

**PRE-ART CARE IN ETHIOPIA: A QUALITATIVE LOOK AT PRACTICE AND  
GUIDELINE IMPLICATIONS FOR TOP DOWN AND BOTTOM UP  
IMPLEMENTATION**

by

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Submitted to the Graduate Faculty of  
Graduate School of Public Health in partial fulfillment  
of the requirements for the degree of  
Master of Public Health

University of Pittsburgh

2013

UNIVERSITY OF PITTSBURGH  
GRADUATE SCHOOL OF PUBLIC HEALTH

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**ABSTRACT**

Background: Pre-ART, defined as all services provided between the timeframe of a patient testing positive to HIV till the first dose of antiretroviral, can be a crucial period in patient retention and attrition. Therefore, this study aims to examine practices around facility level Pre-ART throughout Ethiopia based on discussions with clinicians and facility staff and to determine potential considerations for country specific Pre-ART guidelines and future public health practice in other resource constrained countries.

Methods: Framework Analysis was applied to secondary data derived from key informant interviews with facility level clinicians and staff in Ethiopia regarding themes around Pre-ART. We identified significant data surrounding the practices and processes currently taking place at a sample of six sites. An exploratory understanding of the challenges and best practices surrounding Pre-ART was highlighted and themes to be taken under consideration by a Pre-ART guideline-working group in Ethiopia were noted.

Results: Study sites indicated various service provisions and practices around Pre-ART care along the testing to treatment cascade. Patient tracking, Cotrimoxazole prescription, access to CD4 machines, and data management practices varied by facility. Similar practices around linkages from testing to treatment were noted across facilities.

Conclusion: Combining the local resource reservoir with a national guideline plan allow for the ideal meshing of top down and bottom up implementation and will minimize the pitfalls of system wide rollout of Pre-ART guidelines. The ultimate goals behind any Pre-ART program should be to provide a measure of care and support which patient's value. The benefits then derived from this valuation result in the key public health outcomes, namely in terms of patient retention, early initiation onto ART, and continued monitoring of patient progress across the testing to treatment cascade. Meeting these goals and objectives hinges on a collaborative effort and one that bridges the divide of policy makers and practitioners.

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## **PREFACE**

In 2008 I began a fortuitous journey to a historical country in the horn of Africa. The land of 13 months of Sunshine, Ethiopia. I became enamored with the country and all of the people I met on that continuous journey. So I must start by simply saying “Amesegenalehu”

I must also recognize the family and friends who have provided immeasurable terms of support. Mom and Dad, you provide unending support from afar. To those locally, who have been a constant reinforcement of inspiration and encouragement, Sharon, Teagen, Kristen, Jeff, and Lane; I wish to share my gratitude. To my committee members, Jessie, Joanne, and Dr. Veldkamp, you have provided instrumental support and freely given of your time, and I appreciate the efforts you have made to aid me in this process. Adam and Raph, a large thanks to you both is in order, as you invited me in and showed me the opposite of the “sleepy’ NGO perspective. That has made a considerable difference. Finally, to a young man known to me simply as “Jaguar”, you are not forgotten and I draw purpose from your life and memory.

## **1.0 INTRODUCTION**

This master's thesis discusses the practices of Pre-Antiretroviral Treatment (Pre-ART) identified by clinicians and administrators working day to day on the ground in the network of care for those with HIV/AIDS administered by the government of Ethiopia; and it seeks to highlight best practices and perspectives of field level Pre-ART implementation as it currently is provided in Ethiopia.

Pre-ART is often defined as all services provided between the timeframe of a patient testing positive for HIV till the first dose of antiretroviral (ARV) are prescribed. This timeframe can be a crucial period in patient retention and attrition. A strong Pre-ART program that works in combination with early initiation of Antiretroviral Therapy (ART) is associated with higher ART patient retention.

A recent study conducted by the Ethiopian Federal HIV/AIDS Prevention and Control Office (FHAPCO) noted that Pre-ART programs are not standardized and facilities across the country operate under various programming, staffing, and service delivery models.<sup>1</sup> With no standardization, quality and access to Pre-ART services may vary. This results in little to no understanding of what practices are taking place at the field level, and the effects on those issues of quality, access, and patient retention.

Currently the Ethiopian Ministry of Health has guidelines for ART treatment but guidelines are not in place in regards to Pre-ART care and practices within the country. Understanding the models and typologies of care at the field level regarding Pre-ART is crucial to driving policy change, particularly regarding adoption and utilization of Pre-ART guidelines by the Ministry of Health (MOH) in Ethiopia. Additionally, other countries can utilize the Pre-ART themes emerging during this thesis in understanding challenges and facilitators to delivering care in a similar resource constrained environment.

This thesis will begin with a review of literature around HIV/AIDS care and treatment in Ethiopia and other similar settings, a theoretical perspective behind policy implementation, and an overview of the policy environment surrounding HIV/AIDS care and treatment, namely ART service provisions. The research methodology, evolving from a series of prior studies, will be described. The objective is to determine the practices taking place at the ground level for Pre-ART practices in sampled sites in Ethiopia based on discussions with clinicians and facility staff. Themes around Pre-ART derived from a previous study, will be analyzed as secondary data and will be presented as reported processes and practices amongst and across facilities studied. Based on these reported practices the thesis will explore themes which emerge and which can inform policy makers when considering perspectives of Pre-ART care and delivery within national level working group of policymakers and influencers in Ethiopia.

## **2.0 BACKGROUND**

### **2.1 HIV/AIDS IN ETHIOPIA**

The prevalence of HIV/AIDS in Ethiopia is estimated at 1.5% of the general population <sup>2</sup>, with a higher prevalence for women at 1.9% than for men at 1.0%. Despite a lower prevalence rate than many other Sub-Saharan African countries, Ethiopia is a highly populated country (almost 85 million people and the second most populous country in Africa); resulting in approximately 800,000 people in the nation living with the virus, and consequently a high burden in terms of increased morbidity and mortality.<sup>3</sup> Most of those affected are Ethiopians of productive and reproductive age, and higher prevalence rates for both men and women in the group of those aged 25 to 34 exist. The Ethiopian Health System alone spends approximately 20% of its entire health budget on programs for just HIV/AIDS.<sup>3</sup>

UNAIDS has identified Ethiopia as one of twenty countries in which collaborative targeted strategies could have significant impacts on turning the tide of the HIV/AIDS epidemic, notably by addressing ART gaps, decreasing vertical transmission, and significantly reducing global HIV infections.<sup>4</sup> One way the country has taken steps to do this is to use a public health approach to increasing ART coverage in hospitals and health centers throughout the country.<sup>5</sup> Large scale Ethiopian government sponsored free ART rollout began in 2005 began with three ART sites and expanded to 838 sites in 2012, with approximately 663,000 people cumulatively

accessing free ART services by 2012.<sup>6</sup> With an increase in the number of people on treatment<sup>3</sup> the decrease in the cost of ART treatment<sup>1</sup> and research indicating earlier treatment leads to better outcomes, i.e. reduced morbidity and mortality;<sup>7,8</sup> the scale up of ART is becoming more feasible and an important component not only for the care and treatment for people in Ethiopia but also an important strategy by the Ministry of Health for prevention efforts.

## **2.2 PRE-ANTIRETROVIRAL TREATMENT**

### **2.2.1 Definition of Pre-Antiretroviral Treatment**

The terms Antiretroviral Treatment (ART) and Pre-Antiretroviral Treatment (Pre-ART) vary by country and often by context and standardization is difficult due to varying degrees of care, country level health systems, and available treatment and scale up of antiretroviral programs in developing countries. Therefore for the context of this thesis, the model developed by Fox, Larson et al. (2012) is utilized to provide a definitional baseline. This model of Pre-ART provides definitions and stages of Pre-ART and since this model is noted primarily for studies of cohorts of patients, rather than systems and facility level processes, focus is on the standardized definitions, rather than the stages model presented. Table 1 provides the definitions provide by Fox, Larson, Rosen<sup>9</sup> and subsequently used as agreed upon definitions throughout this thesis.

## 2.2.2 Pre-ART as Component of Care and Support

As countries propose scaling up ART and initiating patients on ART earlier, it is important to retain these patients in regular care and ensure linkages with testing to treatment to ensure initiation into ART takes place. This is the essential role of Pre-ART care. Patients who are not monitored and retained in care will receive care only when the CD4 counts are significantly lowered and symptoms from opportunistic infections present more significantly, resulting in the patients becoming ill with more serious complications from the virus. A systematic review of Pre-ART losses in Sub-Saharan Africa indicate patient loss and drop out in each progression along the testing to treatment cascade, with an estimate of less than one third of patients retained in care from testing to initiation of ART.<sup>10</sup> Reasons cited for losses included high transport

**Table 1 Pre-ART Definitions and Concepts**

<b>Concept</b>	<b>Definition</b>
Pre-ART Care	All services provided to patients between testing positive for HIV and dispensing of the first dose of ARV's.
Enrollment in Pre-ART Care	Active (intentional) registration by a patient in any form of pre-ART care, regardless of whether this occurs before or after initial ART eligibility assessment.
ART eligibility assessment	The process of determining if a patient should be referred to or continue in pre-ART care or should initiate ART, typically determined through a CD4 count or on the basis of WHO stage
Retention	Active engagement in pre-ART care as required by the specific care program over time, which is defined for each stage of Pre-ART Care
Loss to care (Attrition)	Discontinuation of active engagement in pre-ART for any reason, including death.

costs, long waiting lines, lack of Pre-ART incentives, and turning to alternative medicines.<sup>11,12,13</sup>



Additionally concerns exist for patients around stigma and discrimination, as well as patient health literacy and general feeling of health and wellness.<sup>13,14</sup> Health system factors have indicated stock outs of necessary drugs, lack of provision of Pre-ART care<sup>12</sup>, and staff shortages. Several strategies have shown to be effective to preventing this lost to follow up, including providing CD4 tests and quick dissemination of results to patients at testing.<sup>15</sup>

### **2.3 PRE-ANTIRETROVIRAL TREATMENT IN ETHIOPIA**

Ethiopian health systems, like many resource constrained countries, struggle to keep retain patients in ART care.<sup>16</sup> While very few studies exist around Pre-ART retention in Ethiopia, the studies have indicated the same is true for losses due to linkages and retention for Pre-ART patients in the country as well. Only 47% of patients were immediately linked to care after testing positive for HIV<sup>17</sup> and mobile testing linkages via referrals from clinicians remain low.<sup>18</sup> Pre-ART patient LTFU (Lost to Follow Up) or attrition is high in Ethiopia. This is partly due to increase in patients presenting to health facilities earlier and with less symptoms present yet the challenges remain of keeping these patients in Pre-ART care.<sup>19</sup>

Several years ago the World Health Organization (WHO) began compiling guidelines for ART provision and service delivery prior to more widespread uptake of ART programs by developing countries. These guidelines provided strategies to deliver care while simultaneously balancing countries limited supply of resources in the forecasting of impending scaling up of ART. These took a public health approach, meaning they were designed for system wide approaches to building an ART health system.<sup>20</sup> Individual countries would then use these guidelines to implement ART programs, and subsequently draft country specific guidelines using

both a public health approach in the country and also providing specific treatment guidelines for clinicians.

