contributing to the unwanted treatment outcomes. The study recommended essential intervention directions to be utilized by service implementers and program managers.

Analytical Framework of Determinants influencing ART outcomes



Objectives

General Objectives

To compare the survival rate and antiretroviral treatment (ART) outcome among the treatment naïve patients in a general public hospital versus that of rural health centres.

Specific Objectives

1. To compare clinical improvements among patients on ART in the two categories of health facilities.
2. To compare immunological progress (change in CD4 count) among patients on ART in the two categories of the facilities.
3. To compare survival rate among ART naïve patients on treatment in the two categories of the health facilities.
4. To identify factors affecting the treatment outcomes among patients on the treatment.

Methods and Materials

1. Design and Study Period

Retrospective cohort study design supported by qualitative method was used. Secondary data from medical records of patients on antiretroviral treatment at a general Hospital and three rural health centers in the southern central Oromia were used as major data source. The key informants participated in the interview were ART clinic head, laboratory and pharmacy department heads in respective health facilities.

The data used in the current study included medical records of the patients which were collected between October 2006 and January 2010 in the selected facilities.

2. Study area

The study was conducted involving four public health facilities, which have been providing ART service October 2006, in the West Arsi zone of Oromia region. The zonal capital town, Shashemene, is located 250 Km south of Addis Ababa. This zone is one of the 18 zones in the region. It is one of the densely populated zones hosting over two million people in a land area of 11,746 square KM [(32)]. The zone is crossed by multiple high roads coming from different parts of the country and characterized by high in & out flow of transient people a day. This character is assumed to contribute to exposing people to high risk of HIV infection.

Currently there are two hospitals (Public and one NGO) and 16 functional health centers in this zone. The two hospitals and five health centers provide ART service in addition to other comprehensive services. Other services such as health centre and PMTCT are delivered in all

hospitals and health centers. Antiretroviral treatment service has been initiated in Shashemene hospital in February, 2005 and then expanded to the three health centers since October, 2006.

Shashemene General Hospital was used as reference in this comparison, having health care providers ranging from specialists to others less qualified health workers. It had a total bed capacity of 105 of which 23 beds belonged to pediatrics age group. As it is the case in most hospitals in the country, it lacks viral load machine for monitoring patient improvement. The three health centers, included in the current study, were type 'A' (better of the health centers). They have technical staff ranging from health officers to junior health workers. The ART clinicians are either health officers or clinical nurses with special training on ART.

3. Source and Study population

All new adult HIV/AIDS patients who have ever started HAART (highly active antiretroviral therapy) regimen in the study area were taken as source population in this study. All adult HIV/AIDS patients who started receiving the regimen for the first time (naïve) in the selected health facilities were considered as study population.

4. Inclusion and exclusion criteria

Inclusion Criteria

For a health facility to be included in the current study, it must be a public heath facility and have been providing ART service since October, 2006.

This study included patients' medical records based on the following inclusion criteria:

- Patients who have been taking the first line regimen for the first time (ART naïve) in the selected facilities,

- Patients categorized as adults in the national treatment protocol (Age 15 years or above),
- Patients who were on treatment for at least three months in raw in a given facility before transferred out.
- For the key informants, being leader of the ART clinic, Pharmacy and Laboratory departments or longer experience of work in respective departments of each facility.

Exclusion Criteria

Patients were excluded from the study based on the following criteria:

- Patients who were alive & on treatment, having less than three months follow up in a given facility and all who did not meet the above inclusion criteria were excluded from this study.

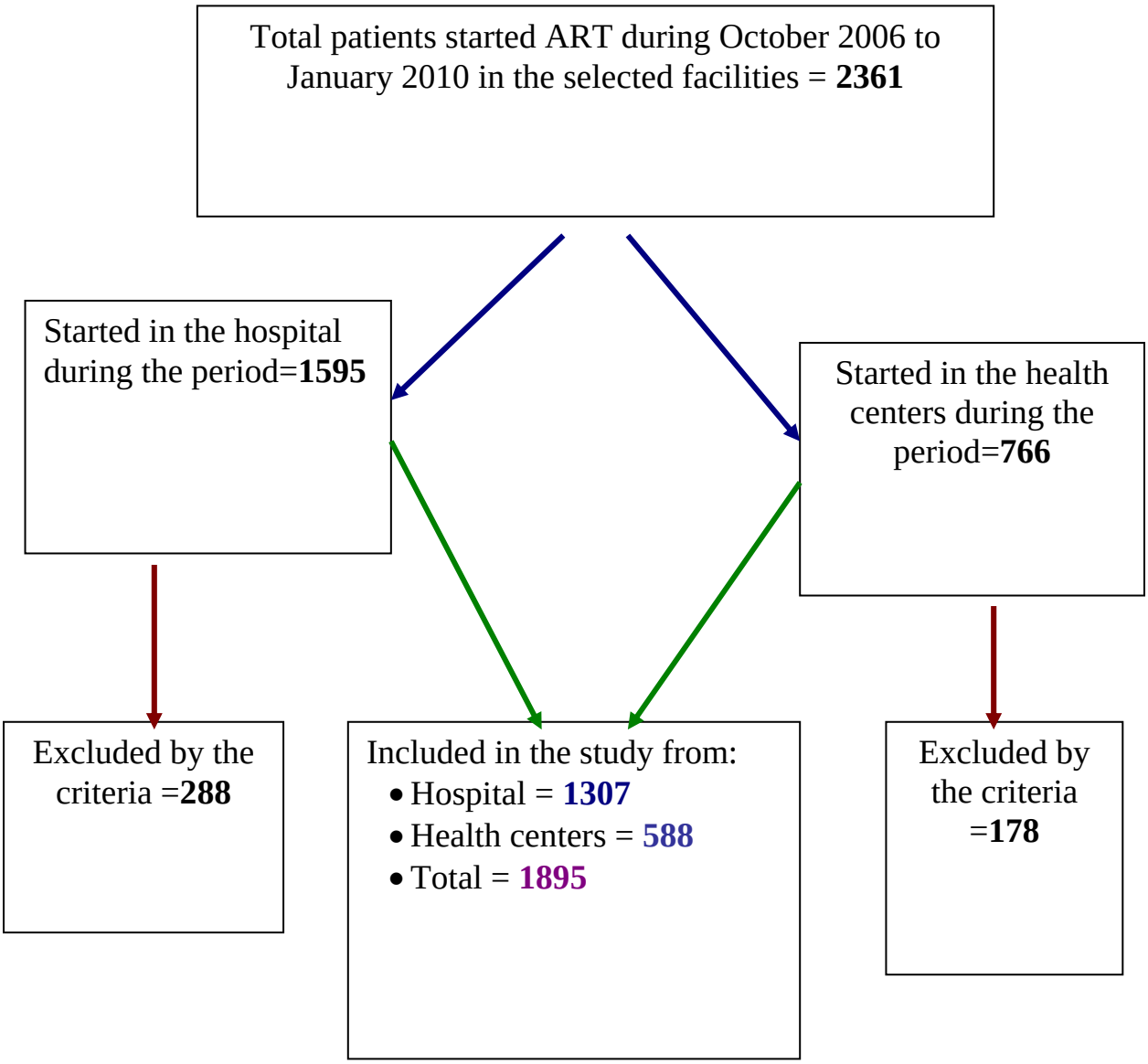
5. Facility selection and Sample size

As there was only one public hospital providing ART in the study area, it was included to serve as a reference facility. The three health centers were the pioneering ART service providing facilities with experience of over three years. Excluded health centers were those either have no ART service or started the service very recently.

Sample Size

The sample size was calculated using Epi Enfo version 3.5 statcal formulae for cohort study considering 95% confidence level, 80% power, 3:1 ratio of hospital patients to health center patients and 30% of the estimated outcome variable (LTFU) to detect relative risk of at least 1.4% for open cohort of over three years. With these criteria, a sample size of 700 was obtained [(33)]. All the data available and that meet the inclusion criteria was used to maximize the power of the study. The studied records were included according to the following procedure:

Schematic Presentation of sample selection procedure



6. Variables of the study

Dependent Variables

The dependent variables were:

- The Survival rate (Patient retention in the treatment follow up),
- Lost to follow up and death rate,
- Immunological progress (change in CD4 count),
- Clinical improvement or prognosis (WHO clinical stages), change in Functional status (WHO performance-scale) and weight gain among the patients in both treatment facilities.

Independent Variables

Predictor variables included factors that are potentially determining the treatment outcomes;

- Level of health care facility (health center or hospital),
- Socio-demographic factors (age, sex, literacy status, residence, occupation),
- Baseline patient immunological status (CD4 level) and
- Baseline patient clinical status (WHO clinical stage, performance scale).

7. Data collection Procedure

At the starting point of ARV treatment, patients' detailed socio-demographics are recorded on an ART intake and follow up forms. Baseline clinical and bio-logical parameters including a patient's functional status, WHO clinical stage and CD4 cell count are recorded. Patients are expected to attend ART clinics on monthly basis. During each visit patients are provided with ART drugs for the upcoming month and their status is also assessed and recorded.

