

**GUIDELINE FOR IMPLEMENTATION OF  
ANTIRETROVIRAL THERAPY  
IN ETHIOPIA**

**Ministry of Health  
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Addis Ababa, Ethiopia**

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## Acronyms

AAU	Addis Ababa University
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
BCC	Behavior Change Communication
CBO	Community Based Organization
CDC	Centers for Disease Control and Prevention
CRDA	Christian Relief and Development Agency
DACA	Drug Administration & Control Authority
DHD	District Health Desk
EHNRI	Ethiopian Health and Nutrition Research Institute
FBO	Faith Based Organization
HAART	Highly Active Antiretroviral Therapy
HAPCO	HIV/AIDS Prevention and Control Office
HBC	Home-Based Care
HIV	Human Immune Deficiency Virus
HMIS	Health Management Information System
IEC	Information, Education and Communication
I-TECH	International Training and Education Center on HIV
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NGO	Non-Governmental Organization
OI	Opportunistic Infections
PEP	Post-Exposure Prophylaxis
PLHA	People Living with HIV/AIDS
PMTCT	Prevention of Mother-to-Child transmission
Q/A	Quality Assurance
Q/C	Quality Control
RHAPCO	Regional HIV/AIDS Prevention and Control Office

RHB	Regional Health Bureau
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
TB	Tuberculosis
TBA	Traditional Birth Attendant
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

## FORWARD

The human immune-deficiency virus (HIV) has created an enormous challenge worldwide. Since recognition of the disease, HIV has infected close to 71 million people, and more than 30 million have died due to acquired immune deficiency syndrome (AIDS). More than 66% of the 40 million plus people living with HIV/AIDS (PLWHA) are in Sub-Saharan Africa, where AIDS is the leading cause of death.

*Highly Active Antiretroviral Therapy (HAART)* was the breakthrough in the industrialized world, leading to the reduction of mortality and the improvement of quality of life of PLWHA. Antiretroviral (ARV) drugs also significantly lowered the rate of HIV transmission from mother to child. Thus antiretroviral therapy (ART) has become an integral part of the continuum of HIV care.

With more than 1.5 million PLWHA, Ethiopia is one of the countries most heavily affected by the epidemic. An estimated 265,000 persons require treatment. In response, the Government of Ethiopia has taken measures to reduce the risk of transmission of HIV and mitigate the impact of the HIV epidemic on society.

Several policies are in place to support the implementation and scaling up of the national response, including the National HIV/AIDS Policy, the National Strategic Framework on the Prevention and Control of HIV/AIDS, and the Supply and Use of Anti-Retroviral Drugs Policy. Based on these policies and the recommendations of the United Nations General Assembly Special Session on HIV/AIDS (UNGASS), The Government of Ethiopia launched its ART initiative in 2003. The country is now preparing to rapidly scale up its ART program.

This guideline, developed by the Ministry of Health in collaboration with the Drug Administration and Control Authority (DACA), the HIV/AIDS Prevention and Control Office (HAPCO), Addis Ababa University (AAU), Center for Disease Control and Prevention (CDC)-Ethiopia, International Education and Training Center on HIV (I-TECH), and the World Health Organization (WHO) Country Office will guide the implementation of the National ART Program. This implementation plan will serve to harmonize and standardize all related programs, including *training, health management information system (HMIS), diagnostics, prevention, care and support*. It is also hoped that as the national ART program is being scaled-up attention will be given to *sustainability*.

The Ministry believes that this guideline will serve as the foundation on which to build country experience and by which to maximize benefits from activities with international partners. International and national non profit organizations, multilateral organizations, bilateral agencies, and other partners, in collaboration with facility health care leaders and providers, should refer to this guideline for effectively implementing the national ART program at all levels.

The Ministry of Health thanks all the many institutions and individuals who have provided valuable input into the preparation of this guideline.

Department of Disease Prevention and Control Team  
Minister of Health

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## **1. Introduction**

Ethiopia is among the countries most heavily affected by the HIV epidemic. The cumulative number of PLWHA is about 1.5 million, with 95,000 under 15 years of age. The 2003 national prevalence in the urban and rural population are 12.6% and 2.6% respectively. Since 2004, there are an estimated 105,453 and 27,226 new AIDS cases in the adult and children population respectively. Some 90,000 adults and 25,000 children have died of AIDS. About 265,358 PLWHA need antiretroviral treatment, and of this population, only 2% can afford to pay for ARVs and healthcare services.

Ethiopia has significantly expanded its response to the epidemic since the enactment of the National HIV policy in 1998. In 2001, the National HIV/AIDS Prevention and Control Council declared that HIV was a national emergency, leading to various interventions particularly focusing on prevention and behavior modification. In 2003, fully cognizant of competing demands of equal magnitude such as famine, malaria and tuberculosis and the uncertainty of program sustainability, the Government of Ethiopia elected to introduce the ART program with the goal to prolong the lives, to restore the mental and physical functions and to improve the quality of life of PLWHA. This program will impact mortality, reduce fatalistic attitudes, promote increased voluntary HIV testing, and provide a rationale for making healthy living choices. The declaration of ART as a human rights issue and support for universal access to ART from world leaders will benefit the national ART program through several donor-led initiatives. The implementation of safe and effective ART is a serious challenge in such a resource-constrained country, where there is little experience in managing this type of complex treatment program.

In 2003, the MOH, DACA and HAPCO developed the National Guidelines on ARV and began providing ART training to teams of healthcare providers. As a result, 690 physicians, nurses, pharmacists and laboratory technicians from 58 centers have been trained in ART, and as of July 2004, 10,400 patients receive ARVs. Several challenges have already been identified, including the need to strengthen the overall program oversight structure, to integrate program monitoring & evaluation, and to develop discipline-specific standardized clinical training. Baseline viral susceptibility studies and minimum assurance of standardized therapeutic monitoring will also be required. Public private partnerships need to be encouraged and supported.

In order to address these gaps and to prepare for rapid scale up of ART, the MOH has developed this guideline to help foster a flexible, creative, and energetic response. This guideline is based on sound scientific and ethical standards and promotes sustainability and equitable access to treatment. Its primary goal is to support the development of a standardized, safe and effective ART program nationwide. The target audiences of this guideline include health providers, community health workers, community based organizations' staff, PLWHA, and program managers in the public and private sectors.

## **2. Guiding Principles**

The National ART Program is based on the following guiding principles:

- ART, which is comprehensive services, will be an integral part of the HIV continuum of care.
- The chronic care model will be applied to deliver ART.
- Treatment and clinical procedures will conform with national ARV treatment guidelines, which are based on international standards and best practices.
- Greater involvement of PLWHA will be encouraged.
- Equitable universal access will be strongly promoted.
- National prevention strategies will be emphasized.
- The National ART Program will strengthen the national health care system.
- Efforts will be made to ensure sustainability.
- Only one National ART Implementation Guideline will be followed.
- Public-private partnership will be encouraged and promoted.
- National and international networking will be valued and supported.