Guidelines for Pre-ART care, similar to guidelines many countries implement for ART care, are essential for implementing and monitoring systems level of care nationwide. The guidelines reduce confusion by calling for specific roles for cadres of staff at facilities, and provide important clinical as well as public health approaches to undertake. The guidelines are generally derived from evidence-based practices, but should provide flexibility for local concepts to be addressed.

Currently Ethiopia does not have clinical or implementation guidelines for a standardized Pre-ART program. The MOH has established a standardized HIV care/ART patient monitoring system, patient intake and follow-up forms, pre-ART and ART registers, cohort, and monthly reporting forms. This system supports monitoring of program implementation, access to patient care and treatment outcome, as well as logistical capacity and performance. The only formalized Pre-ART portion of this system is the provision of standardized Pre-ART registers and patient intake charts, which provide a measure of record keeping and logging of patient histories and status for treatment typology.<sup>21</sup>

## **2.4 ART POLICY ENVIRONMENT IN ETHIOPIA**

It is important to understand the health system structure and policy decision-making and implementation structure in Ethiopia. The Ethiopian has a decentralized system for HIV/AIDs and ART implementation, but a centralized policy and guideline making system for making policy and guidelines. This practice allows local level implementation to be adapted to local

contexts, so long as implementers follow guidelines and larger level policies instituted by the National Ministry of Health (MOH).

For Ethiopia ART service provision is implemented via two primary mechanisms:

*1. Program implementation and coordination*

*2. ART Service Deliveries*

Figure 1 provides a diagram of the ART service provision hierarchy in the Ethiopian Health System context.<sup>22</sup>

A network of private sector and ART training models supports these initiatives, but since this thesis focuses on the scope of Pre-ART service delivery and programing processes, these other supportive initiatives are not highlighted herein.<sup>22</sup>

Program Implementation and Coordination relies on a hierarchical system with various responsibilities by coordinating level. It is important to understand each level in the process; therefore the responsibilities associated with each level of implementation are highlighted below:

***National Level:*** Responsible for formulating policy, standardizing programming, capacity building, monitoring and evaluating

***Regional Level:*** The regional health bureaus are considered the first level of implementers and provide leadership and guidance by promoting coordination, linkages, and dictating importance of policy actions from the National Level.

***Zonal Level:*** The zonal level implementers work to create and nurture linkages between larger zonal hospitals and surrounding health centers, identify and select future ART sites in the zone, and provide supportive supervision to ART sites.

**Woreda Level:** The woreda level health offices are charged with supporting ART at each community site, work to engage community mobilization of resources, and provide training on home base care, adherence support, and treatment literacy.

**Kebele and Community levels:** These are the smallest levels of ART support and implementation, and the kebele office and community organizations work to support the health center and health posts and link these facilities to households and community members. Local level initiatives are encouraged to mobilize local resources, and support community programs including home based care and coordinate local Non Governmental Organizations (NGO) efforts in order to lessen duplication and increase local efficiency in prevention, care and support.<sup>22</sup>

Service delivery of ART, which is the routine provision of HIV/AIDS and ART services, hinges on the health facilities (hospitals and health centers) as implementers. These facilities bear the brunt of the burden of implementation and in addition to basic service delivery responsibilities and patient management, they are tasked with creating referral linkages for patients between services, ensure facility clinicians and staff are properly trained, initiate task shifting (from doctors to nurse or health officer level for delivery of ART), expand patient entry points for HIV care in the facility, and coordination of all HIV services within the facility to expand access for patients to HIV/AIDS services, including both prevention and treatment options.

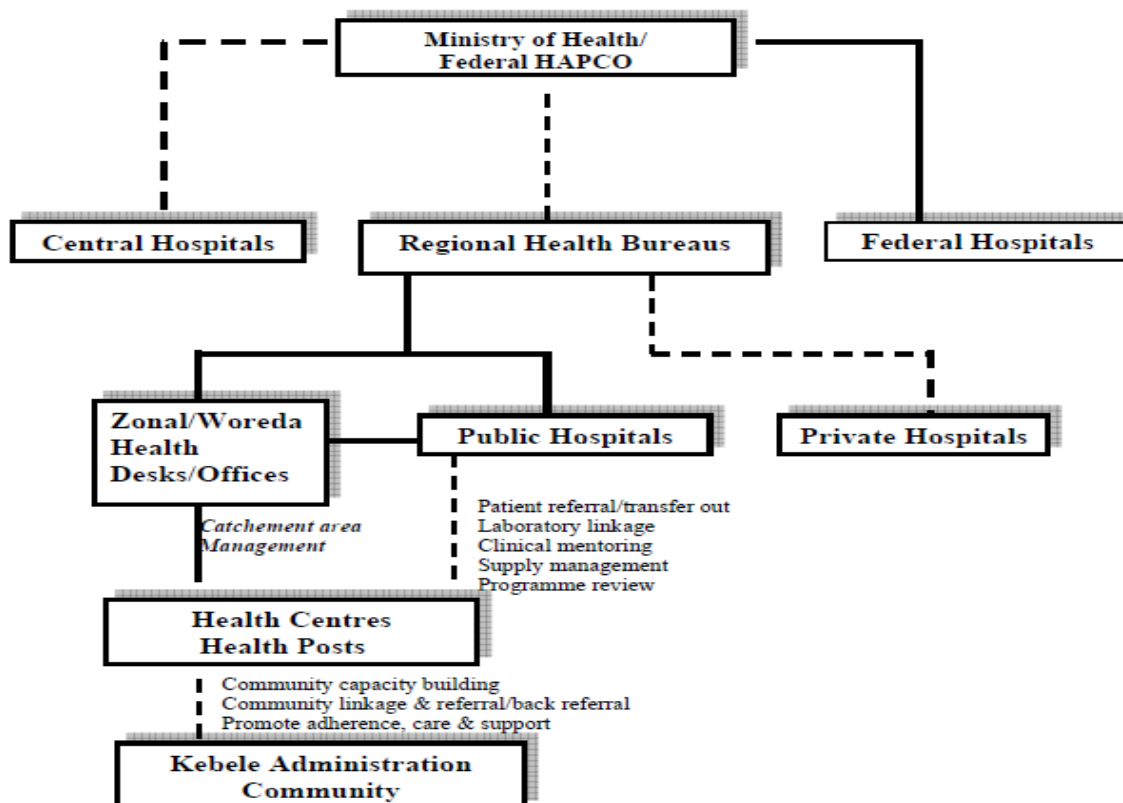


Figure 1 Ethiopian ART Management and Coordination Structure

#### 2.4.1 Program Goals and Requirements:

Ethiopian implementation guidelines for ART call for a several important components for implementing a national level guideline, including a call for adherence to National ART policies and guidelines by health facilities and lower level program implementers. Other components noted as essential to implementation are the usage of clinical tools and monitoring (in accordance with relevant clinical guidelines), accrediting service delivery facilities, development of standard operating procedures, providing appropriate training, and development of standardized health management information systems.<sup>22</sup> These components mirror what one would expect from Pre-

ART guidelines for the nation. Future draft guidelines around Pre-ART therefore can use this as a basis for drafting goals and objectives.

## **2.5 THEORETICAL PERSPECTIVE**

An important component to Pre-ART and ART guidelines is the theoretical basis for how policies and guidelines are formed and ultimately implemented. This thesis focuses primarily on the implementation approach and uses the concepts from Policy Implementation Theory to explain the environment in which policy changes (and concurrently best practice guidelines) can happen, both on a macro and micro level implementation scheme.

Policy Implementation Theory has seen undergone several evolutions of understanding, with current theory and research in a “Third Generation” evolution. It is however important to understand all prior levels to gain the necessary perspective to apply the third generation implementation theory.

First generation implementation theory was developed in the 1970’s and early 1980’s to look at the notion of how a decision is made and implemented in an authoritarian manner and examined the barriers and facilitators to actual policy implementation, examining the responses in implementation versus policy directives.<sup>23</sup> The second generation of implementation theory expanded upon this approach, primarily by adding the notion of two distinct approaches, a top-down approach vs. a bottom up approach to policy implementation.

Top-down approaches emphasize standardizing or ‘generalizing’ policies, primarily through a statutory measure that filters down to implementers. Elmore (1978)<sup>24</sup> describes this as :

*“It begins at the top of the process, with as clear a statement as possible of the policy-maker’s intent, and proceeds through a sequence of increasingly more specific steps to define what is expected of implementers at each level. At the bottom of the process, one states, again with as much precision as possible, what a satisfactory outcome would be, measured in the terms of the original statement of intent”*

The bottom up perspective’s focal point is essentially the inverse. It relies on “street level bureaucrats”, people at the micro level who have a better understanding of what is taking place on the local level they work in.<sup>23</sup> It works under the understanding that program success is dependent on those with a true local perspective, who then can make changes and adaptations if necessary to policies to ensure the policies fit the local or micro context. Berman (1978) also labels these same processes as macro level versus micro level.<sup>25</sup>

Third generation policy implementation theory seeks to build on the first two levels of policy implementation theory and mesh the macro and micro levels into an integrated system. It also seeks to apply appropriate outcome measure focuses and recognizes the inherent problems associated with both top down and bottom up methods. Top down (or macro) approaches do not provide an understanding of program outcomes, alternatives, necessary implementation requirements, and practical implications with each enacted policy. Bottom up approaches (or micro) approaches are limited in applying policies and practices on larger, system wide scale and do not aid policy and decision makers in generating total systems implementation. The generation approach is still evolving and it is noted that in practice this theory has not been effectively realized. Despite this, it is important to understand the concepts involved when evaluating Pre-ART practices at the field level and envisioning how these processes can be

scaled up with a systems approach, and concurrently made implemental in an effective manner in the local context.



## **3.0 METHODOLOGY**

### **3.1 STUDY HIERARCHY**

This data for this thesis was generated over an evolution of several prior studies conducted in Ethiopia centered on understanding ART and the network of factors in Ethiopia's health and service provision delivery system for HIV/AIDS care and treatment. Figure 1 below highlights the study hierarchy and the following sections detail the methods, objectives and progression of how data was collected, derived, and analyzed for each study, ultimately leading to a secondary analysis of data presented in this thesis.