This study used two methods of data collection: use of log-book to retrieve secondary data and a topic guide based in depth interview. Secondary data collection log-book was derived from the standard HIV care/ART follow up form developed by Federal Ministry of Health-Ethiopia. The key informant interview topic guide was derived from the national ART implementation Guideline (standard of care) with some additional related questions. Both tools were developed in English as all records were kept using this language. In each health facility secondary data was retrieved by trained data clerks under supervision of oriented supervisors. Antiretroviral treatment log-book was used as main source of information while patient monitoring cards were used to complement this data. Based on the fulfillment of the inclusion criteria, a total of 1895 (1307 from hospital and 588 from health center) patient records were included in the study. The in depth interview was conducted by the principal investigator involving ART clinicians and the HIV/AIDS chronic care coordinators in respective health facilities.

Key informant interview was conducted with 12 (three from each facility) knowledgeable health workers working in the facilities.

8. Ascertainment of the outcomes

All the outcomes were taken from the medical records of the facilities of the facilities. The facilities ascertain their data through mechanisms such as monthly measurement body weight, after treatment clinical staging monthly and CD4 count biannually. Other outcomes such as death and lose to follow up are confirmed through trained and deployed case managers who work in respective catchments community.

9. Data Quality management and Analysis

Data Quality Management

To ensure data quality, the principal investigator (PI) trained all data collectors and supervisors for a day on the tools, over all objectives of the study and data collection procedures. During the data collection strong supervision was undertaken both by the PI and the supervisors to check for data completeness, consistency and ensure the respect of ethical aspects. EPI-Info version 6 [(34)] based templates, which are designed based on the coding done by the principal investigator, was used for quantitative data entry. The collected and checked data were entered into computer by the PI and 10% of the entered data were randomly selected and cross checked for reliability with respective original data. The entered data were cleaned through the phase by phase screening after exporting to the SPSS version 15 [(35)].

Data Analysis

For the data analysis both descriptive and analytical statistical methods were used based on the nature of study variables. Summary tables were generated using cross-tabulation comparing outcomes with predictor variables. Hypothesis testing was also done using either parametric or non parametric methods according to the distribution of the study variable [(36)]. Survival analysis was done by using Kaplan Meier and Cox regression models to compare the survival rate among patients of the two categories of health facilities. Hazard ratios were calculated to measure relative risks and incidence rates for the outcomes of interest. For the data analysis computers statistical soft-wares (EPI-Info version 6 and SPSS version 15) were used [(35)].

10. Operational and standard Definitions (11, 37-39):

ART patient treatment outcome _ This refers to what happens to the patient until end of the study and categorized as Lost to follow up (LTFUP), Transferred out, dead or alive and on treatment.

Lost to follow up - Patients who are absent or lost from clinical follow up for more than one month.

Functional Status_ Described as Working, Ambulatory and Bed ridden.

Working _ *Able* to perform usual work in or out of house.

Ambulatory_ Able to perform activities of daily living.

Bed Ridden _ not able to perform activities of daily living.

ART naïve patients – patients who are new to antiretroviral treatment.

11. Ethical Considerations

Ethical clearance for the study was secured from the Institutional Review Board of Addis Ababa University Medicine Faculty. Following this, letters of permission were written to respective facilities from the Regional Health Bureau (to the Hospital) and the Zonal Health Office (Health Centers). Permission was also received from the Medical Director of the Hospital and respective heads of Woreda health Offices as well as health centers before starting data collection.

The inclusion and exclusion criteria set during the protocol design were strictly respected throughout the study. Patient record based data was collected by respective data clerks who were already working as data managers for the facilities using only ART codes and no name were used in connection with results. Verbal consent was obtained from patients who visit the facilities during data collection period.

Funds required for the study was secured from the Ethiopian Public Health Association, a non profit making professional association, and hence there was no room for any conflict of interest in relation to the generated results.

Results

Data Completeness

Since information was directly copied onto the questionnaire from patients' registry books, it was not possible to judge or comment on the quality of the data available. However, information could be evaluated for completeness. As depicted in the table, which brought only some variables with incompleteness in either or both of the facility categories in to view, collected information appeared to have a high completeness rate for selected key variables. The data completeness ranged between 71% and 100% for the hospital while it ranged between 65.8% and 100% for the health center. The lowest completeness rate was for recent CD4 count in both facility groups. It was evident from the records that few patients 350 (26.8%) and 160 (27%) for hospital and health center respectively were with in less than six months of follow up and hence could not have the follow up CD4 count. This indicates that 1.6% of hospital and 6.2% of health centre ART patients did not have recent CD4 count data while they should get it (Table 1).

Table. 1: Completeness rate of patients' medical records for selected variables in studied health facilities, Oct 2006 to January 2010

Variable	Hospital (n = 1370)		Health Center (n = 588)	
	# not missing	% not missing	# not missing	% not missing
Occupation	1305	99.8	588	100.0
Initial body Wt	1268	97.0	587	99.8
Initial CD4count	1285	98.3	547	93.0
Recent body Weight	1230	94.1	555	94.4
Recent CD4 count	936	71.6	387	65.8
Recent functional status	1307	100.0	555	94.4
Recent WHO stage	1307	100.0	554	94.2
Adherence to ART	1304	99.8	555	94.4
Regimen category*	1304	99.8	587	99.8

*Note. Patients with missing treatment category were known to be on the first line regimen.

Baseline Data

The study analyzed medical records of 1895 ART naïve patients with 1307 (69%) and 588 (31%) from hospital and health centers respectively. Among the studied cases most (75%) fall in the age range of 15-39 years while 56% of them were female. Over 70% were urban dwellers and 55% of them were people with in marital union. Only small proportion (28.3%) of the patients had educational level of high school or above. Half of the HIV/AIDS patients included in the current study were either self employed or employed by other. When the records are analyzed as segregated by facility categories some peculiar features could be identified.

The baseline case registration characteristics indicated that the socio-demographic distribution of patients treated in the hospital was significantly different from that of health center except for sex distribution of patients which was similar for both facilities; X^2 close to zero and p-value of 0.983. Baseline data of HIV/AIDS patients treated in the health centre and hospital were different for most variables. Hospital patients tend to be more educated than that of health centre. Hospital ART patients were seemingly younger as compared to that of health center patients. Sex distribution was the same between patients of both facilities and hospital ART patients tend to be more educated. Health centre ART patients tend to be less urbanite and less employed as compared to hospital ART patients. Among the hospital ART patients 40.2% (n = 431) were bed ridden or ambulatory while only 25.6% (n = 151) of health center patients were bed ridden or ambulatory. Relatively higher proportion of health center ART patients (66.9%) were in WHO clinical stage three or four while only 62.1% of hospital patients were in WHO clinical stages of three or four (table 2).

Table 2: Case registration characteristics of ART patients by facility type, Oct 2006 to January 2010

Variables		HOP, n(%)	HC, n(%)	$X^2_{(df)}$	P-Value
Age	15-29	491 (37.6)	171 (29.1)	15.4 $_{(3)}$	0.002
	30-39	519 (39.7)	247 (42.0)		
	40-49	197 (15.1)	116 (19.7)		
	>=50	100 (7.7)	54 (9.2)		
Sex	Male	575 (44.0)	259 (44.0)	0.0 $_{(1)}$	0.983
	Female	732 (56.0)	329 (56.0)		
Marital Status					
	Unmarried	226 (17.3)	57 (9.7)	72.9 $_{(4)}$	0.001
	Married	643 (49.2)	400 (68.0)		
	Divorced	90 (6.9)	50 (8.5)		
	Separated	138 (10.6)	31 (5.3)		
	Widowed	210 (16.1)	50 (8.5)		
Literacy level					
	Illiterates	317 (24.3)	228 (38.8)	95.1 $_{(4)}$	0.001
	Read and Write	38 (2.9)	52 (8.8)		
	Elementary school	522 (39.9)	202 (34.4)		
	High school	382 (29.2)	92 (15.6)		
	Diploma and above	48 (3.7)	14 (2.4)		
Residence	Urban	999(76.4)	377 (64.1)	30.2 $_{(1)}$	0.001
	Rural	308 (23.6)	211 (35.9)		
Working situation					
	Employed	195 (14.9)	51 (8.7)	80.5 $_{(3)}$	0.001
	Self Employed	397 (30.5)	303 (51.3)		
	Student	8 (0.6)	6 (1.0)		
	Jobless	703 (53.9)	228 (38.8)		
Functional Status					
	Bed Ridden	104 (8.0)	32 (5.5)	37.9 $_{(2)}$	0.001
	Ambulatory	421 (32.2)	119 (20.1)		
	Working	782 (59.8)	437 (74.4)		
WHO stage	WHO stage 1	124 (9.5)	64 (10.9)	21.0 $_{(3)}$	0.001
	WHO stage 2	372 (28.5)	131 (22.3)		
	WHO stage 3	662 (50.7)	352 (59.9)		
	WHO stage 4	149 (11.4)	41 (7.0)		

From the total subjects involved in the study, 1844 (97.3) had baseline weight documented. The median weight was 50 kg with inter quartile range (IQR) of 12 kg. The mean weight was 50.3kg with 95% CI (49.8-50.7) kg. The distribution of baseline weight was asymmetrical and failed to be normally distributed after transformation (skewness =0.174). Non parametric model (Mann Whitney U test) was used to test for significant difference in the baseline weight between hospital and health center ART patients and it indicated that there was no significant difference between the mean ranks of the two groups. Further more, the median CD4 count was 130 Cells/ml with IQR of 118cells/ml. Mean CD4 count was 144 Cells/ml with 95% CI (136-151) cells/ml. It was indicated that there was no significant difference between the mean ranks of the two groups of patients (Table 3).