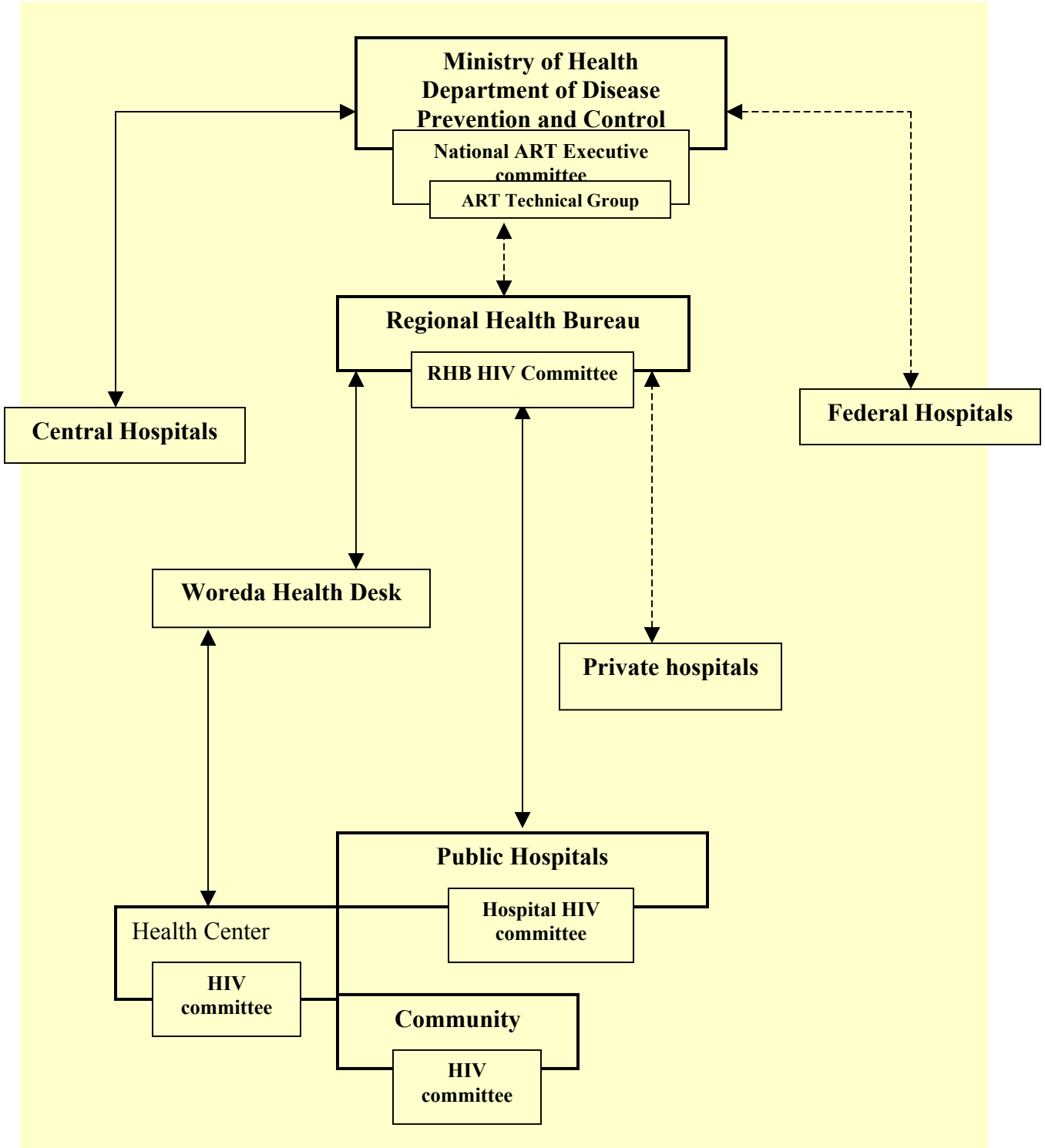
## **3. Goal**

The national ART program will be implemented as a safe, effective and equitable program as part of an HIV Continuum of Care, and at the same time, will strengthen the health care system of the nation.

## **4. Program Management & Coordination**

The ART program will be implemented at the national, regional, facility, and community levels. Program management and coordination will be in effect at all organizational levels and integrated into the existing health care systems. Figure 1 provides a schematic representation of the ART implementation structure. The key functions and organizations are highlighted and the information flow described.

**Figure 1. ART Management and Coordination Structure**



#### **4.1. National level**

At the national level, the MOH oversees overall coordination for the ART program by providing technical assistance to the regional health bureaus (RHB). Its primary focus is to integrate, coordinate, and standardize delivery of ART and to continuously improve quality of care. The MOH is also responsible for policy formulation on ARV treatment, development and updating of guidelines, preparation of country-specific ART plan, procurement and supply management, capacity building, monitoring and evaluation (M&E), advocacy and operational research. The MOH is supported by *the ART Technical Working Group*, which provides advice on issues related to ART as described below. The Ministry of National Defense and the Federal Police have hospital level committees that will directly report to the ART Technical Working Group.

##### **ART Technical Working Group members:**

- MOH
- HAPCO
- DACA

The technical group will invite additional bilateral and non-governmental agencies when appropriate.

##### **Responsibilities**

- Advise/support national policy on ART program
- Establish standards of care for ART program
- Establish and review eligibility criteria
- Determine criteria for expansion of ART program
- Set accreditation policy and guidelines
- Review ART program monitoring and evaluation data
- Advise on resource mobilization
- Review the appropriateness of technology transfer and application
- Oversee the activities of National ART training and technical support network

#### **4.2. Regional level**

The RHB assists in implementing the ART program by providing technical and budgetary support to the healthcare facilities and the districts. The RHB manages and coordinates all ART activities at the district and facility level, including reporting data to MOH and to facilities, enforcing policies and guidelines, and facilitating accreditation of facilities. The RHB plays a key role in integrating all ART activities, including those of community-based organizations, into the national program. It is supported by *the Regional HIV/AIDS Committee* to perform the tasks stated below.

##### **Regional HIV/AIDS Committee Members:**

- RHB
- RHAPCO

- Regional/referral hospitals
- Regional universities
- Regional laboratories
- PLWHA
- NGO representatives
- Private health sector

### **Responsibilities**

- Assure site readiness for ART program accreditation
- Assure national ART standards are followed
- Respond to hospital ART committee needs
- Review M&E reports from hospitals in the region and regularly submit to national steering committee
- Establish link with national task force and national HIV/AIDS training and technical support network
- Facilitate linkages between clinical care and care and support programs

### **4.3. District level**

The district health desk (DHD) assists in implementing the ART program by linking facilities, kebeles, and the community. Its primary role includes supporting ART activities at the community level and encouraging community mobilization among NGOs, CBOs and FBOs. DHD has the responsibility to respond to facility needs and report M&E data to the RHB. It is supported by the *District HIV/AIDS Committee* to perform the tasks stated below.

#### **District HIV/AIDS Committee Members:**

- District health office representative
- District hospital
- Health center
- PLWHA
- NGO representatives
- Private health sector

#### **Responsibilities:**

- Establish contact and link with higher health facilities and region
- Expedite bi-directional flow of information
- Establish coordination between public-private partners and NGOs
- ART Resource mobilization

#### **4.4. Facility level**

The facilities' primary role is to provide ART services, including referring PLWHA to local community support groups. They are also charged with patient care monitoring, and data collection, analysis, action, and reporting to the DHD or RHB. They are supported by the *Hospital and Health Center HIV/AIDS Committee* to perform the tasks stated below.

##### **Hospital HIV/AIDS Committee Members:**

- Facility director
- Physicians
- Nurses
- Pharmacist/ Pharmacy technician/ druggist
- Lab technicians
- Counselors
- Matron
- PLWHA

(All health personnel should be ART trained)

##### **Responsibilities:**

- Develop an ART work plan
- Prepare site for accreditation
- Assure that access to ART is in line with national guidelines
- Institute weekly meetings
- Review ART clinical monitoring data
- Act without delay on emergent corrective measures
- Submit M&E to regional ART task force via appropriate channel
- Assure integration of ART with other services
- Assure logistics system
- Coordinate capacity building
- Assure that all staff participate in ART

##### **Health Center HIV/AIDS Committee Members:**

- Physicians / Health officers
- Nurses
- Lab technicians
- Pharmacy technicians / druggist
- Counselors
- PLWHA

##### **Responsibilities**

- Establish referral system to and from the community
- Serve as an entry point for ART care and provide referral to the hospital

- Provide technical support to Kifle Ketemas and Kebeles
- Assist in establishing the community care monitoring system
- Assist in analyzing and reporting community care data
- Assume hospitals' responsibilities in areas where hospitals do not exist

#### **4.5 Community level**

The primary role of the community is to provide prevention, care and support, including efforts to reduce stigma and improve adherence. The existing HIV/AIDS Kebele committees support these efforts. It is highly recommended that communities determine the composition of the committee.