Study	Objectives, data collected and used in analysis
<b>Parent Study: Facility Based ART Costing Study</b>	Quantitative Study conducted by CHAI Measured cost of <b>ART</b> and <b>Retention</b> of patients 39 Sites (N=39) Systematic Random Sampling Primary Measures: Cost (\$ PPPY) and Outcomes (% Patient Retention)
<b>Follow Up Study: Outlier Analysis</b>	Study conducted by CHAI Qualitative Key Informant Interviews with facility staff 6 Sites (n=6) Purposive Sampling Focus on Service Delivery, Facility Admin, Patient Management, Infrastructure, Auxiliary Programs
<b>Secondary Pre-ART Analysis (derived from Outlier data)</b>	Secondary Analysis of CHAI Outlier Study De-identified field notes provider to researcher 6 sites (n=6) Convenience Sample Focus on Themes around PRE-ART

Figure 2 Study Hierarchy

### 3.2 PARENT COSTING STUDY:

In 2011 the Clinton Health Access Initiative (CHAI) and the Bill and Melinda Gates Foundation (BMGF) undertook a multi-country ART costing study totaling 161 health facilities across 5 Sub-Saharan African countries: Ethiopia, Malawi, Rwanda, South Africa, and Zambia. Analysis of the 2011 costing data yielded a range of costs of ART (per person per year) and outcomes (patient retention percentages) by facility within each of the countries. This thesis references the

Ethiopian facilities. Study data combined with follow up studies referenced herein refer only to the Ethiopian portion of the multi-country study.

All facilities offering ART services in Ethiopia were eligible, and CHAI used stratified random sampling to choose 39 sites for the study (n=39). This quantitative analysis will help to inform many global and country-level policy decisions and scale-up plans, however it did not fully explain the drivers of best practice or poor performance. In order to gain a qualitative perspective of the drivers of these factors, CHAI undertook an in depth “Outlier Analysis” based on a sample of sites from the Parent Costing Study in these same five countries to begin to identify the key characteristics of cost efficient ART service delivery models.

### **3.3 OUTLIER ANALYSIS STUDY:**

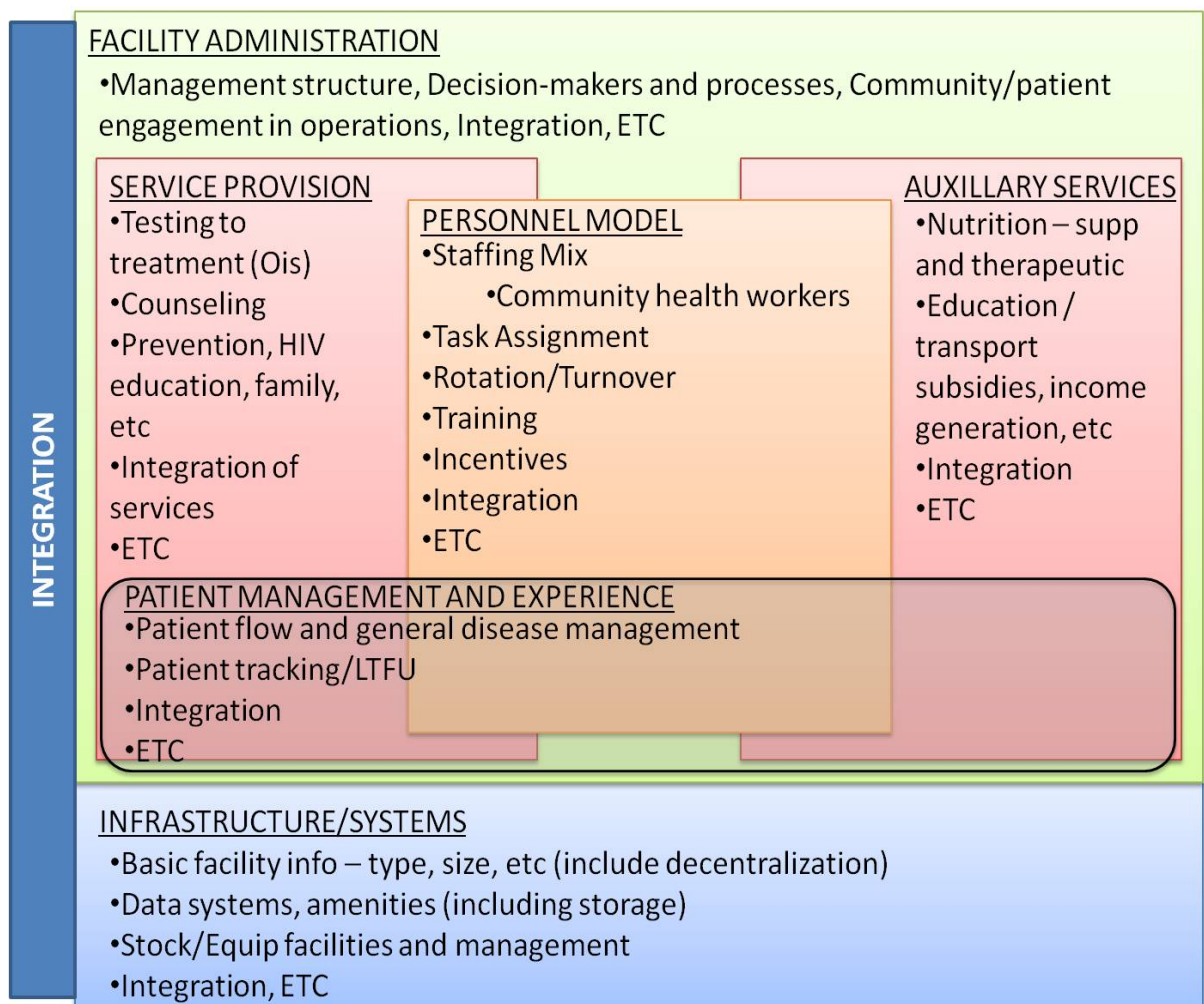
CHAI conducted the Outlier Analysis as a follow up qualitative study to determine the facility and system level drivers of cost and retention in Ethiopia. It is important to note the thesis author participated as a researcher and data collector on the Outlier Study, primarily in the capacity of a note taker and interviewer.

#### **3.3.1 Specific Objectives: Outlier Analysis**

The Outlier Analysis study consisted of six thematic areas: Facility Administration and Management, Service Provision, Personnel Models, Patient Management, Auxiliary Services, and Infrastructure. Within each of these specific focus areas for facilities, the following objectives were developed:

1. Describe and define the characteristics or structure it relates to the specified category
2. Describe and define the functions and decision-making processes which enable operations and provision of relevant services or systems
3. Evaluate strengths and limitations of systems and processes
4. Evaluate the impact on cost and retention
5. Understand and describe the cross-over points of each category i.e. interrelated processes and systems between defined categories

Figure 3 shows the conceptual framework for the Outlier Analysis study.



**Figure 3 Conceptual Framework for Outlier Analysis**

### 3.3.2 Sampling and Site Selection

The sampling frame for the Outlier Analysis was sample of 39 sites from the Parent Costing Study. Of these, a purposive sample was taken of 6 facilities (n=6). It is important to note each site has been providing ART for varying times and practices at each may be a factor of experience providing services, however this was not a factor for selection of outlier sites. The site numbers and criteria used to determine each site are outlined below:

1. ETH\_03:

Outlier Characterization: *Cost*: High (\$231 pppy) *Retention*: Low (76%)

This site was selected as an outlier site for further investigation because it had the lowest baseline CD4 among new patients in the sample, 4<sup>th</sup> highest CD4 testing frequency, and the highest first line regimen to first line regimen (ART) switch rate. The site is a government-run tertiary facility located in a highly populated urban area and has the third highest patient load of any of the original study sites.

2. ETH\_10:

Outlier Characterization: *Cost*: Low (\$140 pppy) *Retention*: High (98%)

This site was chosen due to it's low per patient per year costs and high retention rate (approximately 98% of patients were retained). Additionally the facility is located in a highly pastoralist community and as a result presented unique circumstances for study.

3. ETH\_29

Outlier Characterization: *Cost*: High (\$267 pppy) *Retention*: Moderate (84%)

This site was chosen primarily because it had the highest cost per patient per year for ART of all the sites in the original study. It also had the highest dedicated Full Time

Equivalency's of any site, indicating more permanent staff, in addition to the highest CD4 testing rates.

4. ETH\_31:

Outlier Characterization: *Cost: Low (\$179 pppy) Retention: Moderate (88%)*

This site was chosen due to having the highest CD4 initiation of any of the original study facilities. Additionally the site had a 100% retention rate over the original study period.

5. ETH\_32:

Outlier Characterization: *Cost: Moderate (\$188 pppy) Retention: High (96%)*

This site was chosen due to a high patient retention rate and a high baseline CD4 count among patients (195 average). The facility also had a low CD4 testing frequency in comparison to a similar sized facility located nearby.

6. ETH\_39:

Outlier Characterization: *Cost: Low (\$158 pppy) Retention: Moderate (86%)*

Site selection was driven by anecdotal data collected in the original costing study. This evidence suggested unique programs in place at the facility to promote staff retention, including various means of providing housing and transportation options for staff.

Additionally this site was reported to have well-organized data management systems and a high CD4 testing rate.

### **3.3.3 Data Collection**

The Outlier Analysis utilized a multiple case study approach, containing both qualitative and quantitative components with each health facility comprising one case. Structured in-depth

interviews were conducted with health facility service providers and administrators centered on the pre-determined themes noted in Section 3.2.2. The study augmented the qualitative data derived from interviews with quantitative data related to Pre-ART chart data from a systematic random sample of 100 patient charts at each site. Patient chart data was used to determine stages of Pre-ART. Secondary analysis did not involve the patient chart abstractions as this data was outside of the scope of this thesis.

### **3.3.3.1 Interviews**

The qualitative data collection consisted of structured interviews with facility service providers and administrative staff. The interviews used a questionnaire that contained both close-ended and open-ended questions. The close-ended questions were used to gather specific information investigating each of the topical areas objectives. The open-ended questions allowed the service providers and administrative staff the opportunity to describe in their own words the challenges and accomplishments of the facility's ART-program in regards to the five main components of the model of care framework.

The interviewers obtained verbal consent with participants before conducting interviews. A translator was used to facilitate the interviews between Amharic and English speakers. The interviewers also attempted to incorporate principles of cultural awareness and sensitivity during the interview phase. The background of the fieldwork interview team aided this, as the interviewers were former Peace Corps volunteers; both of which lived in a small local setting in Ethiopia and were familiar with the language and culture of Ethiopia.