Table: 3 Comparison of base line body weight and CD4 count between studied facility types, Oct 2006 to January 2010

Variables	Number	Mean Rank	P-value
Base line body weight			
Health center	587	931.3	0.571
Hospital	1268	916.2	
Baseline CD4 count			
Health center	547	897	0.313
Hospital	1285	925	

Patients treated in health centers were followed for the total of 7,951 person month of observation while hospital patients were followed for 20,039 person months. Incidence of death in health center patients was 5.7 per 1000 person month of observation while that of hospital patients was 6.3 per 1000 person month of observation. The incidence of LTFU was 7.9 and 8.6 per 1000 person months for health centers and hospital ART patients respectively. If all LTFU cases were considered as dead, the total failure rate was 13.6 and 14.9 per 1000 person months of observation for hospital and health centers respectively. There was no true difference in incidence of death, LTFU and failure rate among patients treated in the hospital and health centers (Table 4).

Table 4: Incidence of events per 1000 person-months of observation by facility category, Oct 2006 to January 2010

Event by Facility	Person-time in months	Number	Incidence/ 1000 person month	RR (95%CI)
Death				
Health Center	7,951	45	5.7	0.79 (0.6,1.1)
Hospital	20,039	127	6.3	1
Lose to follow up				
Health Center	7,951	63	7.9	0.81 (0.6,1.1)
Hospital	20,039	172	8.6	1
Failure (Death + LTFU)				
Health Center	7951	108	13.6	0.8 (0.7,1.0)
Hospital	20039	299	14.9	1

Clinical and Immunological outcome Analysis

Among the ART naïve patients treated in the health centre about 73% gained weight while the remaining proportion had either lost weight or remained unchanged during the follow up period. Among these patients, 92.1% (n=511) were improved from being bed ridden or ambulatory (performance scale 3/4) to performance scale 1/2 where they can work while only about 76% of hospital patients showed similar improvement. About 23% (n=214) of the hospital ART patients failed to gain or lost CD4 cells while only about 15% (n=55) of patients treated in health centres failed to gain or lost the cells (Table 5).

Table 5: Comparison of patient's risk of failure to Clinical and Immunological Improvement between the facility groups, Oct 2006 to January 2010

Event by Facility	Number Worsened/ Unchanged (%)	Number Improved (%)	RR (95%CI)
Body weight			
Health Center	148 (26.8)	405 (73.2)	0.9 (0.8,1.1)
Hospital	346 (28.9)	852 (71.1)	1
WHO clinical stage			
Health Center	170 (30.7)	384 (69.3)	0.8 (0.7,0.9)
Hospital	537 (41.1)	770 (58.9)	1
Performance scale			
Health Center	44 (7.9)	511 (92.1)	0.3 (0.25,0.5)
Hospital	311 (23.9)	992 (76.1)	1
CD4 count			
Health Center	55 (14.9)	315 (84.1)	0.6 (0.5,0.8)
Hospital	214 (23.1)	713 (76.9)	1

Survival and related factors

Death and lose to follow up were termed as failure in the current study. These were taken as the events of interest and the Kaplan Meier model was fitted to test for the difference between the mean survivals (mean treatment retention) of ART patients treated in the two categories of the health facilities. The mean survival was 31.3% [95% CI (30, 32.6)] and 30.3% [95% CI (29.4, 31.1)] for health center and hospital patients respectively. The survival rate was not different for patients of both facilities. The Log Rank test showed non significant difference (X^2 = 2.6 and P-value 0.108) between the two patient groups (Table 6).

Table 6: Comparison of Mean survival of patients treated in HOSPITAL versus that of HEALTH CENTER, Oct 2006 to January 2010.

Facility	Mean Survival (95% CI)	$X^2_{(1)}$	P-Value
Health Center	31.3 (30.0,32.6)	2.6	0.108
Hospital	30.3 (29.4,31.3)		

A survival function curve was fitted to compare the survival probability of patients treated in both facility groups by considering two extreme scenarios. The first extreme scenario was where all LTFU patients were considered as dead. Under this scenario, the survival probability curve pictorially shows higher for health centre patients (Figure 1).

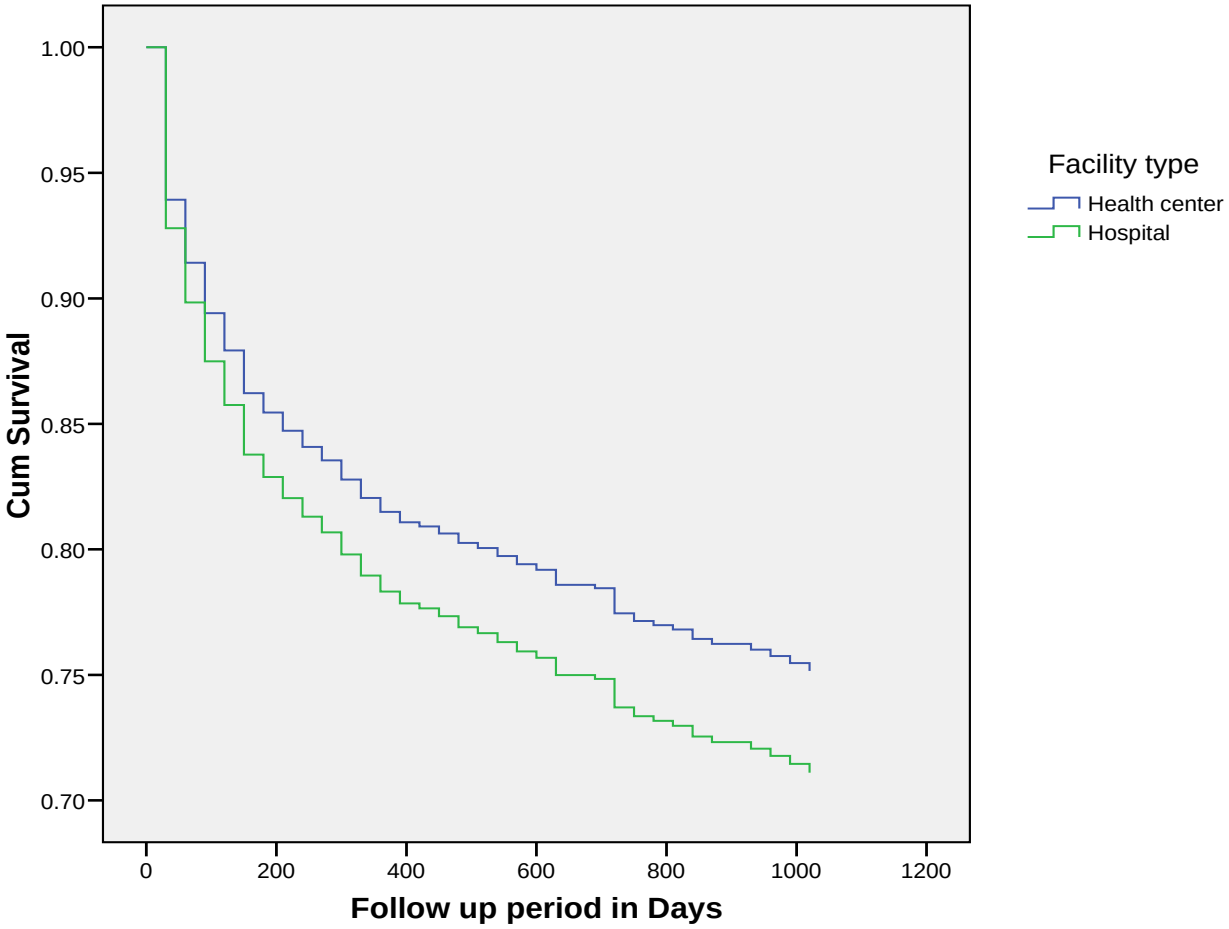


Figure 1: Over all survival function curve comparing health centre and hospital ART patients based on risk of failure (Death + lose to follow up), Oct 2006 to January 2010.

The second scenario was where all LTFU patients were considered to be alive after defaulting from the treatment. Similar to that of the first scenario, the survival curve shows pictorially higher for health centre patients as compared to that of hospital patients. However, this finding did not indicate true difference between the two categories of health facilities as depicted in table 6 above (Figure 2).