##### **Members:**

- Kebeles
- PLWHA
- CBOs
- Community health workers (CHW)
- Traditional Birth Attendants (TBA)
- Community leaders
- Traditional healers
- Health Center provider or team leader

##### **Responsibilities**

- Build capacity for care and support at the community level
- Provide training on Information, Education, Communication/Behavior Change Communication (IEC/BCC)
- Counsel on adherence, risk reduction, disclosure
- Provide care and support
- Conduct home visits

#### **4.6 Private sector**

The private organizations, such as for-profit and non-profit organizations (NGO, PLWHA & Representatives from the Ethiopian Private Physicians Association) play a supportive role both at the facility and community levels. Currently, the private hospitals are providing a large part of the fee based ART services. Therefore, collaboration with the private sector needs to be maintained and best practices adopted when scaling up ART. Members of the private sector are represented in the committees at each level. Their responsibilities should be to: provide comprehensive HIV care, including ART in the private sector, provide VCT as a prerequisite to access ART, prepare sites for accreditation, monitor and evaluate care, report findings related to patient care to the National ART steering committee, harmonize data collection and reporting with national HMIS, provide training on HIV care using MOH approved content and engage in drug importation and drug manufacturing (optional).

#### **4.7. National ART Training and Support Network.**

This is an essential entity that is not yet established. The main purpose of this network will be to support the training and technical needs of the Continuum of HIV Care (VCT, STI, OI, TB prevention and treatment, PMTCT and palliative care), including ART at all levels. Activities of the network will also include training development and coordination, clinical care, laboratory services, drug management, community mobilization, and communications and media relations. The network, to be located at Addis Ababa University (AAU), will be composed of seven teaching hospitals: AAU, Alemaya University, Dilla University, Defense University, Gondar University, Jimma University and Mekele University.

The following are suggestions for its structure and responsibilities.

#### **Organizational structure**

- The function of the Network will be subcontracted to AAU
- The Network Director will report to the MOH and dean of faculty of medicine at AAU
- The Network will support the National ART Steering Committee, the Regional ART Committee, the Facility HIV Committees, and ART service delivery

#### **Responsibilities**

- Train national and regional HIV/AIDS training teams (training of trainers)
- Support regional HIV/AIDS training teams
- Develop continuing education, pre-service training, and follow-up training
- Develop and upgrade HIV and ART curricula at AAU
- Develop training materials
- Develop certification programs, i.e. laboratory technicians/laypersons
- Assist in regularly updating ART guidelines
- Identifies areas for operational research
- Monitor and evaluate the performance of the national HIV/AIDS training and technical support network

### **5. ART Program Requirements**

Successful implementation of ART program requires appropriate and standardized structures, processes, measurements, and monitoring. This entails:

- Strictly following national ART policies, guidelines and protocols
- Using clinical tools and monitoring
- Establishing minimum requirements for facility accreditation
- Enforcing standard operating procedures
- Standardizing training curricula and materials
- Developing and applying standardized health management information system

#### **5.1. Policies and guidelines**

This implementation guideline, which addresses public health approaches to ART, is guided by the national HIV/AIDS policy and the policy on supply and use of ARV drugs. Guidelines on



ARV, PMTCT, OI, STI, VCT and Infection Prevention, including post-exposure prophylaxis serve to standardize the national approach to ART.

## **5.2. Protocols**

HIV/AIDS clinical care is standardized with the help of protocols, especially when care is dependent on a multidisciplinary team. Protocols are also instrumental in the delegation of care to the appropriate level. Protocols cover wide range of clinical activities: intake processes, including patient selection, diagnostic steps, treatments, procedures and referral systems.

## **5.3. Clinical Tools**

The skill, competency and capacity of health care providers are directly proportional to the degree they are supported and their activities facilitated. Care providers of patients with complex chronic illnesses must be supported with clinical tools, systems and adequate support staff. Reference materials should be easily accessible, and items such as pocketbooks and wall-mounted charts made available. Clinical documentations must be simplified with standardized checklists to obviate writing. ART ready facility should thus have clinical tools adapted to local situations that cover comprehensive HIV care.

## **5.4. Clinical Monitoring**

Program adequacy, clinical outcomes, clinical process monitoring and reporting are expected of each facility providing ART. National program indicators must be adopted. In addition, facilities will be expected to develop an M&E system, capable of informing a full evaluation of HIV care, including ART. The MIS/referral system will include:

- A two-way referral system between clinical service delivery sites and community, and home-based care and support programs
- Standardized and upgraded documentation tools and forms
- Using patients as carriers of their own medical information

## **5.5 Accreditation**

It is essential that facilities be accredited before implementing an ART program. The process of accreditation will require the facilities to:

- Demonstrate the capacity to provide comprehensive HIV care, including ART
- Have standard operating procedures for HIV/AIDS comprehensive care
- Have the resources necessary to counsel and test those who ask for it
- Be able to diagnose and treat sexually transmitted illnesses, tuberculosis, opportunistic infections
- Provide supportive care for or refer patients to CBOs
- Be able to continuously monitor patient care and health status
- Have a linkage with a higher referral center within the catchment area
- Meet the minimum requirements for **clinic, pharmacy and laboratory services** as described below

**TABLE 1. Clinical Minimum Package**

	Referral Hospital	Regional/Zonal Hospital	District Hospital	Health Center
<b>Infrastructure</b>	Examination room <sup>1</sup> One ART confidential counseling room <sup>2</sup> →			
<b>Equipment</b>	- Exam Tools and supplies (Ophthalmoscope, Otoscope, Stethoscope, BP Cuff, Reflex hammer) - Supplies (gloves, tang blade) →			
<b>Human Resources</b>	- 2 MD trained on ART <sup>3</sup> - 2 ART trained nurse - 1 data clerk		- 2 ART trained MD - 2 ART trained Nurse - 1 data clerk	- 2 ART trained MD/HO - 2 ART trained Nurse - 1 data clerk
<b>M&amp;E/MIS</b>	- Log book - Recording/reporting forms - Special ART prescription → - Lockable filing cabinets			
<b>Services</b>	Comprehensive HIV services (STI, OI, TB & Palliative care) (VCT, TB, STI and OI Services) →			
<b>Referral Systems</b>	Referral slip, feedback forms, receiving and disposition slips →			Referral slip

**TABLE 2. Pharmacy Minimum Package**

	Referral Hospital	Regional/Zonal Hospital	District Hospital	Health Center
<b>Infrastructure</b>	On-site pharmacy Secure storage space → Confidential counseling room or space			
<b>Equipment &amp; Supplies</b>	Refrigerator →			
<b>Human Resource</b>	2 pharmacy staff <sup>4</sup>	2 pharmacy staff (pharmacist or pharmacy technicians or druggists trained on ART)		2 pharmacy technician trained on ART
<b>M&amp;E/MIS</b>	Drug supply and management system (bin card, stock card, receiving voucher, models, prescription forms, registration book, report forms) Lockable drawer →			

<sup>1</sup> One room per practicing ART physician

<sup>2</sup> The ART counseling room should be different than the VCT counseling room

<sup>3</sup> At least one of the practicing MD should be a specialist

<sup>4</sup> At least one of the pharmacy staff should be a pharmacist

**TABLE 3. Laboratory Minimum Package**

	<b>Referral Special Hospital</b>	<b>Regional/Zonal Hospital</b>	<b>District Hospital</b>	<b>Health Center</b>
<b>Infrastructure</b>	- Specimen collection area and 2 additional rooms		- Specimen collection area and 1 additional room	- 1 room
<b>Type of tests</b>	All tests done at <b>District Hospital</b> Plus CD4 Count		- All tests done at <b>Health Center</b> Plus - Clinical Chemistry (BUN, Cr.) - LFT	- Full blood count - AFB smear - Gram smear - O &P - Malaria smear - Pregnancy test - Serology for HIV - RPR / VDRL - Indian ink
<b>Equipment &amp; Supplies</b>	- Equipments & Supplies included under <b>District Hospital</b> Plus - CD4 Count Machine		- Equipments & Supplies included under <b>Health Center</b> Plus - Hematology auto-analyzer - Clinical chemistry auto-analyzer	- Sterilizing equipment - Microscope - Refrigerator - Centrifuge - Test Kits - IP supplies - Reagents
<b>Human Resources</b>	2 trained laboratory staff (at least one laboratory technologist)		2 trained laboratory technicians	
<b>M&amp;E/MIS</b>	Log book Recording/reporting forms Lockable drawer			

Facilities that meet **all** the requirements will be granted **full accreditation** valid for one year. Those with major deficiencies will be granted **no accreditation**, but will be reviewed in one year. There may, on the other hand, be instances when a facility meets major requirements and has easily correctable deficiency, e.g. run out of Ziehl Nelson stain, but has “no stock out” plan in place. In this case, the facility will be granted **conditional accreditation** and will be reviewed within three months. A checklist will be used to assess site readiness and accredit accordingly. Same standard and process for accreditation will be applied to private hospitals expect they will not be required to have the pharmacy and laboratory components on site.