Additionally the fieldwork interviewers had experience working with ART staff at health centers in Ethiopia and were familiar with processes and expectations of service providers locally. This localized knowledge allowed for appropriate questioning according to culturally

appropriate nomenclature. This was further enhanced by the use of a trained experienced translator. The translator had prior experience working both with the interview team and on health related projects and therefore was also knowledgeable ART processes. Due to these experience levels, the fieldwork team was able to provide a level of comfort and openness to the participants, which is important to generating honest, reliable responses to interview questions and reduce levels of bias associated with qualitative data collection. This includes minimizing a potential reluctance to report processes, as they actually happen due to fear of punishment or retribution.

Detailed fieldworker notes were compiled during the interviews. Each interview was audio recorded and had two fieldworkers taking notes. One fieldworker would ask the participant the questions and simultaneously recorded notes on a laptop computer, and the second fieldworker took detailed notes on a laptop computer, focusing more on dictating responses from the participant and translator verbatim, to the greatest extent possible. Each day, after interviews were finished, the fieldwork staff combined notes, compared discrepancies, and discussed discrepancy resolution. The fieldworker notes reflected this process.

The head ART Nurse was the first person interviewed at each site. This allowed for the interviewers to gain a total overall perspective from the individual with the primary responsibility of overseeing the Pre-ART and ART service delivery in the facility. Then interviews were conducted with other facility staff based on staff availability. Finally, the researchers conducted a follow up interview with the ART Head Nurse to gain clarification on thematic areas needing more follow up and to understand disputing information between interviewees, if applicable.



### 3.3.3.2 Participant Selection

During the Outlier Analysis, in each of the selected sites, 2-4 clinic staff was selected as participants, consisting of service providers and administrative staff. Specifically the ART coordinator at each site was asked to participate. Additionally, service providers including ART nurses, lab technicians, case managers, and pharmacy technicians were selected for participation based on their willingness to be interviewed and their knowledge and experience with providing ART-related services at the facility. Inclusion criteria was based on two factors: 1) Participants must have held a current position as a service provider or administrative staff member at the selected facility and 2) have direct knowledge and experience providing services or coordinating the facility's ART program.

**Table 2 Participant Interviews by Site**

	<b>Participant Interviews by Site</b>					
	ETH_03	ETH_10	ETH_29	ETH_31	ETH_32	ETH_39
ART Nurse	2	1	2	1	1	2
Lab Technician	1	1	1	1	1	1
Facility Administrator	0	1	1	1	0	1
Pharmacist	1	1	1	1	1	1
Data Clerk	2	1	1	1	1	1
Case Manager	0	1	1	1	0	1
VCT Nurse	0	0	2	1	1	1

### **3.3.4 Interview Questions**

Interviews were conducted according to the various themes. To gain an understanding of questions regarding each theme, the thematic areas are explained in more detail for each section and followed by an example question per thematic area.

#### **Facility Administration and Management**

This section focused on administration personnel and decisions made to run the facility and administer services. Questions centered on evaluation of how and why decisions are made in terms of staffing, services offered, how/why specific services are provided, and how patients are managed.

Example Question: *How are administrative decisions made at the site, including service provision, budgeting, procurement, personnel management, etc. Are decisions made by facility management/board, or are decisions made at a higher level (e.g., regional)?*

#### **Service Provision**

This section focused on clinical and psychosocial services provided to patients at risk and/or HIV positive. Service provision included a description of the services themselves but also the decision-making processes which determine how and why these services are administered including, decentralization and how it is implemented within the selected facility. It included relevant components of the services and specifics of how and why these are provided (for example, ART includes provision of drugs, lab tests, and counseling).

Example Question: *If I were: (1) a patient suspected of HIV, (2) a patient who just tested positive for HIV, (3) a patient who is positive and now eligible for treatment, (4) a patient on treatment - responding/failing, how would I be treated?*

#### **Personnel Models**

The staffing mode is one of the primary structural components of a model of care and substantially impacts costs of service provision and patient outcomes. Five subcategories that further stratify the structural differences and drivers expected in health facilities:

- Staffing Mix
- Task Assignment
- Rotation/Turnover
- Training
- Incentives
- Staff integration with other non-HIV services

Example Question: *Describe the staffing model. The number and types of staff, what services they perform, how they are scheduled on a daily/weekly/monthly basis, etc.*

### **Patient Management**

Patient management included all processes experienced by patients as they access services at the facility. The patient management processes employed by the facility are also contingent on its level of decentralization and the types of patients and services it is scoped to provide. This category allows for understanding and evaluating how and why the facility directs patients through the services provided and ensures that they continue to access appropriate relative to their individual needs (whether at this facility or when referred).

Example Question: *Describe the full patient flow through the facility from both the facility perspective as well as the patient perspective (include referral process from OPD if suspected of HIV).*

### **Auxiliary Services**

Auxiliary services are defined, as those are not directly related to HIV treatment. These services are often necessary for patients whom are HIV positive or are provided to improve the overall quality of service provision. The main themes for these questions are:

- Prevention Services
- Family Focused Services
- Nutritional Support
- Incentives

Example Question: *What are the strengths of the selection of services provided and how they are administered?*

### **Infrastructure**

This section is extensive and includes everything from basic facility characteristics to the general physical amenities and utility services available. Interview-based information on infrastructure centered on:

- Type of Service Provision (facility type, level of care)
- Equipment and IT systems
- Stock/Equip management
- Amenities

Example Question: *Describe the stock and commodity management system and infrastructure (i.e. electronic, stock cards, etc)*

### **3.3.5 Data Analysis**

The Outlier Analysis used Framework Analysis for data analysis. Framework analysis consists of four steps: familiarization, identification of thematic framework, indexing and charting<sup>26</sup>. In the familiarization stage, all field notes, questionnaire responses, and quantitative data were aggregated and categorized according to facility. The data analysis team used the model of care framework, consisting of four major components, including personnel, lab services, pre-ART

availability and care, and other available services, to inform the analysis. In the indexing stage, field notes were coded using categories derived from the four components of the model of care framework. Additional themes, which emerged during this process, were coded and added to the existing framework. Once this process was complete, tables (charts) were generated to organize coded data thematically across all cases. Variations seen across themes were utilized to derive the model of care typology.

Two groups completed the analysis: the country offices (primarily consisting of fieldwork data collection team) and the CHAI global team. This was to provide a measure of additional rigor and structure to the analysis. Both the country office and the global team compiled and analyzed data generated from the facilities visited. The teams then categorized country-level data into matrices based on outlier cost drivers to generate an analytical framework. A group discussion/analysis between the global team and the fieldwork team who provided input to complete the matrices for each of their facilities and to further compare and analyze shared themes across facilities and countries. Each team's framework was compared and discrepancies were resolved. When a discrepancy was determined to be unresolved, the fieldwork team placed telephone calls to the sites as a follow up measure and to resolve the discrepancy.

## 3.4 SECONDARY ANALYSIS

### 3.4.1 Secondary Analysis Objectives

The Outlier Analysis study provided a wealth of information and data around the processes of HIV/AIDS care at facilities in Ethiopia and focused on many drivers of these processes and decision-making mechanisms. Significant data surrounding the practices of Pre-ART were identified and a need to synthesize the data further than the original scope of the Outlier Analysis was needed. The researchers envisioned an exploratory understanding of the challenges and best practices surrounding Pre-ART to develop initial suggestions to be taken under consideration by the Pre-ART working group in Ethiopia as they go about the challenging process of drafting, revising, accepting and ultimately implementing national level guidelines for Pre-ART to be integrated into the existing network of ART and HIV/AIDS care and support within the country. As a result of this process of synthesizing the Outlier data further, eight important themes to examine regarding Pre-ART practices at the facility level in Ethiopia were identified. These were:

1. Testing
2. Pre-ART Linkage
3. Pre-ART Care and Tracking
4. ART Linkage
5. Laboratory Services
6. Opportunistic Infection Prophylaxis
7. Community Health Workers
8. Community Programs

### **3.4.2 Data Collection and Sampling**

Data from Outlier Analysis study were provided to the researcher in de-identified field note form. A convenience sample (n=6) based on the data provided by CHAI from the Outlier Analysis was used and field notes were compiled into individual site case studies, centered around six themes: Service Provision, Patient Management, Personnel Models, Facility Administration, Infrastructure, and Auxiliary Services (alternately referred to as Community Programs).

### **3.4.3 Data Analysis**

Framework Analysis was applied to the secondary compiled case studies to categorize and index themes around Pre-ART that emerged throughout the case studies. The inclusion criteria for the indexed responses and case study data was based on the following thematic areas: Testing, Pre-ART Linkage, Pre-ART Care, Pre-ART Tracking, ART Linkage, Laboratory (CD4 Testing), Opportunistic Infection Prophylaxis, Community Health Workers, and aspects of Community Programs (consisting of Nutritional Services, Prevention Services, Family Planning and Birth Control, PLWHA Organizations, and Linkages to NGO's and other services).

### **3.4.4 Ethical Considerations**

Ethical approval for the Parent Costing Study and Outlier Analysis was given by the Ethiopian Health and Nutrition Research Institute (EHNRI) after a review of the study protocol by the EHNRI Ethical Review Committee. Ethical approval for the secondary thesis level analysis was

granted by the University of Pittsburgh Institutional Review Board. All health facility staff members interviewed was informed of the study and study objectives; and all staff interviewed provided verbal consent to participate.



## **4.0 RESULTS**

### **4.1 TESTING TO PRE-ART LINKAGE**

All sites offered Provider Initiated Testing and Counseling (PICHt). Additionally, other than ETH\_03, all sites offered Voluntary Testing and Counseling (VCT). ETH\_03 offered only PICHt, as it was a referral hospital, therefore patients come to the facility directly referred for Pre-ART and ART, or are testing by a provider when visiting the hospital for another medical condition.

Patients at all sites testing negative were counseled for on-going prevention methods and recommended to return for testing in 6 months. A VCT or ART Nurse provided immediately counseling to patients testing positive for HIV. All positive testing patients receiving VCT or PICHt in the facility are given an intra-facility transfer form and physically and provided a “warm hand off” to the ART clinic. The warm hand off occurs when facility staff physically escorts a patient to the ART clinic to begin processing for Pre-ART procedures. Clinicians across facilities noted the importance of this process for many reasons. First it ensured the patient was properly linked to the ART clinic to begin intake, and secondly it added a level of comfort for patients in what was noted as a difficult, emotional, and confusing process.

Several sites also utilized mobile VCT testing via community outreach programs of the localities health departments. At these sites clinicians indicated a higher risk of patients not be

adequately linked to Pre-ART care from mobile testing due to reluctance by the patient to come in for reasons of fear of stigma and discrimination, lack of access for the patients (transportation, opportunity costs), and lack of ability to properly counsel and educate patients about HIV/AIDS care options and feasibility. Sites used various means to increase the linkage from mobile community based testing to the facility. ETH\_10 utilized salaried government health outreach workers called Health Extension Worker's to track these patients tested at mobile sites, either by physically escorting patients from the mobile sites or providing home visits to the patients testing positive to provide counseling and encouragement to seek care at the facilities ART clinic.