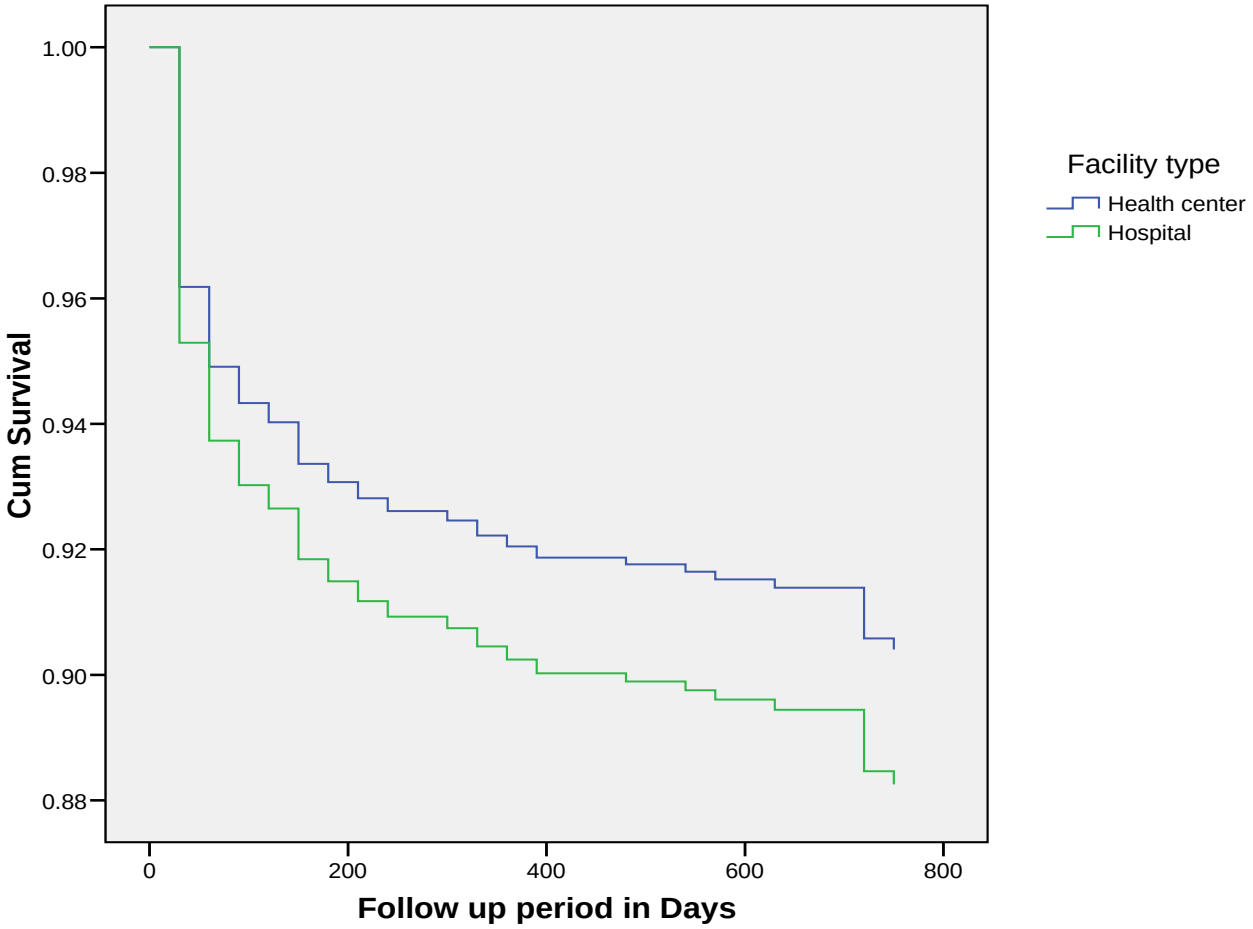


Figure 2: Survival function curve comparing health centre and hospital ART patients based on risk of death, Oct 2006 to January 2010.

The probability of no LTFU was also compared for the facility categories and the probability curve showed relatively lower risk of LTFU among health centre ART patients (Figure 3)

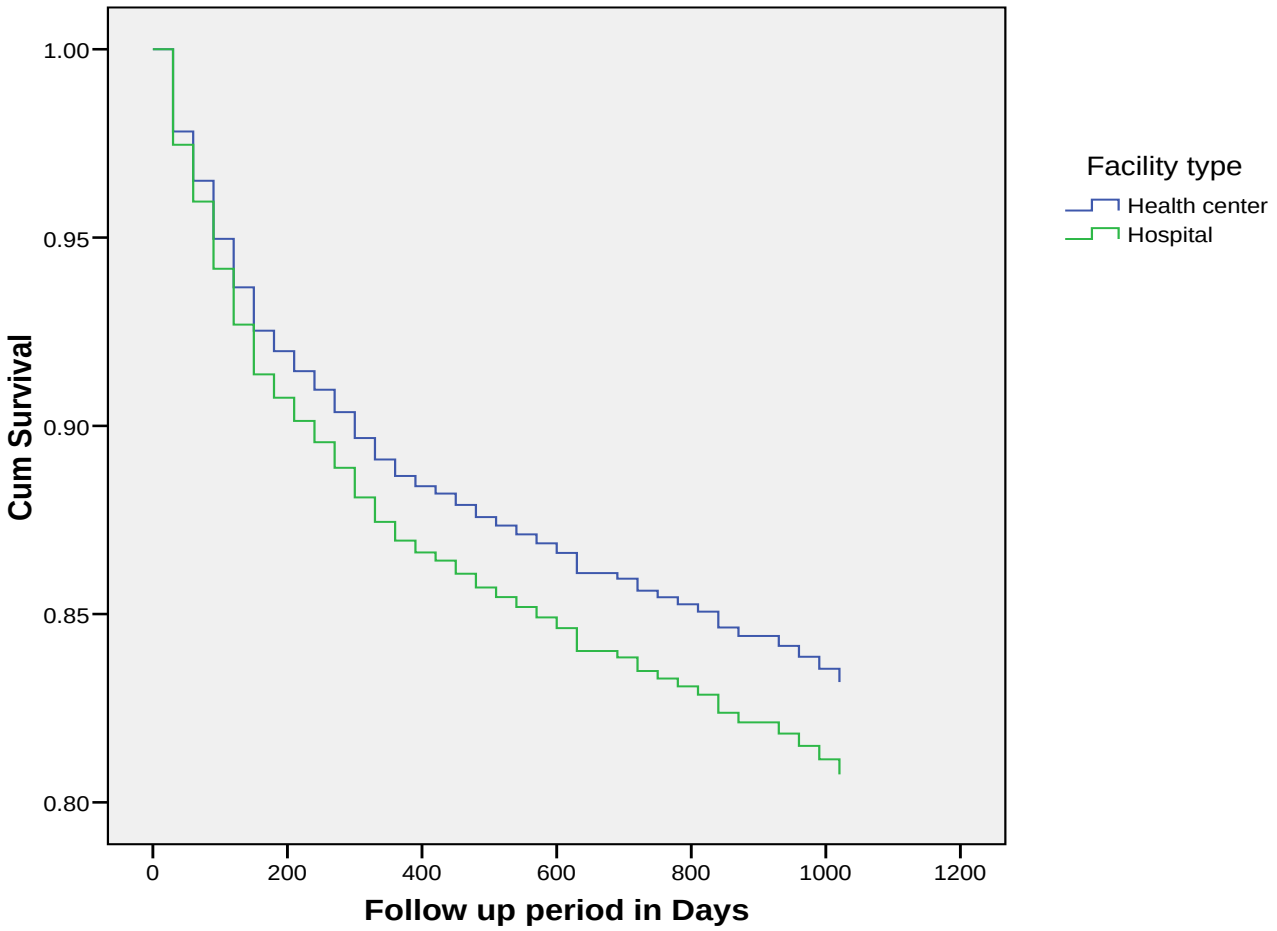


Figure 3: Survival function curve comparing health centre and hospital ART patients based on risk of lose to follow up, Oct 2006 to January 2010.

The incidence density of death and Lose to follow up from ART treatment among ART patients was higher in male than in females. Relative risk of death among male ART patients was 1.4 (95%CI 1.0, 1.9) times that of female with similar risk of lose to follow up from the treatment. Risk of death among ART naïve patients with baseline WHO stage three/four was more than two fold as compared to those patients with baseline WHO stage one/two; (RR 2.2; 95%CI 1.5, 3.3). Further more, risk of death was more than six times higher among ART patients who did not receive CPT regular refilling as compared to those who got the prophylaxis on regular basis; RR 6.6 (95%CI 2.8, 15.8). Patients with adherence to ART less than 95% had higher risk for LTFU; RR 6.4 (95%CI 4.9, 8.3). However, there was no difference in risk of death and LTFU among HIV/AIDS patients on ART with difference in patient's residence, occupation, initial performance scale and CD4 count (Table 7).