**Accrediting roles and responsibilities**

- The RHB will be responsible for facility accreditation, in consultation with the MOH
- The MOH will develop guidelines & SOP on accreditation
- As appropriate, the RHB could delegate, contract out, or partner with others in the process of accreditation
- The MOH will be responsible of the overall quality assurance oversight

## 5.6 Standard Operations Procedures (SOP):

There must be a standard operations procedure (SOP) on every **clinical** process and procedure, **lab** test, and **pharmacy** practice. SOP should be prepared and approved by practitioners and management. Clinical leaders and lab and pharmacy supervisors must make sure that there are adequate supplies for patient and health care provider safety in their respective practice areas. These supplies will be identified in the SOP.

## 5.7 ART Training

The short-term strategy during the rapid ART scale-up will be to provide in-service training to a large number of health professionals. Eventually, appropriately designed pre-service curricula will also increase the numbers of trained providers. Training materials and curricula must be standardized and training must be:

- Reflective of the comprehensive nature of ART program
- Discipline tailored (physicians, nurses, pharmacists and lab technicians)
- Standardized (one national training content and duration per discipline) and coordinated
- Certification is automatic when the national content and trainers' credentials are satisfied

Training needs and responsibilities at the various levels are:

- **Community level:** PLWHA, CHA, TBA, CBOs, NGOs, FBOs should be trained on adherence, supportive counseling, treatment literacy and preparedness.
- **Health Center level:** All disciplines should be trained to follow stable patients on ART. As health center level providers will eventually prescribe ARV, their training needs will be upgraded accordingly.
- **Hospital level:** Physicians will be certified to prescribe first and second line ARVs for stable and unstable HIV patients. All other disciplines will be trained on care and support of HIV patients.
- **Regional level:** Develop capacity to train and coordinate. Provide training for program managers. Training should be decentralized to regional levels.
- **National level:** the MOH and DACA should coordinate and assure standardized content and delivery of ART training. Provide training for program managers.

## 5.8. Health Management Information System (HMIS)

The HMIS must support the monitoring of program implementation, the documentation of patient care and outcomes, as well as logistical capacity and performance. In order to have a unified national ART program, tools, systems and reports must be standardized. MOH, as the responsible body, must lay down mechanisms to eliminate uncoordinated individual operations. Regions, likewise, must assure that reporting materials, tools and systems follow national standards in support of the national HMIS system.

## 5.9. Drugs and supply management

### Selection of ARV Drugs and Related Supplies<sup>5</sup>

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<sup>5</sup> Drugs for Opportunistic Infections, Sexually Transmitted Infections and Infection Prevention and Control supplies

The National List of Drugs for Ethiopia describes the ARVs and related supplies for use in Ethiopia. This list will be revised as required. Forms containing information about strength and dosage of individual drugs are available (e.g. for pediatric use).

### **Procurement of ARVs and Related Supplies**

All ARV drugs and related products for use in public or private sector should be procured at affordable prices, with assured quality, adequate shelf life and reliable supply. This will enable organisations and institutions supporting ART to determine the minimum safety stock of ARVs they will need in order to prevent stock-outs. Drug suppliers to different programs need to base their safety stock on quantities issued or dispensed.

Procurement of ARVs will be done according to national and international regulations, including pre-import approval by DACA. ARVs should be procured through tender or other methods of procurement, but have to comply with quality requirements set by DACA. To ensure quality tenders, provision of ARV drugs should be limited to suppliers that meet World Health Organization's standards.

### **Distribution of ARVs and Related Supplies**

Efficient distribution and redistribution systems are critical to responding to varying commodity needs at individual sites. Scheduled distribution to health facilities will be maintained.

Proper storage of ARVs, including refrigeration, is critical to maintain the quality of ARVs and related supplies. Adequate space and facilities for proper handling must be ensured at various levels. Mechanisms for control of expiration, stock rotation and proper disposal should be implemented.

ARVs are a valuable commodity and the risk of theft is high. In addition to financial loss, theft and distribution of ARV drugs to patients not under supervised care could result in improper use of the drugs, thus increasing the chances of drug resistance. Hence, security in the supply chain must be assured.

ART implementing organizations (governmental organizations, NGOs, private sectors) should be allowed to contract services of pharmaceutical businesses for specific tasks such as procurement, clearance, storage, distribution, and delivery. Concurrently, efforts need to be undertaken to strengthen the logistical capacity of the public-sector health system. Existing mechanisms of the drug and supply management system should be used and strengthened to facilitate rapid scale-up.

## Use of ARVs and Related Supplies

National standards are needed to ensure and monitor correct prescribing, dispensing and patient use of ARVs. To enhance efficacy, decrease toxicity and promote adherence, ARVs should only be dispensed after proper counseling in a private and confidential setting. In addition, patient and public education to enhance drug adherence, proper handling and storage at home and avoiding drug sharing should be promoted.

### Quality assurance

Mechanisms must be put in place to assure the quality of drugs entering the country through pre-procurement certification and post marketing surveillance. Appropriate quality assurance mechanisms for ARVs should be developed and implemented by DACA. Quality standards should also define storage conditions at wholesale and facility stores. National laboratory must have the capacity to assure the quality of ARV. Quality assurance of drugs and supplies will be maintained using simple visual methods. First-In-First-Out (FIFO) system will be used to avoid expiration and ensure use of fresh supplies.

### 5.10 Eligibility

Ideally, access to ART should be universal and equitable. The “right to treatment” has now been recognized as a natural extension of the right to health. However, the reality in Ethiopia today dictates eligibility criteria as a result of inadequate supply of free ARVs. Therefore, not all those who qualify for free ART will be able to get it initially. Since only a very limited percentage of those estimated to need ART will access the treatment initially, **criteria for access to free ART, with a contingency quota plan**, have been established. The framework for access to free ART will be transparent and participatory to ensure that all people will be considered for high quality services on equal basis.

At the national level, the following are the minimum access criteria, given in order of importance:

1. HIV regional prevalence and population density
2. Access priority for vulnerable groups<sup>6</sup> (stated below)

At the facility level, access to ART should be prioritized based on:

1. Clinical initiation criteria<sup>7</sup>
2. Clinician determined last resort priority
  - a. The sickest with ART reversible conditions
3. Non-clinical priority
  - a. The most vulnerable groups
  - b. Gender equity, i.e. equal representation of women
4. Consultation with HIV/AIDS Committee at the facility level

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<sup>6</sup> Vulnerable groups are defined as children, pregnant women, health workers exposed in the line of duty (PEP) and rape victims.

<sup>7</sup> See ARV Guidelines

- a. Based on best practices, it is highly recommended that facility HIV/AIDS committee serve as the ART access committee

**Safety of those who do not start indicated ART will be assured through:**

- An open access practice set up that guarantees same day evaluation and care of patients who seek care.
- Prompt evaluation and care of OIs and other clinical conditions.