Site ETH\_32 utilized a different strategy to link mobile testing patients to Pre-Art, which was devised by the VCT Nurse. If a patient tested positive they were given a coded number and told to come into the facility to determine the result of the testing. Patients testing negative were not given this code and counseled on prevention methods and referred for testing in 6 months time. The coded number was to encourage patients to come into the facility, in which they could then be given a warm hand off to the Pre-ART clinic, while also maintaining confidentiality of test results. According to the VCT Nurse at this site, the patients testing positive believed the coding process was given to every patient, regardless of results, to encourage confidentiality. No data was obtained to determine linkage rates for this process, but the VCT Nurse believes this led to higher linkage rates and better counseling access for patients.

**Table 3 Linkages to Pre-ART Service by Site**

Site	Linkages to Pre-ART				
	Offer VCT	Offer PICT	Warm-Hand Off	Mobile VCT	Unique Mobile VCT Linkages
ETH_03		X	X		
ETH_10	X	X	X	X	X
ETH_29	X	X	X	X	
ETH_31	X	X	X	X	
ETH_32	X	X	X		X
ETH_39	X	X	X	X	

## 4.2 PRE-ART CARE

### 4.2.1 Patient Intake

Upon linkage to Pre-ART, the first person a patient encounters is a data clerk. Data clerks are non-clinical staff who manage appointments, track patients, record patient data into patient logs, and transcribe clinician-entered data from a patient’s chart into applicable databases and registers. Data clerks are not trained in counseling techniques. As a result many clinicians at study sites noted patients are believed to be uncomfortable during the intake process; as the first step is to reveal personal information, which is recorded in logs and charts directly in view of the patient. Patients may be unsure of the confidentiality of their data, may have privacy concerns by providing personal information in a busy setting, and may feel reluctant to give this information to somebody not in a clinically (medical or psychosocial) trained position.

Following a patient's data intake, a clinician will perform a clinical screening and staging of the patient and scheduled for CD4 and basic laboratory testing (chemistry and hematological tests).

One site (ETH\_10) has a case manager see the patient immediately following the data clerk and prior to clinical screening procedures by a clinician. This is to provide counseling on the process, appointment scheduling and to discuss a patient's levels of barriers to attending appointments and understanding of the care to be undertaken.

The clinical procedures are standardized across the country via MOH procedural processes. Variation occurs at each site regarding the level of counseling provided.

#### **4.2.2 Opportunistic Infection Prophylaxis**

Ethiopian health facilities are able to prescribe Cotrimoxazole (commonly referred to as Cotrim) as prophylaxis for opportunistic infections in patients; and Isoniazid (INH) for patient co-infected with TB to manage symptoms and improve health prior to starting antiretroviral medications. Prescribing practices for Cotrim are not always used in Pre-ART practices and some facilities use this both as a prophylaxis for opportunistic infections and also a means to measure a patient's aptitude for adherence to medications in preparation for ART initiation and continual usage of ARV's.

##### **4.2.2.1 Medication Adherence Testing**

ETH\_31, ETH\_39, ETH\_32 use Cotrim prescriptions as a prophylaxis for opportunistic infections and as a means to test medication adherence behavior in patients. ETH\_31 integrates Cotrim into its prescription practices to patients as a regular function of Pre-ART activities. This

was emphasized by the ART Head Nurse in noting: “ART is not an emergency drug” and therefore properly testing a patient's ability to adhere to medication is important to ensuring ARV's efficacy in the future. The clinicians at this facility also noted Cotrim provides added benefits for patients. It helps them become accustomed to taking medication and builds a comfort level with adherence practices and patients feel they are receiving a direct benefit from the facility during the Pre-ART process and therefore contribute to lower LTFU rates.

Facilities in the study have utilized other methods using Cotrim as predictor of medication adherence. Facility ETH\_32 used a pill count, but discontinued this process believing it was not an effective way to measure adherence because patients could simply remove the pills prior to the test without actually ingesting the medication. Therefore the facility uses a pre-prepared questionnaire regarding adherence behavior with a numbered score given to rate likelihood of adherence to medications. This questionnaire is scored and appropriate counseling is provided to augment the applicable score.

ETH\_03 provides both Cotrim and INH to eligible patients but since the facility deemphasizes Pre-ART care and many patients present with other illnesses (indicating high rates of PIHCT) and present with lower overall CD4 counts, patients receiving these prophylaxis medications are predominately on ART. Very little usage of these medications is used to aid retention efforts for Pre-ART at the facility.

#### **4.2.2.2 Eligibility Requirements**

Facilities follow various eligibility methods in Cotrim prescription packages. Three sites follow eligibility requirements for patients before prescribing Cotrim. All of these sites requirements are based on a CD4 threshold ( $CD4 < 350 \text{ mm}^3$ ) and adds a clinical staging component to

eligibility as well for prescribing during Pre-ART (WHO stage I or II). Only one facility noted they prescribe Cotrim to all patients regardless of clinical stage or CD4 count.

ETH\_39 noted they provide Cotrim to Pre-ART patients and integrate prescription pick-ups into scheduling, with occasional unscheduled follow up phone calls to the patient to ensure prescription renewal. ETH\_39 maintains an eligibility requirement of CD4 counts less than 350 mm/3 for Cotrim prescription, however this is not an operational policy at the time of the study due to non-CD4 testing as a result of machine disrepair. Consequently clinicians prescribe Cotrim and ARV's based on clinical staging and clinical symptoms.

**Table 4 Pre-ART Care: Patient Intake and OI Prophylaxis Services by Site**

Study Site	Pre-ART Care				
	Patient Intake		OI Prophylaxis		If yes, Eligibility Requirements?
	First Encounter with Data Clerk?	Counseling built into Pre-ART initiation	Cotrim as Medication Adherence Testing	Follow Cotrim Eligibility Criteria	
ETH_03	Yes				
ETH_10	Yes	X		X	CD4 < 350 mm/3 and Clinical Stage I or II
ETH_29	Yes			X	CD4 < 350 mm/3
ETH_31	Yes		X		
ETH_32	Yes		X		Cotrim provided to all patients, regardless of CD4 or clinical Stage
ETH_39	Yes		X	X	CD4 < 350 mm/3

### 4.3 LABORATORY TESTING

CD4 testing and availability varies by site. Four of the six study facilities had a CD4 machine on site. Of these, it was noted site ETH\_10 was the only facility classified as a health center in the

country with an on-site CD4 machine. Study sites without a CD4 machine on site referred laboratory tests to other facilities. Viral load testing is limited nation wide and generally not used in Pre-ART decisions, but rather to determine when to switch patients from first line ART medications to second line medications and therefore is not detailed in this analysis. Chemistry and Hematology tests are conducted primarily on site at each facility, but are not a critical component of Pre-ART care in the country, so practices around these tests are not included in the analysis.

The sites without a CD4 machine (ETH\_32 and ETH\_31) referred patients to the same hospital for CD4 testing since they are located in the same geographic radius. This provides a good case study in small rural health center laboratory referrals in Ethiopia. Both facilities reported taking blood samples on site and sending lab technicians with packaged samples weekly (on a designated day of the week: Wednesday for ETH\_32, Thursdays for ETH\_31) to referral hospital for testing. The tests results were picked up the next week, and new samples were dropped off, giving each facility the ability to receive weekly test results. However, variation occurred between the sites in terms of regular access to testing. ETH\_32 reported instances of longer wait times for test results and instances of sample transport problems, including lack of transport reimbursement. ETH\_31 reported similar transport issues, but noted due to staff motivation, samples were deposited and picked up in a timely manner.

CD4 machines located onsite do not guarantee a facility will have consistent access to point of care CD4 testing due to issues of maintenance and disrepair. This is evidenced by facility site ETH\_39. This facility was noted to have a CD4 machine on site, however it was inoperative for over year and in need of repair. At the time of the study, ETH\_39 was operating without the use of CD4 tests for patients. Clinicians were able to refer patients for CD4 testing

to a hospital approximately 60 kilometers away, but were unable to provide sample transport to the site or stipends for the patients to cover travel costs. According to facility staff, very few patients had the time or the income to cover round-trip transportation costs to the testing hospital, so the facility relied on the clinicians to make treatment decisions based on clinical staging and patient symptoms.

**Table 5 CD4 Laboratory Service Provision by Site**

<b>CD 4 Laboratory Testing</b>			
<b>Site</b>	<b>CD4 Machine on site (POC testing)</b>	<b>CD4 Referral Ability</b>	
ETH_03	X	N/A	
ETH_10	X	N/A	
ETH_29	X	N/A	
ETH_31		Yes	
ETH_32		Yes	
ETH_39	X	N/A	CD4 in disrepair, Site was operating without testing for over one year

#### **4.4 PRE-ART PATIENT TRACKING**

##### **4.4.1 Definition of Lost to Follow Up**

The definition of what constitutes a patient who is Lost to Follow Up (LTFU) and therefore requires tracking by the facility (also referred to as defaulter tracing) varied by site. Variation was seen amongst study sites with regard to the operational definition of site specific LTFU. Four of the six sites used a one to two week range (5-14 days) as the working definition for



considering patients LTFU. After these timeframes, the site would begin tracking procedures on the defaulting patient. The remaining study sites used a period of 30 days and 60 days, ETH\_29 and ETH\_32 respectively.

Clinicians at each site noted no standard accepted definition for LTFU and each facility's timing window practice was based on a combination of guidance and input. Facilities mentioned the timeframes were often provided as guidance by a supporting NGO for the facility, a recommendation from a regional or Woreda level health office as part of oversight, or a best practice determination by the facility based on a facility led decision specific to the patient and service provision environment at that specific locale.

The 60-day definition appeared to be the greatest outlier among the study sites. This facility noted they do not attempt to initiate tracking procedures inside this timeframe. However by this timeframe, facility staff indicated patients are less likely to be located and tracking is significantly less effective in encouraging patients to return to the facility for appointments. Additional challenges noted by staff that inhibited tracking after LTFU were lack of reimbursement for transport costs for home-based tracking and lack of reimbursement for or provision of prepaid cell phone cards to call LTFU patients. This is combined with what a staff noted as a landline phone that as been inoperable for over a year. Staff noted very little guidance or aid to from facility administration or supporting NGO's to overcome these barriers.

#### **4.4.2 Data Management**

All sites manage their Pre-ART and ART patients together utilizing similar logbooks and registers, similar follow up services and patient flows within the facility. However variation was noted in robustness and tracking prioritization for Pre-ART to ART patients at sites.