Table 7: Over all Crude Risk Analysis among all study subjects in the health facilities, Oct 2006 to January 2010

Variable	Person-time in months	Risk of Death			Risk of lose to Follow up		
		Number of Death	Incidence /1000 In months	RR(95%CI)	Number of LTFU	Incidence/ 1000 In months	RR(95%CI)
Sex							
Male	12,326	90	7.3	1.4 (1.0,1.9)	125	10.1	1.4 (1.1,1.9)
Female	15,664	82	5.2	1	110	7.0	1
Residence							
Urban	21,019	134	6.4	1.2 (0.8,1.7)	166	7.9	0.8 (0.6,1.1)
Rural	6,971	38	5.5	1	69	9.9	1
Occupation							
Unemployed	24,337	158	6.5	1.7 (0.98,2.9)	208	8.6	1.2 (0.8,1.7)
Employed	3,653	14	3.8	1	27	7.4	1
Init. Performance Scale							
Performance Scale 3 or 4	10,495	73	7.0	1.2 (0.9,1.7)	73	7.0	0.8 (0.6,1.0)
Performance Scale 1 or 2	17,495	99	5.7	1	162	9.3	1
Base line WHO stage							
WHO stage 3 or 4	18,127	138	7.6	2.2 (1.5,3.2)	162	8.9	1.2 (0.9,1.6)
WHO stage 1 or 2	9,863	34	3.4	1	73	7.4	1
Base line CD4 count							
$\leq$ 200cells/ml	20,194	134	6.6	1.4 (0.9,1.9)	169	8.4	1.0 (0.7,1.3)
> 200cells/ml	7,796	38	4.9	1	66	8.5	1
CPT Regular refilling							
No regular refilling	120	5	41.7	6.6 (2.8,15.8)	1	8.3	1.0 (0.1,7.0)
Had regular refilling	27,140	165	6.1	1	229	8.4	1
Adherence to ART							
Fair/Poor (<95%)	3,228	21	6.5	1.1 (0.7,1.8)	99	30.7	6.4 (4.9,8.3)
Good (>= 95%)	24,626	141	5.7	1	116	4.7	1
Total	**27,990**	**172**	**6.2**		**235**	**8.4**	

Hazard of death and LTFU was 1.4 times higher among male sex male HIV/AIDS patients as compared to that of female patients; AHR 1.4, (95%CI 1.1, 1.7) after adjustment for age, educational status, marital status, working situation, residence, baseline functional status, base line WHO stage and facility type. Employed patients had higher risk of failure (death and lose to follow up) from ART as compared to unemployed patients; AHR 1.3 (95%CI 1.0, 1.6). Other socio-demographic variables such as age of the patients, education, marital status and patient's residence were not associated with risk of death and lose to follow up of ART patients. Type of health facility attended by patients was not related to the risk of death and follow up (Table 8).

Table 8: Scio-demographic variables as determinants of failure (Death + LTFU) among ART patients in studied health facilities, Oct 2006 to January 2010

Variables	Crude	**Adjusted
	HR (95%CI)	HR (95%CI)
Sex		
Male	1.4 (1.2,1.8)	1.4 (1.1,1.7)
Female	1	1
Age		
15-39	1.1 (0.9,1.4)	1.2 (0.96,1.5)
>=40	1	1
Education		
Elementary/above	0.8 (0.6,1.0)	0.8 (0.6,1.0)
Illiterate	1	1
Marital Status		
Married and in union	0.9 (0.8,1.1)	1.0 (0.8,1.2)
Not in Marital union	1	1
Work situation		
Employed (self or Others)	1.3 (1.04,1.6)	1.3 (1.0,1.6)
Jobless/student	1	1
Residence		
Urban	1.0 (0.8,1.3)	1.0 (0.8,1.3)
Rural	1	1
Facility		
Health Center	0.8 (0.7,1.0)	1.0 (0.8,1.2)
Hospital	1	1

NB: "**" Adjusted for age, educational status, marital status, working situation, residence, baseline functional status, base line WHO stage and facility.

The risk death and LTFU from ART was more than two fold among ART patients with baseline performance scale three/four as compared to those patients with baseline performance scale one/two; AHR 2.4 (95%CI 2.0,3.0). Further more patients with baseline WHO stage three/four had higher risk of death and LTFU from the treatment than those patients with baseline WHO stage one/two; AHR 1.3 (95%CI 1.0,1.6). Risk of death and LTFU was almost three times higher among ART patients with advanced disease stage at the start of the treatment as compared to those who had no advanced disease; AHR 2.8 (95%CI 2.3,3.4). Other variables such as difference in baseline CD4 count were not important risk factors (table 9).

Table: 9 Association between Base line patient data and hazards death & LTFU among ART patients in studied health facilities, Oct 2006 to January 2010

Variables	Crude	**Adjusted
	HR (95%CI)	HR (95%CI)
Baseline Performance Scale		
Performance Scale 3 or 4	2.5 (2.0,3.0)	2.4 (2.0,3.0)
Performance Scale 1 or 2	1	1
Baseline WHO stage		
WHO stage 3 or 4	1.6 (1.3,2.1)	1.3 (1.0,1.6)
WHO stage 1 or 2	1	1
Baseline CD4 count		
CD4 less than or equal 200cell/ml	1.1 (0.9,1.4)	1.0 (0.8,1.3)
CD4 less than 200cells/ml	1	1
Advanced disease*		
Yes	3.3 (2.7,4.0)	2.8 (2.3,3.4)
No	1	1
CPT regular refilling		
No regular refilling	2.3 (1.0,5.2)	2.0 (0.9,4.5)
Had regular refilling	1	1
Adherence to ART		
Poor/Fair (<95%)	3.6 (2.9,4.4)	3.4 (2.8,5.2)
Good (>= 95%)	1	1

NB: "**" Adjusted for age, educational status, marital status, working situation, residence, baseline functional status, base line WHO stage and facility.

Findings from the key informant interview

Clinical Service Minimum Package

Key informant interview was conducted with selected knowledgeable program leading health workers in all studied health facilities. Although the infrastructural requirement for both the hospital and health centers was to have separate examination room and counseling room, almost all the facilities reported to have single room used for both purposes. One of the key informants working at ART clinic in a health centre said, “let alone having one examination room and another separate counseling room, the non-health professional data clerk shares the same single room with me.” Other health centers’ ART clinicians reported similar problem of sharing a single room with the data clerks. This problem was not reported by hospital ART clinicians. Like health centers, the hospital also lack separate room for ART patients counseling service. The clinician in the hospital reported to have most clinical service minimum package in place while that of health centers uniformly reported to lack some equipments and supplies like Otoscope stethoscope blood pressure cuff and reflex hammer. The ART clinics in the health centers were sharing these required equipments with other units. Both facility groups reported to have enough trained human power at the time of study. Both facility groups reported to have good monitoring and evaluation system including documentation facilities. Regular mentoring services were similarly received by hospital and health centers both from the government and nongovernmental partners. The most regularly engaged clinician working in ART clinics of both facility groups were clinical nurses. Some of the nurses working in health centers ART clinics reported that they can not get enough technical assistance from their senior when they need; because ART trained health officers and nurses with first degree were occupied by some leadership activities. All

interviewed clinician stated that their health facility had a comprehensive HIV prevention, treatment and good linkage with care and support services. These include voluntary counseling and testing, provider initiated HIV testing and counseling, prevention of mother to child transmission of the virus, ART, opportunistic infection preventive treatment and referral linkage with partners providing care and support with palliative care.

Pharmacy Service Minimum Package

All pharmacy personnel interviewed reported to have onsite ART pharmacy with relatively enough storage space. But none of them reported to have separate adherence counseling room. No ART drug shortage was reported from both facility types. A druggist working on one of the health centers reported to have difficulty in obtaining prophylactic antibiotics and antifungal drugs; because of confusions in the implementation of health care financing in health center and delayed decision making. Refrigerator is one of the equipments required to ensure the potency of Pediatrics ART drug. It was uniformly reported from health centers to be unavailable. Trained human resource was not sited as problem from all facilities except one health center where the trained druggist left the facility few days before the date of data collection. The drug supply chain management was weak in health centers as compared to hospital. Use of bin cards, stoke card and receiving vouchers was not well practiced in health centers. Adherence monitoring system was not implemented in both the hospital and the health center. Most interviewed pharmacy professionals reported that they simply ask ART patients to know whether they correctly took their drugs or not. Some said they give few pills in extra of their dose so that the patients can take these extra pills if they miss their appointment date or vomit the drug. Both facility types reported to have required documentation material and lockable drawers.

Laboratory Service Minimum Package

The key informants from health centers uniformly reported that they have laboratory infrastructure required for their level. On the other hand they witnessed that they run short of some important reagents which should be available at their level. For investigations which were beyond the health center level, the technicians reported to have good network with the hospital. In the hospital, the technicians reported to have separate laboratory with almost all requirement met except for the challenge of damages to CD4 machine which caused some problem to patient immunological monitoring. Trained human power was adequately available in both facility types but the key informants reported problem of skill in maintaining the advanced machines available in the hospital laboratory. For the issues asked as related to documentation, monitoring and evaluation, the respondents similarly reported to have no problem. Hospital laboratories were being assisted by international NGOs in both technical and material aspects which contributed much to their performance not only for their facility but also to health centers.