Based on government prevention and treatment policy and as a matter of human rights, the National ART Program will at a minimum give priority and provide free ARVs to the following vulnerable groups and health workers (see 2 above)

**ARV drugs for prevention**

- **PMTCT services**

According to the recently launched PMTCT program, infected pregnant women and their infants should have priority to receive free ARVs to prevent MTCT. (the issue is when PMTCT involves combination drugs rather than the current NVP)

- **Post-exposure prophylaxis (PEP)** (see ARV Guideline for PEP protocol)

- a. **PEP for health care workers**

Health care providers in medical facilities are constantly exposed to body fluids and blood borne pathogens. Even if the risk of acquiring HIV due to body fluid exposure is low (0.3%), it can create an environment of fear and insecurity in health care settings, which will adversely impact patient care. Therefore in order to further reduce the risk of infection and improve the health care atmosphere and reduce stigma, free PEP should be provided to all health care workers. Standard precautions must be a priority and the Infection Control and Prevention standards of medical facilities upgraded and practiced. PEP is to be provided after a baseline testing of both the source and the exposed

- b. **PEP for rape victims**

PEP for rape victims is based on moral and biological grounds. PEP must be administered immediately when serious ano-genital mucosal damage has occurred, which is invariably the case in children. Adult rape victims must report the crime to the appropriate authority in order to qualify for free PEP. However, the first dose of PEP should be administered on clinical grounds without delay.

- c. **PEP for emergency service workers**

Police, fire fighters and paramedics, including Red Cross volunteers, who get exposed to body fluids and blood in line of duty, will qualify for free PEP.

## ARV drugs for Treatment

- **Children under 18 years of age<sup>8</sup> irrespective of their social status** should be given priority for ARV drugs.

- **Priority for seroconverters after PEP**

PEP is successful 80% of the time when administered within two hours. Individuals who seroconvert after having received PEP will qualify for free ART regardless of when they seroconvert. Because of a lack of logistical and other support, causal relationship between exposure and seroconversion is deferred at this time.

- **PLWHA enrolled in research**

The following groups of patients should be given priority and qualify for free ART:

- Seroconverters as a result of research (vaccine trials) or while on research (discordant couples)
- Patients enrolled in HIV research, other than ARV drug studies
- Pharmaceutical sponsored ARV drug studies will not qualify for free ART. In this case, it will be the responsibility of the Principal Investigator to guarantee the continuation of ART for the rest of the enrollees' lives.

### 5.11 Sustainability

In resource-constrained settings, cost and long-term program sustainability are legitimate concerns of political and public health leaders. Therefore, a successful ART implementation plan should consider cost-effectiveness as a major factor and make an honest attempt to address program sustainability.

- **Resource mobilization**

- Establishing cost sharing with income sliding scale
- Encouraging workplace ART, PMTCT and PEP initiatives
- Establishing tax levies and providing tax exemption of funds raised
- Approaching local groups and persons in the Diaspora for support
- Accessing international initiatives
- Promoting public-private partnerships

- **Cost-saving strategies**

- Realization of national ART implementation plan
- Harmonization and enforcement of national guidelines in diagnosis & treatment
- Integration of services, activities and programs
- Promotion of local production of ARVs
- Improvement of drug and associated supplies management
- Establishment of quality assurance systems for services and commodities
- Training and motivating staff with incentives to be cost conscious

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<sup>8</sup> Eighteen years of age is taken as the cut-off based on the constitutional definition of minor.



- Networks and partnerships within and outside the service
- Promotion of community/family participation and awareness in cost effective care

## **6. Approaches to Implementing ART Program**

In order to implement the ART program, several important steps need to be followed:

- Assess site readiness for ART
- Identify gaps and make recommendations
- Provide resources and build capacity to fill the gaps identified
- Perform follow-up evaluation
- Accredite site
- Initiate ART program
- Provide support for ART program
- Collect monitoring data for ART program and ensure findings lead to program adjustments where necessary
- Perform continuous evaluation of ART program and improve quality of care accordingly.

In addition, capacity building and infrastructure improvement is a priority. Other basic health care services including testing and counseling, psychosocial support, diagnosis and treatment of common HIV-related illnesses will have been strengthened. Referral systems for higher level care must be established; support and provider groups other than facility based HCW, including PLHA must be recruited and involved; existing health care providers must be trained and retrained. The program must then be scaled-up.

## **7. ART Rollout Plan**

The ART program will be rolled out in phases. In the initial phase, the focus will be to prepare the sites already prescribing ART to meet the accreditation criteria by correcting identified gaps. New sites will be added based on HIV regional prevalence, population density and regional equity. In the second phase, treatment will rollout to public and private hospitals and selected health centers where hospitals do not exist. These centers are expected to meet the minimum criteria for accreditation before they are allowed to prescribe. In the third phase, all hospitals and health centers including new NGO supported facilities will prescribe ARVs.

## **8. Facility Level Planning for Service Delivery**

At the level where services are to be delivered, there must be:

- Competent and proactive leaders
- A plan on what services are provided and how to deliver them
- A plan on resource mobilization and allocation
- Infrastructure that matches the plan
- Adequate number of trained staff
- Systems that would facilitate and support care
- Monitoring systems

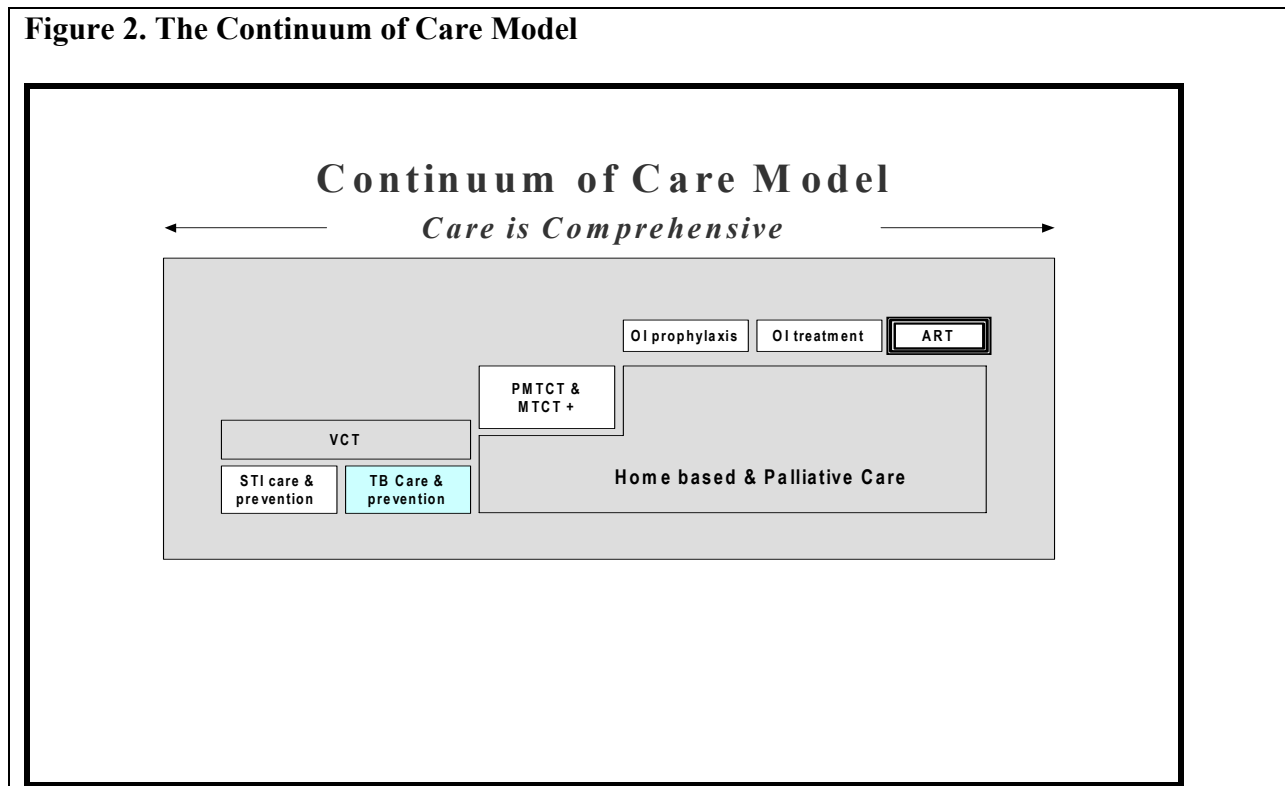
### 8.1. Leadership

Based on the initial site readiness assessment, ART leadership mobilization is needed. The leadership at the facility level must recognize the following fundamentals of ART service delivery:

- Have capacity to deliver comprehensive HIV care including ART
- Identify a practice model that matches capacity
- The care model is that of chronic illness
- Trained staff willing to support comprehensive HIV care
- The leadership has or plans to invest in staff recruitment & retention to meet the minimum necessary staff
- Access to this comprehensive HIV care is equitable, taking women & children into account
- ART resource allocation is patient care centered

### 8.2. The Care Model

ART should be an integral part of the HIV *continuum of care* and should not be seen as a stand-alone activity. ART implementation and scale-up should be in the context of comprehensive care within the continuum, an integrated **chronic illness care model** with a long-term plan and commitment for follow up care. A comprehensive care model that describes the different components of care, including ART, is illustrated below:



*Each box represents a module in the continuum of care model*

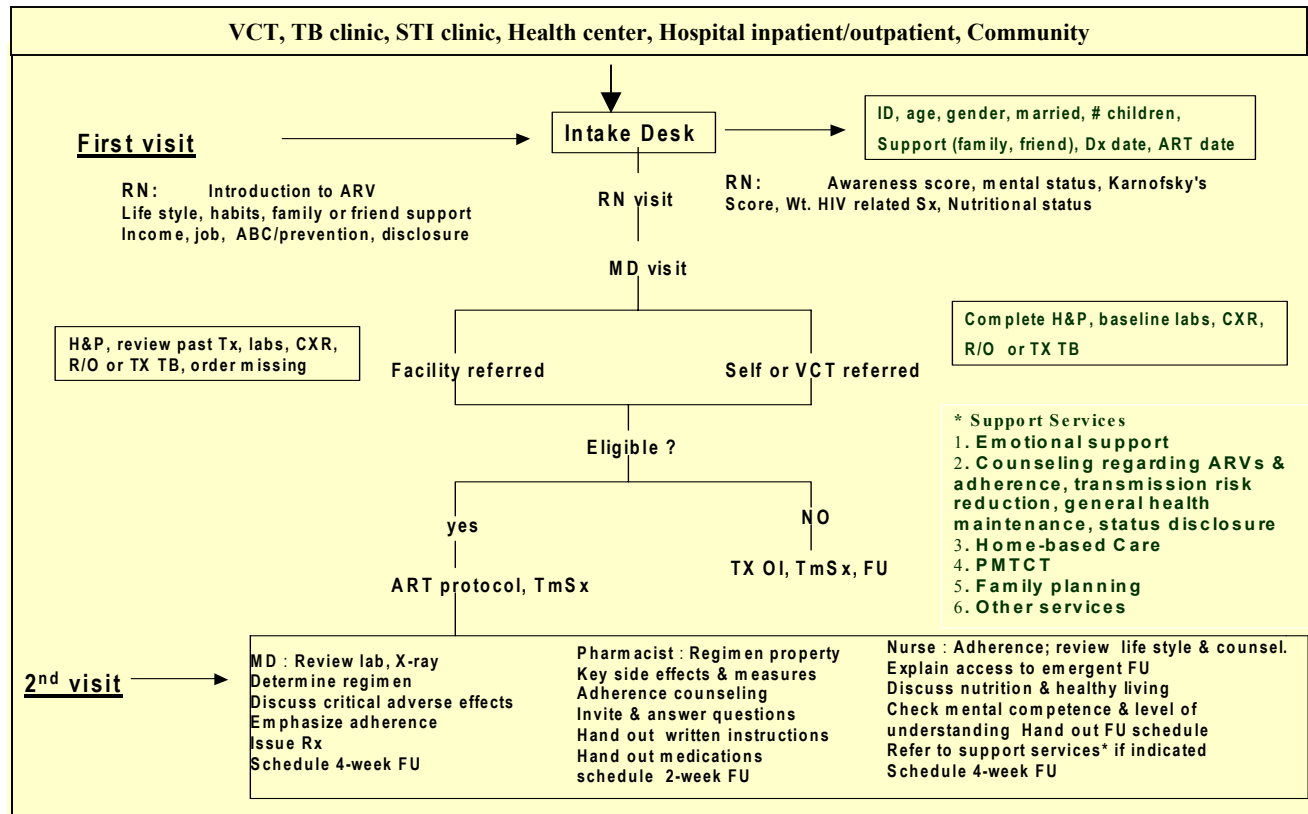
### 8.3. ART Patient flow

The following are considered the points of entry for ART services:

- Self referred
- VCT
- TB clinic
- STI clinic
- Health Center
- Outpatient clinics
- Inpatient Services
- The community

In the HIV care site, the patient has to undergo thorough medical evaluation to determine his/her HIV, TB, and pregnancy status. Multidisciplinary teams best manage candidates for ART. The physician is tasked with overall patient care and safety, but could delegate roles that could be safely and legally handled by a nurse and/or a pharmacist. It is highly advisable that patients not be started on ART on the first visit to an ART clinic. The following patient flow diagram depicts the various stops and interventions.

**Figure 3. ART Patient Flow**



## **8.4 Staffing Needs**

Facility leaders, supported by RHB, must staff their respective sites commensurate to facility level of care. The staffing level must be adjusted according to the clinical workload. It will, otherwise, be necessary to change the care model so that capacity is not overstretched. It is highly recommended that there be a multidisciplinary team approach to ART for the sake of efficiency, but more importantly for better adherence and patient outcome.

## **8.5. Clinical Services**

It is essential that facilities go over their respective patient flows in order to identify gaps before ART scale up is attempted. ART in isolation is no care. Intake processes and patient referrals as well as patient care systems must be reviewed, improved and expanded in order to allow comprehensive care. Programs must be linked and integrated to assure follow up and continuum of care. The proper role of community members must be recognized and the community mobilized to support continuity and home-based care. Community peers, PLWHA, clubs serve different purposes in the provision of care, support and reinforcement of adherence.

## **8.6. Laboratory services**

Accurate patient care monitoring is dependent on competent lab personnel. Their training needs should be identified and regularly scheduled. The minimum tests and the infrastructure to allow adequate laboratory services are identified in the minimum package. Quality assurance and control must be performed with every test, recorded and visibly mounted. In addition, there must be internal and external controls as part of the lab quality control record. Referral linkages between district hospitals and regional referral laboratories will assure this. In turn, the referral labs must be linked with the national lab. Each lab should closely follow the lab SOP.

## **8.7. Pharmacy Services**

Pharmacy service must assure safety of patients on ARV, adherence and uninterrupted supply of the drugs and ART related supplies. Safe and effective ART is dependent on adequate patient counseling and instructions at the facility and at home. Job aids, patient reminders and handouts enhance counseling. Pharmacy services must also ensure that the drugs are safely and securely stored, and that stock levels and usage are monitored through standardized forms and processes and integrated into the HMIS.