All facilities in the study utilize a paper-based manual Pre-ART logbook, which is provided by the Ethiopian MOH to record patient information. Use of databases is generally to store patient data, as sites are not using databases to automatically generate missed appointments. All facilities had computers with databases, though only two facilities (ETH\_39 and ETH\_29) used it to supplement tracking purposes. Clinicians at these sites mentioned the desire to generate automatic lists of missed appointments to give to case managers and patient trackers, but are currently unable to utilize a feature such as this.

Several study sites had databases and computers on site which were provided by a supporting NGO. Most staff at these facilities were not trained in the use of the database and records remained inconsistent or databases went unused.

One facility (ETH\_03) had a database which was provided by the facility's supporting NGO, and records were recorded from the logbook and patient's charts into the database to be used for research purposes by the supporting NGO but not for process and tracking usage by the facility staff, resulting in wasted effort and duplication for limited patient and clinician benefit.

Identifying lost patients varies across sites. A few keep a good listing and track daily (ETH\_29 seems like a model facility in facility identification of Lost patients), while others have to comb through the Pre-ART register and do not have a good grasp of LTFU. (ETH\_32, ETH\_10).

**Table 6 Pre-ART Patient Tracking: LTFU Definition and Data Management by Site**

<b>Pre-ART Patient Tracking</b>			
	<i>LTFU Definition</i>	<i>Data Management</i>	
<b>Site</b>		Use Database to aid patient Tracking	Identification of LTFU Patients
ETH_03	LTFU 11 days after missed appointment	No	High patient volume and limited staff makes this difficult
ETH_10	LTFU 7-11 days after missed appointment	No	Limited ability to identify LTFU promptly
ETH_29	LTFU 30 days (one month) after missed appointment	Yes	Well organized, daily LTFU outputs, leading to prompt tracking
ETH_31	LTFU 7-14 days after missed appointment	No	Simple easy to use tracking chart due to small patient load (< 100)
ETH_32	LTFU 60 days (two months) after missed appointment	No	Limited ability to identify LTFU promptly
ETH_39	LTFU 5-10 days after missed appointment	Yes	Well organized data, prompt LTFU output provided to case manager for tracking

#### **4.4.3 Community Health Worker Tracking**

Good data management practices influence practices of patient tracking. Sites that compile a list of LTFU patients periodically or systematically save time in the tracking process and appear to have a better understanding of the number and demographics of patients LTFU.

Methods of tracking at all sites include one of two, or both, of the following mechanisms: telephone calls to patients to follow up and sending a Community Health Worker (CHW) to track the patient with a home visit. The most variation occurred in terms of frequency of these follow up options. ETH\_29, ETH\_39, ETH\_31, and ETH\_10 sites all will call begin making calls after the patient is deemed LTFU based on the site's definition process. ETH\_32 as noted above waits till patients miss appointments by two months on average before attempting to contact.

CHW's were utilized previously in many sites, though with NGO's phasing out or changing, the funding appears to be diminishing or unresolved, halting the work of CHW's in tracking. Clinicians note the help in retention of patients due to CHW's tracking and clinicians expressed desire to see these programs continue (if existing at site) or to be reinstated (if discontinued at site).

ETH\_03 is the exception for tracking in comparison to all sites. The facility is in the heavily populated capital city and maintains an extremely high patient volume; yet only two data clerks and a small number of lay health workers called Adherence Supporters (AH) aid in tracking. During interviews, clinicians estimated a patient population on ART of approximately 4,000 with an additional 2,000-3,000 more patients on Pre-ART. Therefore the staff indicated tracking in practice is nonexistent. The high volume of patients compared to staff do not allow for this, and non-clinical staff spend the majority of their time checking patients in, and maintaining both Pre-ART and ART registers, and scheduling patients. Additionally the Adherence Supporters work primarily within the hospital itself, escorting patients from place to place and assisting with counseling of patients. Staff mentioned AH willingness to help with tracking, but the high volume and low number of AH staff combined with unsteady funding of the AH positions by the supporting NGO's made extending AH's role in tracking implausible.

ETH\_31 took a different approach to patient tracking. When discussing the facilities low lost to follow up rate, the nurse noted they work to build a friendship with the patients, for example whenever they have money they will try to personally support them from the money in there pockets. Clinicians noted they specifically try to connect to patients and to understand the needs of patients and provide additionally counseling when possible. The head clinician also noted patients would visit him at his home on weekends and he was receptive to treating patients

at all hours of the day and week, and at locations other than the facility. This was the only site visited which staff and clinicians made efforts to connect with patients outside of the facility and in the daily life of the patients. This could be made possible due to the smaller client load (approximately 90 total patients) and the small rural based town this facility was located in. This facility noted Community Health workers were scaled for tracking due to decreased funding from the facilities supporting NGO. The head clinician expressed a desire for the CHW's to continue their work, but noted the personal relationships they built with patients allowed the facility to reduce LTFU despite the limited ability to track patients with CHW's outside the facility.

#### **4.5 COMMUNITY PROGRAMS**

Community programs, often called auxiliary services, as defined in this study consists of either direct provision of social services, commodity provisions (i.e. food, clothing, or medical supplies), membership in community support groups, income generating activities; or linkages (direct or indirect) to obtain these services and benefits. These services can be provided at any point on the testing to treatment cascade, however all sites visited put a focus and premium on offering these services to patients in ART care, with little to no emphasis for such services to patients in Pre-ART services.

The following are discussed in more detail below:

1. Nutritional Services
2. Family Planning Services
3. Support Groups and Linkages

#### **4.5.1 Nutritional Services**

Nutritional services at all sites were limited. The most prominent form of nutritional supplementation was Plumpy'nut; a peanut based ready-to-use therapeutic food (RUTF). ETH\_03, ETH\_39, ETH\_29, ETH\_32, and ETH\_10 offered Plumpy'nut in some capacity. ETH\_03, ETH\_29 and ETH\_39 attached body mass index (BMI) requirements to it, primarily for reasons of moderating supply and targeting those deemed most in need. These facilities did not have distinctions on patient type (HIV vs. non-HIV), as it was available for any patients meeting BMI requirements. ETH\_31 did not provide Plumpy'nut to any patients. The head ART Nurse indicated a desire for it and believed it would be effective as an incentive for patient retention, but noted the small size and patient load of the facility most likely precluded procurement from the government central supply agency.

Clinicians at other sites echoed the retention aspects of offering Plumpy'nut. They indicated patients prefer to see a tangible benefit and Plumpy'nut is well known and desired by patients. Demand was noted as high by patients with occasional stock outs in facilities, but clinicians noted general timely deliveries of the supplement with scheduled medical and pharmaceutical deliveries.

#### **4.5.2 Family Planning Services**

Very little integration of family planning services or linkages to these services exists in the study sites. Many sites noted the counseling provided information about these services to patients. The most common form of this was information about condom use and encouragement of testing for partners. ETH\_03 noted they counsel on condoms, abstinence, and other birth control

methods and when an ART patient receives medications they are asked about their personal supply of condoms, though this was not conducted for Pre-ART patients. It was not noted if condoms were automatically provided. No sites indicated they directly offer condoms to patients as part of ART services and linkages within the facility for family planning services were not indicated.

### **4.5.3 Support Groups and Linkages**

Variation was noticed between sites in terms of existence and status of community based support groups. The primary type of support group is a called a PLWHA (People Living with HIV/AIDS) group. These are associations of people living with the virus either formally or loosely organized by a supporting NGO or government office and provide direct access to income generating activities, nutritional supplements, supplementary small grants for household goods, or group based counseling as a mechanism for social support. These groups did not have any direct affiliation with the sites in the study, but referrals were available by staff at the study sites for patients. ETH\_32 provided a formalized referral slip to these organizations and the other sites mentioned an informal system was used to recommend patients, primarily consisting of providing patients with contact information and directions to the offices of these groups. ETH\_31, ETH\_32, and ETH\_03 noted in their locales these groups were sustained by a supporting NGO, but constant phasing in and out of NGO support made these services sporadic and unpredictable. Referrals amongst study sites to these organizations were made for both Pre-ART and ART patients, though a preference existed for ART patients.

Another support group called Mother's to Mothers (M2M) was noted at ETH\_29 and ETH\_32. Each site's M2M activities were site specific, but both consisted of elements of

providing periodic traditional Ethiopian “bunna” (coffee) ceremonies for HIV positive Mothers to share experiences and provide a mechanism of peer support and peer based counseling. ETH\_29’s program had a trained facility health educator to lead discussions and provide health education. A trained HIV positive woman led ETH\_32’s M2M program and she was supported with a paid monthly stipend by a supporting NGO. Clinicians noted this program was phased out due to dwindling of the NGO’s funding stream and the facility itself did not have the budgetary funding available to sustain this program after the NGO phased out operational support.

**Table 7 Community Programs: Service Provision by Site**

<b>Community Programs</b>			
<b>Site</b>	<b>Nutritional Services</b>	<b>Family Planning Services</b>	<b>Support Group and Linkages</b>
ETH_03	Provision of Plumpy'Nut	Counsel on Condoms, Abstinence, Partner Testing	Former PLWHA linkages by supporting NGO
ETH_10	Plumpy'Nut not available	No direct provision as Part of Pre-ART	
ETH_29	Provision of Plumpy'Nut	No direct provision as Part of Pre-ART	Mother's to Mother's
ETH_31	Provision of Plumpy'Nut	No direct provision as Part of Pre-ART	Former PLWHA linkages by supporting NGO
ETH_32	Provision of Plumpy'Nut	No direct provision as Part of Pre-ART	Mother's to Mother's; Formal referral to PLWHA Groups
ETH_39	Provision of Plumpy'Nut	No direct provision as Part of Pre-ART	



## **5.0 DISCUSSION**

The results outlined above provide a nice snapshot of Pre-ART practices in Ethiopia. While they are not indicative of all sites and all practices, the information gathered can be important in determining components meriting exploration for government officials in Ethiopia as they begin to put together a defined set of guidelines for Pre-ART programs.

Realistically, the clinical component of the guidelines should not vary significantly from the current clinical recommendations for ART in existence nationwide. The major clinical shifts may likely come in the form of universal countrywide access to Cotrimoxazole for all patients, and increased CD4 testing (as a result of foreseeable shifts to more current WHO ART Initiation guidelines). Rather, the guidelines around Pre-ART will most likely focus on more support roles and provide clearer guidance and expectations for staff and clinicians in areas of logistical support, patient follow up and social and emotional support linkages. These type of programs are manifested in common themes mentioned in Pre-ART retention and include defaulter patient tracing, patient counseling practices, improving access to auxiliary or community programs, improved data management, and decreasing patient barriers to access to care and knowledge of treatment options.