Discussion

In the current study medical record of 1895 ART naïve patients was included with 1307 (69%) and 588 (31%) from hospital and health centers respectively. This high case load in hospital was similar with that of the recent (2009) Ethiopian national cohort analysis finding; which showed that 87.8% of ART patients receiving the treatment from hospitals [(11)]. Similar to the findings of the above national study among the studied cases 75% fall in the age range of 15-39 years (younger ages) and this higher proportion of the younger age may suggest better treatment seeking behavior in the age group than older. Further more, this could also be due to higher HIV prevalence among younger population in the country[(40)]. Females accounted for 56% and over 70% were from urban residence which matches with HIV prevalence characteristic in the country [(41)]. Three quarters of the patients started on ART having CD4 count less than 200 Cells/ml. This was lower than the finding of the Ethiopian national ART cohort analysis that reported 81.0% of the patient initiated the treatment with CD4 less than 200 Cells/ml. This difference could be attributed to increasing access to the immunological patient monitoring and the treatment[(11)]. Median CD4 count was 130 Cells/ml and 140 Cells/ml for HEALTH CENTER and HOSPITAL patients respectively in the current study. These findings were higher than the finding of other studies conducted in developing countries [(33, 42)]. This difference could be attributed to the temporal and methodological differences between the two studies. In addition ever increasing access to ART service in developing countries could contribute for earlier initiation of the treatment before extreme decline in the CD4 count.

Our study showed that there was no true difference between recent mean of CD4 count and body weights for health centre and hospital patients. This result agreed with the Kaplan Meier test for

difference in the treatment outcome for the facilities; that is the outcome for both facilities was not significantly different. Further more, the result was in line with the key informant interview summary which indicated no much difference in the facility requirements to provide ART service between the health centre and hospital. The survival probability for patients of both facilities was higher than 80% which was higher than that of the Cameroonian patient studies in 2006 (77%)[42]. The difference could be due to time gap between the two studies.

The mortality rate found in the current study was lower as compared to the finding of the study done in Arbaminch hospital in 2006[43]. The difference could be due temporal difference between the two studies.

Being treated in the health centre did not increase risk of failure (death or lose to follow up). This finding agreed with related study in Malawi which compared the treatment outcome in health centre and hospital[44]. It also matches with the recent national study's finding in Ethiopia which concluded that the survival rate of patients in health centre and hospital as 82% and 72% respectively [11]. This result was also in agreement with the findings of other study in South Africa Lusisiki which reported that task shifting for HIV/AIDS care to relatively new levels of the health system (like health centres) did not compromise quality and even associated with significantly better ART outcomes [14]. Absence of true difference between the treatment outcomes in the two facility groups could also be due to the regular mentoring services provided to both facilities by better qualified clinicians both from governmental and non governmental organizations. Strong predictors of death and LTFU in patients include being male; AHR 1.4 (95%CI 1.1, 1.7) baseline performance scale three/four; HR 2.4 (95%CI (2.0, 3.0); advanced disease stage; AHR 2.8 (95%CI 2.3, 3.4) and adherence to ART less than 95%; AHR 3.4 (95%CI

2.8, 5.2). This finding agreed with related study in Brazil which showed that the AIDS-case definition was strong predictors of survival; HR 4.5 (95% CI 4.3,5.2) [(26)].

The incidence of lose to follow up in overall patients in the current study was 5.7 per 100 person year of observation. It was 5.3 and 5.9 per 100 person year of observation for health centre and hospital patients respectively. This finding was lower than that reported from study Kenya. In the later study conducted in 2007 incidence of LTFU was 20.5 per 100 person year[(45)]. The incidence depicted was higher as compared to the study from Brazil which reported the incidence of LTFU as 3.72 per 100 person-years of follow-up [(24)].

Although there was no much discrepancy identified between the facility groups with respect to the minimum requirement for facilities set by national standard health centers were less equipped with required equipments and materials. This may be due to lack attention to the standards of care in the facilities. Most of the ART clinic work was managed by nurses both in health center and hospital. This might have contributed to less attention paid to opportunistic infection assessments and drug side effects recording. In general all study facilities were in agreement with the minimum requirements of the national ART implementation guide line. Therefore the treatment outcome for both facility groups could be compared and believed to yield reliable evidence.

Limitations and Strength of the study

Limitations

- The study design was retrospective cohort which used secondary data from patient medical records; although the basic assumption is that all the data are valid there was no way to confirm the exactness of the medical records.
- Gaps in the records in documenting some important variables like drug side effects and opportunistic infections forced the study not to account for the contribution of these variables.
- The study suffered from lack of similar studies for comparison.

Strengths

- The study was conducted at zone level (narrow) which can minimize the heterogeneity of the population and capable to pick a particular feature.
- The study involved all public health facilities in the zone which have been providing ART service for over the last four years than sampling from among them.
- The study involved all patient records eligible for the study in all facilities resulting in large sample and this is believed to contribute much for the validity of the data.
- Better study design and advanced models were implemented to come up with sound results.

Conclusion

- The clinical improvement among HIV/AIDS patients receiving ART in heath centre and hospital was similar.

- Immunological improvement (change in CD4 count) among ART naïve patients of both health facility categories was not different.

- Patients started ART in either health facility had similar survival probability.

- The most important predictors of death and LTFU from treatment among ART patients were being male, having base line performance scale three/four, having WHO AIDS clinical stage three/four, advanced disease stage and being poor or fair adherent to ART.

Recommendations

1. Patients with HIV/AIDS and require ART should be educated and encouraged to start the service in any closer facility; whether it is health centre or hospital.
2. Antiretroviral treatment service implementers and stake holders should tailor the service to the identified risk factors: focus on male sex, encourage early health seeking to minimize late arrival of the patients. Attention should also be paid to improve patients' adherence to ART in order to minimize the incidence of death and lose to follow up.

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Annex A: Client Consent Form

ADDIS ABABA UNIVERSITY MEDICAL FACULTY SCHOOL OF PUBLIC HEALTH

Comparison of Antiretroviral Treatment outcomes for a General Hospital versus Rural Health Centers in W/Arsi zone of Oromia Region

Client Consent Form

My name is _____. I am reviewing medical records of beneficiaries attending ART clinic in this health facility on issues related to use of ART drugs. The information is required by a study entitled '*Comparison of Antiretroviral Treatment outcomes for a General Hospital versus that of Rural Health Centers in W/Arsi zone of Oromia Region*' being under way in the zone. We use your medical records only if you are willing and the study includes all clients getting service in this facility based on their willingness. There is no direct benefit or harm you get as a result of the use of your records; but the result of this study may help the service improvement. The information we obtain from the record is very important to understand the results of ART treatment. You are free to decline and this will not affect your service in any way. The information drawn from your medical records is strictly confidential; your name will not be written on this form and you will never be identified in any way based on the information collected from your records. As you are one of our clients I need your willingness to use the records for the study.

Do you have any question concerning this information?

Are you willing to allow me use of your medical records for this study?

Thank you!

Interviewer's signature certifying that informed consent has been given by the interviewee verbally.

Full Name_____

Sign_____

Date of interview_____

Study Information Sheet

- **Title of the project**

Comparison of Antiretroviral Treatment outcomes for a General Hospital versus that of Rural Health Centers in Southern Central Oromia

- **Background of the study**

HIV/AIDS is one of the serious public health problems in the world over the last two and half decades. Our country is among the highly affected countries where more than two people per hundred are estimated to live with HIV and there are different efforts being done to mitigate the challenge among which is provision of ART to infected individuals. ART service is expanding from time to time which is also the case in west Arsi zone. As a result task shifting from higher medical care level to mid-level is going on. This study will help the policy makers and program implementers to understand the difference in treatment out come as task shifting and decentralization goes on.

- **Objective**

This study is designed to compare the survival rate and antiretroviral treatment (ART) outcome among ART patients in a Hospital versus three rural health centres in the zone.

- **Significance of the study**

The result of this study help in planning service improvement activities and may also serve as base line for other studies in the country. Patients will benefit from the study indirectly.

- **Study site and period of the study**

This study is underway in W/Arsi zone in health facilities providing ART service for the last more than three years. Medical records of all consented patients will be reviewed once to collect data required for the study.

- **Potential risks/Benefits associated**

Patients whose medical records are included in this study will not get any direct benefit or harm as a result of their involvement. But the over all result of the study is belied to help in the improvement of ART service in the region.

- **Confidentiality/Justice/Privacy**

All information used in the study will be kept strictly confidential. Medical records of all consented patients who are receiving ART in the selected health facilities for the duration of at least three months will be included and declined patients will be treated as usual regardless of their decision.

The data will be collected by data clerks who are already managing the medical records in respective facilities and they will hand over the filled log books to principal investigator for analysis using codes and hence patient privacy will be maintained.

- **Rights of participation (Voluntary Participation)**

Records of all adult patients who receive ART service from the selected facilities will be reviewed unless the patient declines.

- **Questions rights and complaints** (Specify the address of contact person)

If the patient who took part in the study has any concern regarding the study they can feel free to communicate with the principal investigator Ato Abebe Megerso (Mobile: 0911044525) at Oromia regional health bureau (Addis Ababa).