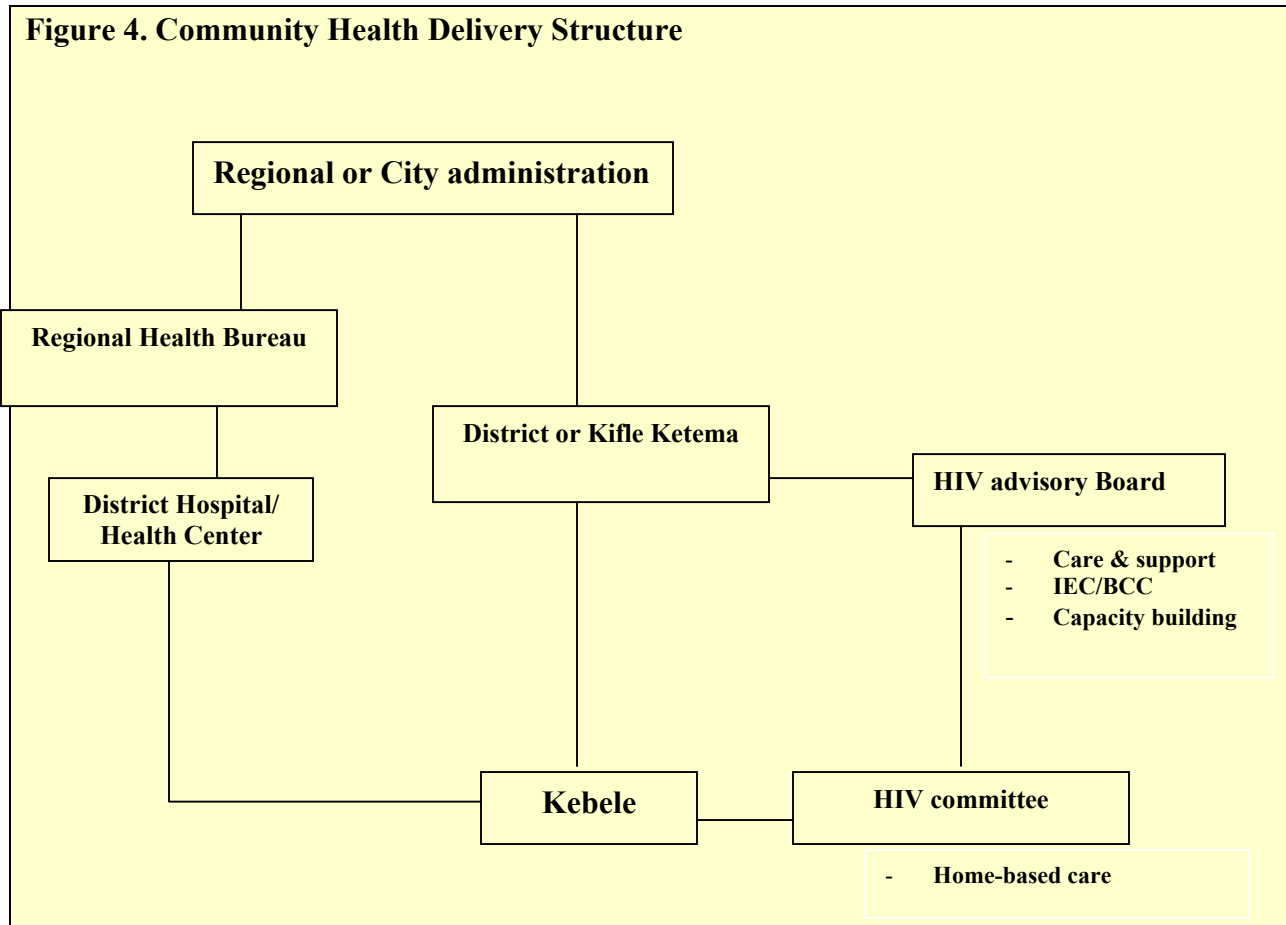
## **8.8. Systems**

Systems that enable patient tracking, clarify patient flow and allow patient follow-up are essential for safe care and continuity of care. At a minimum, there must be a medical record system. Pertinent information must be documented by all disciplines (physicians, nurses and pharmacists) that provide direct patient care. This system should also allow for timely information exchange between disciplines on the patient flow tract. This system is the foundation, not only for patient care but also for monitoring and evaluation and patient referrals.

## 9. Community Level Planning: Care Beyond the Facilities

### 9.1. Community Health Delivery Structure

An effective health care delivery plan beyond the hospitals and health centers takes the community organization into account. Public health administration structure that extends into the community and eventually to the home is illustrated below.



The ART program should use the existing community health delivery structure to reach the community. Moreover, HIV/AIDS prevention, care and support activities are already taking place at these levels, facilitating the integration of ART activities. The district and Kifle Ketemas have HIV Advisory Committees, while the Kebeles, the lowest administrative units in the organization, have HIV/AIDS committees. The districts provide training on home-based care as part of their care and support mandate. Community awareness and capacity building are also conducted at the district level. The Kebeles serve as the link between the Health Center and the home. Through the HIV/AIDS Committee, they refer patients to their respective health centers and volunteers conduct home visits. Most voluntary NGO operate at the Kebele and district level, also providing various prevention, care and support services. These NGO led initiatives of

home-based care should be integrated into the existing government structure, avoiding the creation of parallel systems.

## 9.2. Key Community Stakeholders

The key community stakeholders include:

- PLWHA and groups and associations of which they may be members
- Families and friends of PLWHA
- NGOs, CBOs, and FBOs that are providing prevention, care, treatment or support services
- Community leaders (such as religious and traditional leaders)
- Community health workers
- Traditional Healers

These groups represent significant existing expertise and resources that should be built upon for the implementation and scale-up of ART in the country. This will require increased awareness within the community, which will be generated through the use of well-informed mass and mini media.

## 9.3. Role of the Community

The involvement of the community in ART will be provided within the Health Extension Package and will include:

**Advocacy:** This will include mobilizing political and financial support to ensure that ART is sustainable, secure, equitable, accessible, and acceptable. Advocacy must reduce stigma and discrimination

**Information, education and communications/BCC** will include information, education and communication about HIV/AIDS, such as prevention, testing and treatment.

**Service provision:** This will include HIV testing and counseling, HIV prevention, treatment support (including prevention, and adherence support), peer support, psychosocial and nutritional support, home support and palliative support, spiritual support for people with HIV and assistance with storing and distributing commodities.

In particular, the health care delivery system should:

- Identify and utilize existing community capacity to provide the following prevention, care, treatment and support services:
  - Outreach to vulnerable populations, including sex workers, men who have sex with men and injecting drug users
  - HIV counseling
  - Adherence counseling
  - Prevention, including safer sex, distribution of condoms and preventing sexually transmitted infections
  - Treatment and care for common conditions such as pain relief, diarrhea and thrush; psychosocial support
  - Nutritional support
  - Home visits

- Palliative care
  - Spiritual support
  - Referral to a health center for more complex management
  - Links and referrals to community-based organizations and traditional practitioners
- Initiate training and support for expanded community provision of the services listed above, plus:
    - Counseling (community health workers)
    - Completing patient records (community health workers)
    - Providing assistance with storage and distribution of drugs (community health workers and community based organizations involved in care)
    - Routine clinical monitoring (antiretroviral side effects, weight, infections and cough)
    - Adherence counseling and support
- Promote and protect rights
    - Realizing the right to treatment, participate in ethical and equitable selection of people to receive ART and other decision-making,
    - Protecting human rights and confidentiality
    - Support community oversight of ART program.

## **10. Information Management and Communications**

Multidisciplinary support of comprehensive HIV care is critical for program success. Diverse participants outside the public health care delivery system (see ***Community Level Planning*** section), individuals and organizations (PLHA, private industries, private practitioners, NGO and traditional healers) provide care and support and counsel on prevention. All key players need to be informed on the latest development concerning ART. Therefore, a mechanism to disseminate accurate and timely information to these various stakeholders, starting in the planning phase of ART implementation, must be set-up. A well developed information management and communication plan becomes a crucial component of the ART program because:

- A very complex treatment program is being scaled up very rapidly
- Treatment is to be taken for life and high rate of adherence is expected, allowing no room for supply interruption
- The program requires specific skills and resources in a resource limited setting

Therefore, an ART program requires the highest degree of coordination and integration to succeed in a health care delivery system with very little or no experience. Strong information management and communication will serve as a backbone for this program.

Communication within and outside the program will:

- Create awareness about ART
- Clarify the roles of various stakeholders in the implementation of ART
- Enable the sharing of experiences and adaptation of best practices
- Facilitate coordination and integration
- Standardize the delivery of ART across the nation

- Disseminate standard treatment protocols, procedures and guidelines
- Distribute M&E findings to participants

Maximum effort should be exerted to establish bi-directional communication. This will assure that the program meets the peoples' needs and at the same time disseminate information on the continuum of care, including prevention and ART to a much wider audience.