Based upon the results of the secondary analysis seen several themes warrant exploration and discussion as a means to share the impacts of perspectives the facility and clinicians, administrators and staff have shared as a part of this study. These themes are worthy of informing the Pre-ART working group as they begin to gather information and evidence around guidelines in the country will add to a limited yet expanding understanding of Pre-ART programing and intervention opportunities in Ethiopia. Additionally, these themes mentioned provide a mechanism to provide upward feedback from local providers who often do not have the ability or opportunity to have their voice heard and perspective examined in the higher levels of the Ministry of Health. The themes discussed below are presented according to potential policy level intervention drivers of change or implementation.

### **5.1.1 Top Down Driven Policy Implementation**

#### **Explore guidelines and usage of Cotrimoxazole and CD4 Testing mechanisms**

Exploring the use of Cotrimoxazole and the provisions of making Cotrim available to all Pre-ART patients, regardless of CD4 count or clinical stage, can be useful as measure of providing an incentive for retention and a perceived benefit of remaining in treatment for the patient. In a meta analysis conducted by Suthar AB et al. (2012), Cotrim was shown to reduce mortality in people with HIV/AIDS<sup>27</sup>. Provision of free Cotrim access to Pre-ART patients has been linked with increased patient retention over 12 months for programs in Kenya.<sup>28</sup> Ethiopia maintains guidelines for Cotrim prophylaxis, which mirror what several facilities indicated as their practice, which is to prescribe Cotrim based on eligibility requirements to patients. The guidelines are most likely a factor of logistical concerns to reduce facility stock outs of Cotrim and ensuring adequate supplies. During the study, several clinicians noted stock outs used to

occur but now supplies of Cotrim are adequate and continuous. Combine this with a low incremental cost for providing Cotrim to Pre-ART patients in Ethiopia not currently receiving it<sup>1</sup> and provision to all Pre-ART patients appears more feasible and can provide an easier and potentially effective intervention to patients to aid not only in patients health outcomes directly, but in retention in care.

CD4 testing is underutilized throughout Ethiopia.<sup>1</sup> As the country looks to scale up ART treatment and investigate and institute PRE-ART guidelines, improving health facilities access to CD4 testing will help with retention efforts for patients in Pre-ART and proper initiation of patients onto ART.

The feasibility of placing CD4 machines in every facility is currently beyond the scope of the Ethiopian health system. Only one facility deemed a health center has an onsite CD4 machine (site ETH\_10 in this study), with CD4 machines placed at larger hospitals with referral capabilities for patients in nearby referral catchment area health facilities. Clinicians and administrators noted longer wait times and higher patient loads at these hospitals and complexities and inefficiencies in providing blood sample transport referrals to these referral facilities. The Ethiopian MOH may be benefited by increasing the placement of CD4 machines in lower level health centers and focusing on addressing geographic and transport concerns for increased referrals to these newly placed CD4 machines. In the absence of the feasibility of scaling up CD4 coverage via health center placement, the Ethiopian MOH in conjunction with regional and woreda based government health offices should increase transportation cost reimbursement for patients and health facility staff for sample transport or make stipends available to cover and offset the costs. Increasing access to a clinician's ability to make informed decisions via consistent CD4 counts is crucial to proper care for patients with

HIV/AIDS. Secondly, a patient attending Pre-ART treatments who receives a CD4 test increases the perceived benefit of attending appointments and strengthens the Pre-ART program and ultimately the linkage to ART.

As technology progresses the MOH should also consider more relevant options for CD4 testing. One option could be a trend away from traditional large CD4 laboratory machines to a Point of Care (POC) testing that offers a more mobile testing unit, same day results, and requires less skilled technicians for usage.<sup>29</sup> Early results and trials from POC testing have been positive. It has been shown to improve linkages to care from testing<sup>30</sup>, reduce the potential for patients to become LTFU and aid in identifying patients eligible for ART in a faster manner<sup>31</sup>, while still remaining technically usable for task shifting to nurses and lab technicians.<sup>32</sup> Further research is warranted to consider the feasibility of POC testing in the Ethiopian setting.

#### **5.1.1.1 Public Health Implications**

There are two potential top down implementation themes the Ministry of Health may consider based on the interviews conducted: Provision of Cotrimoxazole prescription to all patients in Pre-ART and increase CD4 testing options for facilities. Both of these interventions are being done to some extent in Ethiopia, though through discussions with clinicians there is a call from the field level to increase access and acceptance of these themes. In order for these to take place, the Ethiopian MOH has to ensure several system level factor criteria are addressed. Proper drug and reagent forecasting will be necessary to predict and fulfill the increased pharmaceutical demands by these interventions. Clinicians have anecdotally noted during the Outlier Analysis that drug and reagent stock outs no longer seem to be a problem. This instills confidence in the Ethiopian drug supply chain, yet to formally adopt these guidelines the MOH will need to solicit

further research on logistical capacity and operation ability with a increased demand for Cotrimoxazole and laboratory testing agents.

One of the most important aspects for addressing these interventions will be availability of funding streams to meet increased demand. CD4 machines are expensive and the Ethiopian MOH is slowly expanding the reach of CD4 testing, but in order to do so, they must determine the feasibility of acquiring and funding increased purchases of CD4 machines. Until the price and availability of POC testing for CD4 becomes a reality for systematic use by developing nations like Ethiopia, these funding issues will remain in the forefront.

From a cost perspective, there is more hope for increased access to Cotrim. The facility based costing study determined the cost of meeting the current gap between patients already on Cotrim to include all Pre-ART patients on Cotrim is \$71,000.<sup>1</sup> Considering the funding stream and government spend on HIV/AIDS this is an incredibly low cost intervention, with potentially much higher impacts.

### **5.1.2 Bottom Up Driven Policy Implementation**

#### **Autonomy of local practitioners to adapt Pre-ART processes to local context, while simultaneously maintaining a standard Pre-ART package of care**

Allowing local level clinicians and facility staff the autonomy to make revisions and alterations to Pre-ART guidelines and best practices developed by the Ministry of Health could allow for the best use of practical implementation based on the contexts. Facility visits indicated examples of clinicians already performing this practice. Whether it entails being flexible with clinic hours to meet the needs of a small rural town, devising a numbering strategy to increase linkages from

mobile testing to Pre-ART, developing an extended rapport with patients and incorporating greater levels of personal social support, or bringing in local government health agents to improve a small facet of tracking and linking patients to the facility; clinicians make decisions and moderations to the existing Testing, Pre-ART, and ART structures to fit the needs they have identified and they have done this with little outside guidance. These ideas evolved over time based on daily experiences of the clinicians and patients and what was considered an approach to make care and treatment incrementally better. This autonomy is crucial for the clinicians to maintain. The ability to make low level, yet high impact adjustments allow them to better meet the needs of their patients, while simultaneously building a greater sense of satisfaction in their own job performance. This provides a level of confidence in trust on behalf of the patient with the clinician, and a level of confidence by the clinician in delivering care in a resource constrained setting.

### **Data Management Implementation at the Local Level**

A basic, standardized paper based model to manage patient appointments, manage patients charts and data, and follow up with patient tracking is the most feasible way to alleviate data management barriers system wide for Pre-ART. Sophisticated databases and electronic medical records may increase the burden on health facilities at the current stage of Pre-ART and ART treatment in Ethiopia. This could be especially true for Pre-ART, as less emphasis is put on tracking these patients. These same phenomena were noted in Rosen and Fox's meta-analysis on Pre-ART retention. They noted electronic medical records and databases, when present, were not often kept updated and feature incomplete information about patients.<sup>10</sup> Further studies should be undertaken to develop a total best practices model based on examination of current

practices at sites across the country. Utilizing a paper-based system appears to be the most efficient and realistic option for data management in Ethiopia. Facilities visited had little to no computer tracking and this is a large barrier to proper defaulter patient tracking. Staff was inadequately trained on computer and database usage for the facilities, yet a comfort level was noted among staff with paper-based approaches. This model is also easily scaled up and will be cheaper to implement on larger scale in comparison with computer and database systems.

Freedom should be given, however, to facilities to continue to incorporate database usage if a perceived benefit is noted. Any system wide move to electronic databases and electronic medical records could be incrementally implemented with appropriate time and budgeting made available for training. Standardization of data management can be an important component for ART care nationwide in Ethiopia, but the drawbacks of implementing a complicated electronic component too swiftly could be detrimental to efficient patient tracking, especially at small facilities with low staffing resources or high patient volume.

### **Community Health Workers role in patient tracing and counseling**

Interviews have indicated various usages of CHW's in defaulter patient tracking and supplemental counseling and patient support. Supporting NGO's providing CHW's for facilities were often noted to be transitioning in and out of contract's to support facilities and as a result the funding for these positions was temporarily suspended, discontinued indefinitely, furloughed, or halted all together. Consequently patients were not tracked continuously at facilities and experienced CHW were lost to other opportunities or frustration due to tenuous funding.

Utilizing a top down approach, policy makers can leverage the call for increased prioritization of CHW with a bottom up approach by facility and community level implementers to tailor patient

tracking and counseling schemes to the appropriate local context. This leverage of approaches provides a manner for policy makers to renew the call for continuous CHW usage at facilities while also allowing best practices for tracking to be dictated by those in the field with the most practical knowledge of the patient and community environment. Ultimately the goal is to increase patient retention in Pre-ART, and the leveraged approach will allow facilities system wide to prioritize tracking for Pre-ART in the same manner for tracking for ART, provide support to a volunteer workforce to offset human resource limitations, and utilize local knowledge to allow the most efficient implementation of CHW.

### **Patient comfort levels upon immediately linkage to Pre-ART**

A primary way to enhance the patient comfort levels is to discontinue the common practice of having a patient first meet with a data clerk to collect information immediately upon enrolling in Pre-ART. Rather, a patient should see a trained case manager, which many facilities have on staff, or a clinician trained in counseling and support techniques. This process was noted as a challenge by facility staff across sites. Patients are immediately asked for personal information and in an environment in which stigma against those with HIV/AIDS is still pervasive this can make the patient feel uncomfortable, distrusting of the facility, and reluctant to return to the facility for fears of confidentiality breaches.



## **Community Programs role in Pre-ART patient retention and social support**

A meta-analysis on community programs and ART programs indicated providing psycho-social support in addition to the counseling providing by nurses and doctors (clinicians) and aiding with defaulter tracing are programs are a benefit to ART programs in resource constrained countries.

<sup>33</sup> At the facilities studied as part of this thesis work, these types of programs, combined with food and nutrition support, were the most likely type of community program to be offered and clinicians repeatedly stated the importance of maintaining and expanding these linkages as opportunities for patients.

It is important to note in Ethiopia, these linkages are likely built through local networks and will vary from community to community. Therefore, these programs should have a level of autonomy to be built up with local adaptations and higher-level policy makers could provide support and funding, while allowing the facility, kebele, and woreda level implementers to utilize this support in an autonomous manner.