Yunivarsitii Finfinnee Faakultii Medikaalaa kutaa Fayyaa Hawaasaattii

Naannoo Oromiyaa godina A/Lixaatti Qorannoo bu'aa Tajaajila qoricha farra 'HIV'

Hospitaala fi Buufata fayyaa walmadaalchisuu

Uunka Hayyamsiisa maamilaa

Maqaan koo_____ dha. Ragaa yaalaa tajaajilamtoota dhaabbata kana irraa qoricha farra HIV/AIDS ii fudhatanii qorachaa jira. Kun haaluma mataduree gubbatti eerameen bu'aan itti fayyadama qoricha kanaa irraa argame maal akka fakkaatu baruu fi dhimmoota qorichaan walqabatan hubachuuf kan yaadame dha. Qorannoon kun godina A/Lixaa keessatti kan gaggeeffamu tajaajilamtoota ga'eessota dhaabbilee filataman keessatti gargaaraman hundumaa kan himaachisu dha. Ragaa yaalaa tajaajilamtoota keenyaa qorannoo kanaaf kan itti fayyadamnu fedhaa fi hayyama tajaajilamaa irratti hundoofnee qofaa yemmuu ta'u sababa kanaaf hayyamamaa ta'ee yoking hayyamamaa ta'uu dideef faaydaan addaa yoking miidhaan tajaajilamaa irra kahu tokkoyyuu hin jiru. Tajaajilamaan kamiyyuu hayyamamaa ta'uu diduu mirga guutuu kan qabu yemmuu ta'u qorannoo kana keessatti hirmaachuun garuu faaydaa ittifayyadama qoricha kanaa irraa argamu hubatanii akka waliigalaatti sagantaa yaalaa kana cimsudhaaf bu'aan inni qabu olaana dha. Odeeffannoon raga yaalaa keessan irraa funaanamu maqaa keessan bifa hin ibsinee fi ogeessota kanaan dura raga kana qindeessaa turaniin kan funaanamu dha. Ragaa kana irratti hundaa'un nama kamiinuu adda baasanii beekuun kan hindanda'amnee fi ragichi qaama biraatif dabarfamee gonquma kan hinkennamne ta'uu isniif mirkaneessa.

Isnis tajaajilamtoota dhabbata filataman keessatti gargaaraman keessaa tokko waan taataniif qorannoo kana keessatti akka hirmaattan isin gaafanna. Gaaffii dhimma kanaan walqabatu yoo qabaattan nagaafachuu dandeessu!

Isin qorannicha keessatti hirmaachudhaaf hayyamamaa dhaa?_____

Galatoomaa!

Hayyama jechaa tajaajilamma irraa argachuu mirkaneessudhaaf maqaa fi mallattoo gaafataa guyya wajjiin:

Maqaa guutuu_____ Mallattoo_____Guyyaa gaafatame_____

Woraqaa odeeffannoo Qorannichaa

- **Mataduree Qorannoo**

Naannoo Oromiyaa godina A/Lixaatti Qorannoo bu'aa Tajaajila qoricha farra 'HIV' Hospitaala fi Buufata fayyaa walmadaalchisuu

- **Bu'uuraa Qorannoo**

Waggoota digdamii shaman darbaniif HIV/AIDS iin rakkoo fayyaa hawaasaa cimaa fi isa olaanaa ta'uun tureera. Biyyit teenyas biyyoota addunyaa rakkoo kaan hubamaa jiran keessaa ishee takka yemmuu taatu uummata biyyattii harka dhibba keessaa harki lamaa ol vaayirasii kanaan kan qabaman ta'uu qorannoon ni ibsa. Miidhaan fayyaa hawaasummaa fi diinagdeetis biyyatti hubaa kan jiru dha. Biyyi keenyas rakkoo kana qolachuudhaf sochii hedduu taasisaa jirtu keessaa inni tokko tajaajila "ART" yeroo gara yerootti babaldhisuun kennudha. Godina A/Lixaa keessattis kan raawwatamaa jiru kanuma yemmuu ta'u kanaan walqabatee kenniinsi tajaajila kanaa jiddugaleessa irraa gara baadiyyaa fi ogeessa olaanaa irraa gara ogeessa giddugaleessaatti gad bu'aa kan jiru dha. Qorannoon kunis dhimma kanaan walqabatee faaydaa argamuu fi hanqinoota jiran madaaluun qaama seera baasus ta'ee qaama raawwataa hubachiisuuf bifa gargaarun kan qindaa'e dha.

- **Kaayyoo Qorannoo**

Qorannoon kun garaa garummaa bu'aa tajaajila yaala qoricha farra HIV/AIDS ii sadarkaa hospitaala fi buufata fayyaatti jiruu madaaludhaan hubannoo uumuuf kan qophaa'e dha.

- **Faaydaa/Bu'aa Qorannoo**

Qorannoon kun yeroo xumurame sagantaa ittisaa fi to'annoo HIV/AIDS ii karoorsu fi raawwii isaa fooyyessuuf kan gargaaru akkasumas qorattoota dhimma walfakkaatu irratti qorannoo gaggessuu barbaadaniif bu'uura ta'a jedhamee amanama.

Akka waliigalaattis hawaasa baldhaa fayyadamaa taasisuuf kan gargaaru dha.

- **Yeroo fi Eddoo Qorannoo**

Qorannichi kan gaggeeffamu Godina kana keessattii dhaabbilee fayyaa tajaajila yaala qoricha farra HIV waggoota sadan darbanii oliif kennaa turan hunda keessatti yemmuu ta'u raga yaalaa tajaajilamtoota hayyamamaa ta'anii yeroo tokko qofaa qorachudhaan kan gaggeeffamu ta'a.

- **Faaydaa/Miidhaa qorannichaa walqabatu yoo jiraate**

Qorannoo kana keessatti hirmaachuu isaa/isheetin faaydaas ta’ee miidhaan kallattiidhan tajaajilamaan argatu yokin irra gahu hingiru.

- **Icciitummaa/Haqummaa/Kabaja dhuunfaa**

Icciitiin raga yaalaa dhuunfaa ciminaan kan kabajamu yemmuu ta’u bifa haqummaa qabuun tajaajilamtoonni yeroo ji’oota sadi’ii oliif tajaajila qoricha kanaa dhaabbilee yaalaa filataman keessatti argataa turan hundi kan hirmaatan dha. Ragaan funaanamu ogeessotuma tanaan dura raga tajaajilamtootaa qindeessaa turaniin lakkofsa koodii qofatti gardaaramuun ta’a.

- **Mirga Hirmaannaa (Hirmaannaa Fedhaa)**

Ragaan yaalaa tajaajilamtoota yeroo qorannoon kun gaggeeffamu dhaabbaticha dhufanii kan ilaallamu hayyama isaanii irratti hunda’ee yemmuu ta’u kan isaan yeroo sana keessatti hinargaminii immoo seera icciitii qorannoo eeguun raawwatama.

- **Gaaffii Mirgaa fi Komii** (Teessoo qaama qunnamamuu)

Tajaajilamaan qorannoo kana keessatti hirmaatee dhimma qorannichaan walqabatu irratti gaaffiis ta’ee komii qabu kan qunnamuu qabu ob. Abbabaa Magarsoo (lakk. Bilb.0911044525 irratti dha).

Annex B: Patients Record Review Form

ADDIS ABABA UNIVERSITY MEDICAL FACULTY SCHOOL OF PUBLIC HEALTH

Log-Book for Patients record Review

Section I: Socio Demographic Variable

Facility Code_____ Log-Book Code_____

No	Questions	Coding Categories
11	Age in years now (Write)	1. 18-29 2. 30-39 3. 40-49 4. ≥50
12	Sex of the patient	1. Male 2. Female
13	Ethnic group	1. Oromo 4. Gurage 2. Wolayta 5. other (Specify) 3. Amhara _____
14	Marital status	1. Unmarried 4. Separated 2. Married 5. Widowed 3. Divorced
15	Religions	1. Muslim 4. Catholic 2. Orthodox 5. Other specify_____ 3. Protestant
16	Literacy level	1. Illiterate 4. High 2. Read & write 5. Diploma or above 3. Elementary school
17	Residence o **Urban** (if from Woreda Towns) o **Rural** otherwise	1. Urban 2. Rural
18	Working Situation	1. Employed & Working active 2. Working on individual 3. Jobless 4. Student 5. other specify_____

Section II: Clinical/Medical Variables (From Clinical monitoring chart)