## 11. Strategic Information

This section is an expanded version of the traditional monitoring & evaluation and includes surveillance, operational research and HMIS, which are critical in the planning and follow-up of program implementation. Planned and systematic data gathering, analysis and interpretation is essential for the purpose of:

- Monitoring clinical care
- Patient outcome improvement
- Logistical appropriateness
- Program cost-effectiveness
- Performance measures and improvement

Data gathering must be clinically oriented, facility based, simple, adaptable and integrated into the existing system. The following data list, by no means exhaustive, would provide useful information:

- Clinical monitoring
  - Demographics
  - Patient monitoring (lab data)
  - Clinical status and progress
    - . Weight gain
    - . Functional score
    - . Occurrence of OIs,
    - . Rate of hospitalization
    - . Death
    - . Adverse drug reactions
    - . Ratio of first to second line regimen
    - . Trends in CD4
    - . Trends of VL
  - ARV selection and changes
  - Adherence
  - Drug resistance monitoring
- Supplies and commodities
  - Tracking storage, expiry dates
  - Tracking stock-outs of drugs and supplies
  - Performance of distribution system



- Human resources
  - Staffing level
  - Skills
  - Gaps and plans to meet them
  - Recruitment and retention
  - Incentives and investment to minimize turnover

At a minimum management of *Strategic Information* will require:

- Trained staff who will
  - Develop forms
  - Collect data
  - Enter data
  - Analyze data
  
- Standardized tools
  - Paper based and/or Electronic **HMIS**
    - . Standardized clinical records
    - . Unique patient numbers. Legislation will be required so that everyone has one national health care identification number
    - . Hospital numbers on the other hand is hospital specific identifier
    - . Standardized data collection forms
  
- Confidentiality
  - Health care information confidentiality must be assured
  - The confidentiality of data gathered for the purposes of M&E must be protected by law
  
- Operational research at a minimum will look at the following critical ART program success defining issues
  - Adherence
  - Drug resistance
  - Drug regimen cost-effectiveness
  - Minimum treatment safety monitoring package
  - Use and availability of ARVs

The monitoring of processes and evaluation of performances and outcomes are dependent on the identification of broad data elements that when collated and analyzed will generate diverse reports. A variety of decision-makers, national and international, will need these reports in a timely manner for well-informed implementation planning and follow up decisions. Strategic Information must be patient centered and clinically oriented. Customer tailored databases will satisfy the needs of managers with oversight responsibilities. Timely and accurate data collection will be assured by designing clinical record forms which incorporate the various data elements so that they are captured as part of the clinicians' routine clinical documentation.

It will, therefore, be essential to develop a user-friendly and time saving initial assessment and follow-up documentation forms. Consequently, this plan will require a thorough understanding of **ART Patient Flow** (see p. 20) or care map in order to capture as much relevant data (national and donor mandated) as possible. The data collection tools will also be sensitive to clinician (MD, RN, RPh) time crunch. The documentation forms will be developed with full participation of clinicians (MDs, RNs, RPhs.). They will be field tested and finalized after further field input.

The process of data management involves

- Clinical documentation by physicians, nurses and pharmacists
- Data entry by data clerk
- Aggregation } By data managers
- Data analysis }
- Reporting by program coordinator (paper and electronic based)

Information will be collected at all care sites (hospitals, health centers, clinics)

- Public
- Private for profit
- Private for-non-profit
- Workplace health care sites

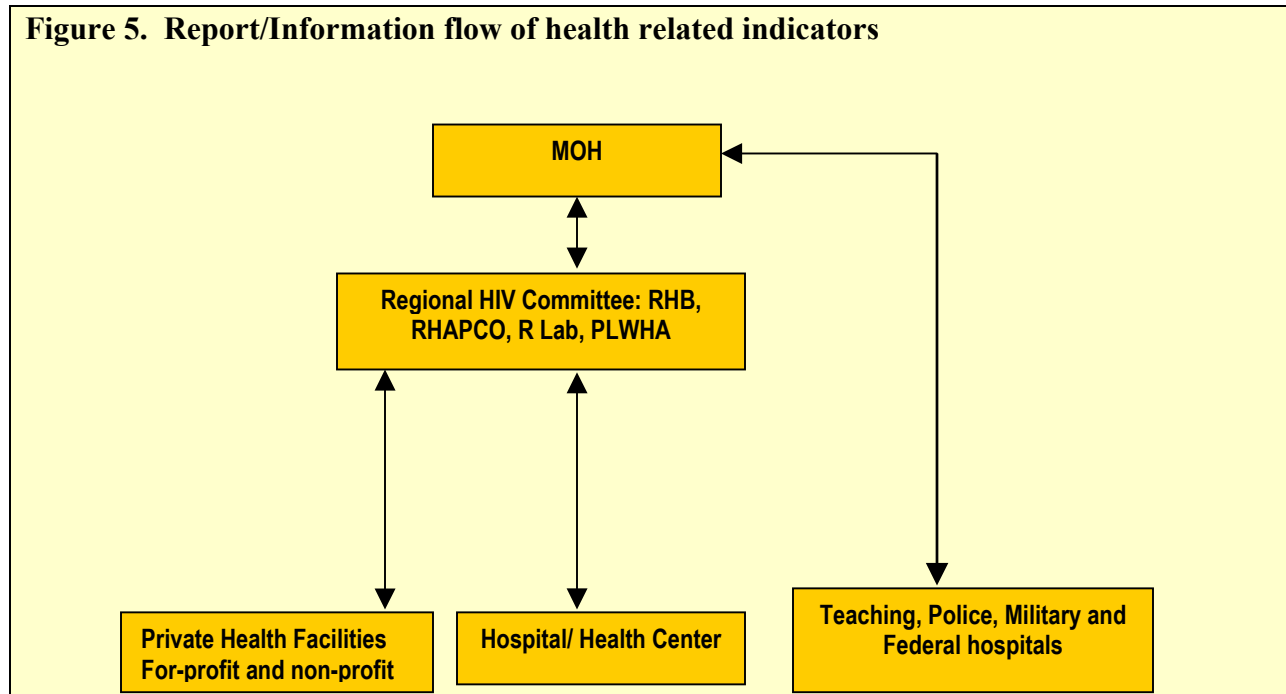
Data collected locally should be aggregated, analyzed and interpreted for intervention and action-plan both locally and centrally and then distributed to all stakeholders on a need to know basis in order to protect health information confidentiality.

**Reporting:** Reports required by different organizations will be passed up the national M&E reporting channels<sup>9</sup>. Note that reporting is bi-directional. M&E data, whether analyzed or raw must be utilized and reported to the section responsible for corrective action. The principles of *continuous quality improvement* dictate that M&E data not be used for punishment nor be accessible for anything else, including the courts, other than for performance and quality of care improvement action.

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<sup>9</sup> HAPCO Dec.2003

**Figure 5. Report/Information flow of health related indicators**



Report on indicators will be prepared by the program coordinators at each region, reported to the RHB, presented to the Regional HIV Steering Committee and then to the MOH and HAPCO.

Other indicators not included in the national report:

- Performance of the Supply system to support ART
- Community preparedness
- Program targets

Interwoven into some of the activities are also monitors that are program specific, e.g. the quality assurance and quality control of pharmacies and labs are integral parts of these programs and must be included in the overall M&E.

## Annex A

### Indicators

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CST3	Percentage of people with advanced HIV infection receiving ARV combination therapy (disaggregated by age, sex, region, and urban/rural)
CST4	Percentage of health facilities that either provide comprehensive care and support services onsite for people living with HIV/AIDS or through an effective referral system (disaggregated by region)
CST5	Percentage of health facilities that have the capacity and conditions to provide basic level HIV testing and HIV/AIDS clinical management (disaggregated by region)
CST6	Percentage of health facilities that have the capacity and conditions to provide advanced level HIV care and support services, including provision and monitoring of ART (disaggregated by region)
CST7	Percentage of designated laboratories with the capacity to monitor ART according to national guidelines

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### In Addition:

- Percentage of people alive and known to be on treatment at 6, 12, 24, 36, etc months after initiation of treatment
- Proportion of adults on standard first-line and second-line ARV regimen

**Detail description of this Indicators is found in the** *National Monitoring and Evaluation Framework for the Multi-Sectoral Response to HIV/AIDS (HAPCO 2003) and National M&E OPM. These Indicators are all International agreed upon (UNGASS etc)*

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