### **5.1.2.1 Public Health Implications for Bottom-Up Interventions**

The bottom up themes presented offer opportunities for low cost interventions with great emphasis on ensuring patient linkages and promoting retention efforts. A crucial component is allowing the flexibility of local practitioners to adapt these interventions in the best way possible to the environments and regions in which they work. This process is not without potential pitfalls, as appropriate monitoring combined with training is crucial to ensure patients are still receiving the appropriate levels of care specified in the national guidelines.

Therefore, to make these adaptations work, communication and supportive supervision by Woreda, Zonal and Regional health offices with implementing health facilities must become a constant component of the monitoring network. This communication and supervision hierarchy

will ensure resources are not depleted and clinicians do not deviate from standardized treatment plans to the extent of endangerment to patient's treatment.

A greater understanding of the costs of both increasing Community Health Worker's involvement and providing access to community programs need to be undertaken. Local and Federal HIV/AIDS offices have been implementing programs like these for several years as part of the national strategy to combat the epidemic, but integrating these interventions more systematically across the country to ensure equitable access by patients while simultaneously building in local adaptability produce greater impacts on costs. A better understanding of these impacts will be necessary to fully adapt and utilize community programs and CHW interventions system wide.

## **6.0 LIMITATIONS & STRENGTHS**

Some limitations of this thesis work should be acknowledged. First, the study was an analysis of qualitative factors from six facilities in Ethiopia and therefore the findings are not generalizable to all regions of Ethiopia or to the entire nation. The findings generated as a result of the interviews are an important component to understanding field level implementation of ART and future Pre-ART systems, but more research is required to develop generalizable findings.

Second, the analysis was a secondary analysis of a sub-section of a larger study framework. Factors examined in the Outlier Analysis, which influence Pre-ART decision making in Ethiopia, may have been excluded from the secondary analysis as a result of the limiting scope of the secondary analysis. These factors include staffing models of facilities, issues around task shifting in ART care, facility level administrative decision making, cost of care and support, laboratory and pharmaceutical supply chains and logistics in Ethiopia, and human resources capacity at the Woreda, Regional and National levels.

Addition, it is important to note the scope of the study is focused on a clinician's and facility's staff role and assessment of the processes and best practices. While this approach is insightful into developing policy recommendations and identifies system wide strengths and weaknesses, however it does not take into account the perspectives of the patients receiving care.

A patient perspective would add insight into the barriers and facilitators to accessing care, remaining in care over time, and the levels of service quality provided to patients.

Since the HIV/AIDS epidemic in Ethiopia is considered to be a very generalized epidemic this thesis did not delve into the treatment and pretreatment contexts for Most at Risk Populations (MARPs) in Ethiopia for HIV/AIDS. MARPS in Ethiopia include (but not limited too) commercial sex workers, migrant laborers, itinerant truck drivers and single and double orphans. Additionally, patients presenting with co-infection of Tuberculosis and HIV/AIDS were not included in the scope of this work. These populations experience unique health risks and require different responses. While they may access care in much the same way as lesser risk groups, interventions for remaining in care, patient-provider interactions, and defaulter tracking for example, may need to be tailored. These themes were not covered in the scope of the work presented; however they warrant further considerations in future research.

During the data collection phase of the Outlier Analysis, direct transcribing of interviewees responses was not used. Fieldworkers took detailed field notes through the use of a translator to record the interviewee responses. Therefore, it is possible bias exists in the recorded responses via fieldworker notes and subsequently carries over to case studies generated for analysis.

## 7.0 CONCLUSION

Ethiopia has undergone a rapid transition in provision of care and treatment for those with HIV/AIDS since they began free ART rollout in 2005. This transition has seen a growth in patients beginning and remaining on treatment with simultaneous processes by the government and Ministry of Health to keep these services available and efficient despite limited resources. They have been able to use treatment guidelines as a tool to achieve this goal, and the next logical step is to expand these guideline offerings to Pre-ART.

The thesis highlighted several aspects essential to Pre-ART care and laid out an exploratory framework for gaining insight into the how facilities deal with the important yet complicated issue of providing Pre-ART with little guidelines and in the face of constant challenges. These local clinicians and staff have proven to be a resourceful and solid foundation for implementing of Pre-ART and ART programs. By calling on their local expertise and allowing them a distinct level of local freedom, they can tap into a wealth of locally based resources to maximize the quality and access to care for the populations they serve.

The methodology used allows for clinicians and staff on the ground to not only provide information on what practices occur, but also to provide their own perspective and share their deep and intimate knowledge of how care is being realistically delivered across the country. As many other countries are providing similar care and support in resource limited settings, the methodology used is applicable for many other resourced constrained countries.

Combining the local resource reservoir with a national guideline plan allow for the ideal meshing of top down and bottom up implementation and will minimize the pitfalls of system wide rollout of Pre-ART guidelines.

The ultimate goals behind any Pre-ART program should be to provide a measure of care and support which patient's value. The benefits then derived from this valuation result in the key public health outcomes, namely in terms of patient retention, early initiation onto ART, and continued monitoring of patient progress across the testing to treatment cascade. Meeting these goals and objectives hinges on a collaborative effort and one that bridges the divide of policy makers and practitioners.

The methods used in the Outlier analysis provide a sound means for understanding the local context of HIV/AIDS treatment implementation in Ethiopia. These methods provide a voice to service providers working on the ground allowed insight and input by this vitally important group. Service providers at this level in Ethiopia are often overlooked and underrepresented in decision making in the country. The Ministry of Health in Ethiopia can utilize additional studies and processes outline in this thesis to gain a greater understanding of the challenges and facilitators to implementing Pre-ART care in all regions and environments throughout the country. These perspectives are not however, limited to Pre-ART. As Ethiopia looks to expand PMTCT programs to option B+, overhaul medical record data management and explore the use of electronic medical records, adopt and change guidelines based on expanding and new scientific research and consider additional means to provide CD4 testing; the perspectives provided by local practitioners are going to be crucial to determining the success of these programs.

## APPENDIX A

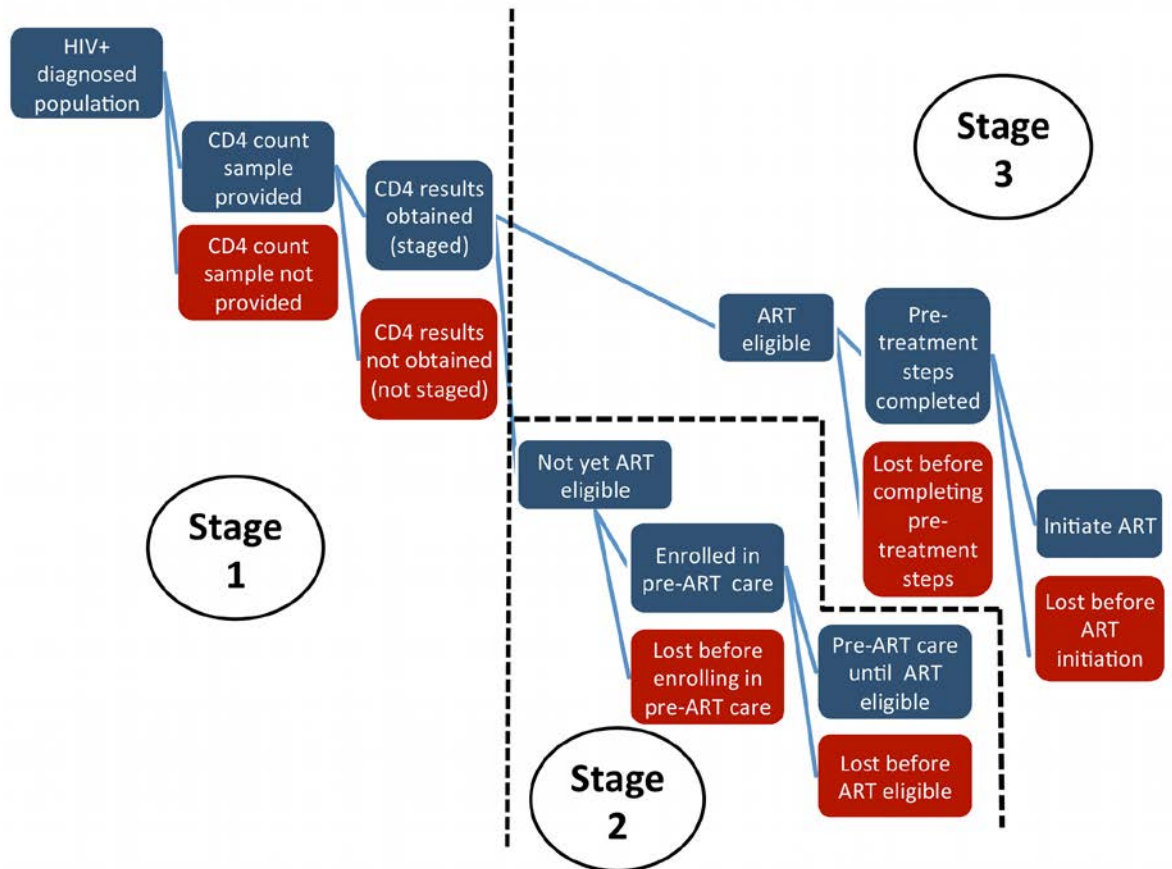
### ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
AH	Adherence Supporters
ART	Antiretroviral Therapy
ARV	Antiretroviral Drugs
BMGF	Bill and Melinda Gates Foundation
BMI	Body Mass Index
CD4	Cluster of Differentiation 4
CHAI	Clinton Health Access Initiative
CHW	Community Health Worker
Cotrim	Cotrimoxazole
EHNRI	Ethiopian Health and Nutrition Research Institute
FHAPCO	Federal HIV/AIDS Prevention and Control Office
HIV	Human Immunodeficiency Virus
INH	Isoniazid
LTFU	Lost to Follow Up
M2M	Mother's to Mother's
MARPS	Most At-Risk Populations
MOH	Ministry of Health
NGO	Non-Governmental Organization
OI	Opportunistic Infection
RUTF	Ready to Use Therapeutic Food
PIHCT	Provider Initiated Counseling and Testing
POC	Point of Care
PLWHA	People Living with HIV/AIDS
Pre-ART	Pre-Antiretroviral Therapy
UNAIDS	Joint United Nations Programme on HIV and AIDS
VCT	Voluntary Testing and Counseling
WHO	World Health Organization

## APPENDIX B

### STAGES OF PRE-ART MODEL

The following model outlines the stages of Pre-ART, from HIV Testing, enrollment in care, eligibility for care and initiation of ART.<sup>10</sup>





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