No	Questions/Variable	Coding Categories/Responces
21	Date HIV diagnosed (MM/YY) G.C	_____/_____
22	Date started on ART (MM/YY) G.C	_____/_____
23	Criteria to start ART	1. WHO stage 2.CD4 count 3.TLC count
24	Initial Body Weight (**KG**) with date	_____ _____/____/_____
25	Initial CD4 count (**CD^4/MM^3**) with date	_____ _____/___/_____
26	Initial Functional status	1. Bed ridden 3. Ambulatory 2. Working
27	Initial WHO stage	1 2 3 4
28	Initial OIs	
	Herpes zoster	1. Yes 2. No
	Bacterial Pneumonia	1. Yes 2. No
	Pulmonary TB	1. Yes 2. No
	Extra pulmonary TB	1. Yes 2. No
	Thrush (any)	1. Yes 2. No
	Diarrhea (chronic)	1. Yes 2. No
29	Date of record review (MM/YY) G.C	_____/_____
210	Current status of the patient	1. On treatment 2. LTFU 3. Died 4. Other
211	If not on treatment date of event (MM/YY) G.C (Died LTFU Stop ART)	_____/_____
212	Recent Body Weight (**KG**)	_____ _____/___/_____
213	Recent CD4 count (**CD^4/MM^3**)	_____ _____/___/_____
214	Recent Functional status	1. Bed ridden 3. Ambulatory 2. Working
215	Recent WHO stage	1. Stage One 2. Stage Two 3. Stage Three 4. Stage Four

No	**Questions/Variable**	**Coding Categories/Responses…**
216	Opportunistic Infections in **last three** months	
	Herpes zoster	1. Yes 2. No
	Bacterial Pneumonia	1. Yes 2. No
	Pulmonary TB	1. Yes 2. No
	Extra pulmonary TB	1. Yes 2. No
	Thrush (any)	1. Yes 2. No
	Diarrhea (chronic)	1. Yes 2. No
217	Drug side effects ever observed/diagnosed	
	Nausea 1. Yes 2. No	Abdominal pain 1. Yes 2. No
	Diarrhea 1. Yes 2. No	Jaundice 1. Yes 2. No
	Numbness 1. Yes 2. No	Dizzy night mare 1. Yes 2. No
	Anemia 1. Yes 2. No	Rash 1. Yes 2. No
218	Number of ATR consecutive doses missed by the patient since on treatment	1. No dose missed 2. Missed two and less consecutive doses 3. Missed greater than two consecutive doses
219	Regular refilling of Chemoprophylaxis for the patient	1. Yes 2. No 3. Not known
220	Adult first line regimen category the patient put on initially	1. 1a (30) 2. 1a (40) 3. 1b (30) 4. 1b (40) 5. 1c 6. 1d

Annex C: Key Informants Interview Topic Guide

Key Informants interview Topic Guide (adapted from National ART Guideline)

1: Clinical Service Minimum Package by level of facility

1.1 Infrastructure

Examination room (separate and convenient)

One private counseling room

1.2 Equipment and supplies

Exam Tools and supplies (Otoscope stethoscope blood pressure cuff reflex hammer)

Supplies (infection prevention materials tongue blade)

1.3 Human Resources

Hospital

1 MD trained on ART for special/referral hospital and

1 Health officer for regional and district hospitals

2 ART trained nurses

1 data clerk

Health Center

1 ART trained health officer and

1 ART trained nurse or 2post-basic ART trained nurses

1 data clerk

1.4 M&E/MIS

Log book

Recording/reporting forms

Special ART prescription

1.5 Services

Comprehensive HIV services

(VCT PITC PMTCT TB STI and OI Services palliative care)

1.6 Referral Systems

Referral slip feedback forms

2: Pharmacy Service Minimum Package by level of facility

2.1 Infrastructure

On-site pharmacy

Secure storage space

Private counseling room or space

2.2 Equipment & Supplies

Refrigerator

2.3 Human Resources

2 ART trained pharmacy personnel (Hospital)

1 ART trained pharmacy personnel (HEALTH CENTER)

2.4 M&E/MIS

Drug supply and management system (bin card stock card receiving voucher models prescription forms registration book report forms)

Lockable drawer

3: Laboratory Service Minimum Package by level of facility

3.1 Infrastructure

Specimen collection area and 1 additional room

Laboratory (HEALTH CENTER)

3.2 Onsite or networked laboratory services

CD4 Count (**not for health centre**)

Clinical Chemistry (BUN Creatinine LFT Indian ink) (**not for health center**)

Full blood count (Hb WBC and Diff.)

AFB smear	Gram smear
Ova & Parasite	Malaria smear
Pregnancy test	Serology for
HIV	RPR / VDRL

3.3 Equipment & Supplies

CD4 Count Machine (**not for health centre**)

Haematology auto-analyzer (**not for health center**)

Clinical chemistry auto-analyzer (**not for HC**)

Sterilizing equipment

Microscope Refrigerator

Centrifuge Test Kits

IP supplies Reagents

3.4 Human Resources

2 trained laboratory personnel

1 trained laboratory personnel

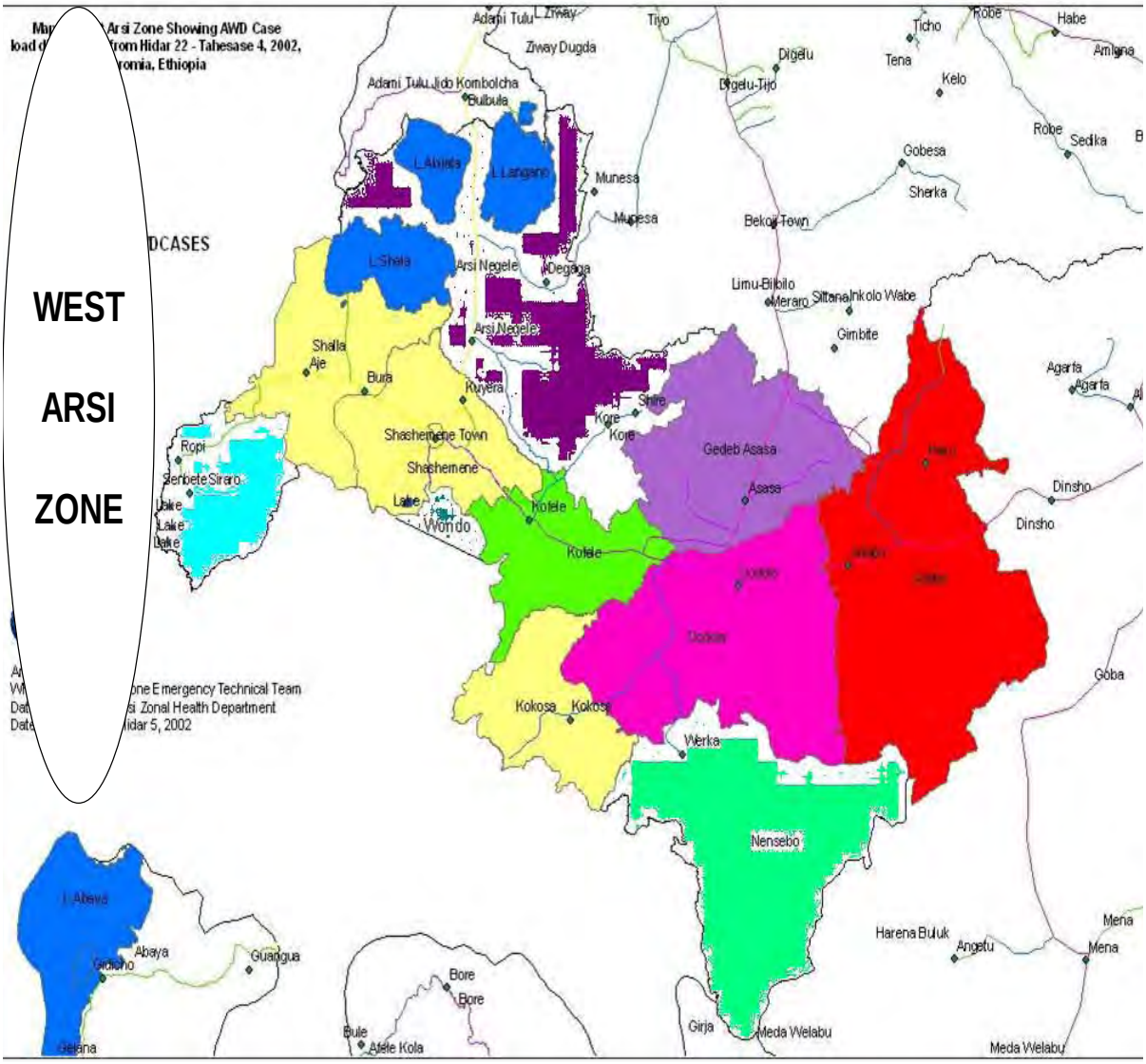
3.5 M&E/MIS

- Log book
- Recording/reporting forms

Annex D: Study Area Map

Oromia Regional State with study zone

West Arsi Zone of Oromia Regional State (Shaded area of the map)



The Zone shares boundary with East Shoa in North and North West SNNPR in South West and South Bale in South East and East and with Arsi in North East.

Declaration

I, the undersigned, declare that this thesis is my original work, has never been presented in any other university and that all sources of materials used in this work have been duly acknowledged.

Name: **Abebe Megerso Adlo (BSC in PH)**

Signature: _____

Place: **Addis Ababa University**

Date of submission**: July 20, 2010**

This thesis has been submitted for examination with my approval as a university advisor.

Name: **Dr. Negusie Deyessa (MD, MPH)**

Signature: _____

Date **July 20, 2010**