GUIDELINES
FOR
IMPLEMENTATION OF THE
ANTIRETROVIRAL THERAPY PROGRAMME
IN ETHIOPIA

Federal HIV/AIDS Prevention and Control Office
Federal Ministry of Health
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Foreword

The human immunodeficiency virus (HIV) has created an enormous challenge worldwide. Since its recognition, HIV has infected close to 70 million people, and more than 30 million have died due to acquired immunodeficiency syndrome (AIDS). More than 66% of the 40 million people living with HIV/AIDS are in sub-Saharan Africa, where AIDS is the leading cause of death.

Ethiopia is the second most populous and one of the seriously affected countries in sub Saharan Africa. With more than 1.3 million people living with HIV and an estimated 277,800 people requiring treatment, the Government of Ethiopia has taken measures to reduce the risk of HIV transmission and mitigate the impact of the epidemic on society.

Highly active antiretroviral therapy (HAART) was *the* breakthrough in care and treatment of people living with HIV, leading to a reduction in mortality and an improvement in the quality of life. Antiretroviral drugs significantly lowered the rate of HIV transmission from mother to child, and antiretroviral therapy (ART) has become an integral part of the continuum of HIV care.

Several policies and guidelines are in place to support the implementation and scale-up of the national response, including the National HIV/AIDS Policy, the National Strategic Framework on the Prevention and Control of HIV/AIDS, the Supply and Use of ARV Drugs policy. Based on these documents, and on the recommendations of the United Nations General Assembly Special Session on HIV/AIDS (UNGASS), the Government of Ethiopia launched its fee-based ART initiative in 2003 and free ART initiative in 2005. Currently 71,500 clients have accessed ART. The country has scaled up its ART programme - the service is now provided at 241 sites- and is planning to decentralize the service further to existing health facilities.

These guidelines are intended to serve as a basis for scale-up and decentralization of the free ART initiative programme management and its implementation at different facility levels. They should serve to coordinate, harmonize and standardize the HIV/AIDS care, treatment and support programme. Programme implementation has to be integrated within and strengthen the existing health system, building capacity and sustainability of the health sector as the national ART programme is being scaled up.

The Ministry believes that these implementation guidelines will be useful in coordinating and harmonizing HIV-related activities in the country by maximally exploiting efforts of 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 guide for effective implementation the national ART programme at all levels.

The Ministry of Health expresses its appreciation to all individuals and institutions who have contributed to preparation of these guidelines.

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Acronyms and Abbreviations

AAU	Addis Ababa University
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
BCC	Behavioural Change Communication
BUN	Blood Urea Nitrogen
CBO	Community-Based Organization
CDC	Centres for Disease Control and Prevention
CHA	Community Health Agent
CRDA	Christian Relief and Development Agency
DACA	Drug Administration and 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 Immunodeficiency Virus
HMIS	Health Management Information System
IEC	Information, Education and Communication
I-TECH	International Training and Education Centre on HIV
LFT	Liver Function Test
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NGO	Non-Governmental Organization
OI	Opportunistic Infections
PEP	Post-Exposure Prophylaxis
PSCMS	PEPFAR Supply Chain Management System
PSLD	Pharmaceuticals Supply and Logistics Dept
PLWH	People Living With HIV
PLWHA	People Living With HIV/AIDS
PMTCT	Prevention of Mother-to-Child transmission
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
TOT	Training of Trainers
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

1. Introduction

Since first evidence of the HIV epidemic was detected in Ethiopia in 1984, AIDS has claimed the lives of millions and left behind an estimated 744,100 orphans. In 2005, an estimated 1.3 million persons were living with HIV. At that time, national HIV prevalence was 3.5%, with urban and rural prevalence of 10.5% and 1.9% respectively. There were an estimated 128,900 new HIV infections, and some 113,600 adults and 20,900 children had lost their lives to AIDS. Nationally, children comprised almost a quarter (23.5%) of new infections and 18.3% of annual AIDS deaths. In 2005, an estimated 277,800 persons, including 43,100 children, needed antiretroviral treatment (ART).

Ethiopia has significantly expanded its response to the epidemic since enactment of the National HIV/AIDS Policy in 1998. In 2001, the National HIV/AIDS Prevention and Control Council declared HIV a national emergency; this was followed by various interventions focusing on prevention, risk reduction, and behavioural change. In 2003, the Government of Ethiopia introduced its ART programme with the goal of reducing HIV-related morbidity and mortality, improving the quality of life of people living with HIV and mitigating some of the impact of the epidemic. In 2005, Ethiopia launched free ART; over 71,000 were initiated on ART by the end of November 2006 and some 241 hospitals and health centres are now providing HIV care and treatment services in all regions of the country.

Ethiopia is currently decentralizing HIV care and treatment services to selected health centres. Decentralization increases access by taking services closer to more people, reducing transport and related costs for patients and families, resulting in improved adherence and enrolment in care and treatment services early in the course of the disease. Decentralization follows the health network model, ensuring linkages between services at hospital, health centre and community levels. Large scale in-service trainings in various programme areas have been carried out to build capacity of different cadres of health care providers. Efforts have been made to demystify HIV care and ART by developing standardized and simplified clinical tools, reference materials, and job aids. Building the capacity of clinical nurses to prescribe first-line ARVs for stable patients and provide primary chronic HIV care including ART was pioneered in 2006. Ethiopia is also piloting the use of trained non-health professional counsellors. Such selected task-shifting from physicians/specialists to clinical nurses and use of trained non-health-professional counsellors will help free physicians and specialists to concentrate on complex cases and allow them to mentor nurses and others to assume more responsibilities in a systematic sustainable manner.

Based on scientific advances, lessons learned and sound ethical principles, these Implementation Guidelines set standards for the ART programme in Ethiopia. This document provides direction for programme managers and service providers at all levels, and supports the planning and implementation of a safe and effective ART programme. The guidelines promote public health approaches to ART and are based on national HIV/AIDS and drug supply policies, harmonized with ARV, PMTCT, STI, HCT, Infection Prevention, and other relevant guidelines. This document targets health care

providers primarily, community health workers, people living with HIV, and programme managers in public and private sectors and non-governmental organizations (NGO).

2. Guiding Principles

- Persons with HIV should be treated with respect, and with complete consideration for human rights, ethics, privacy and confidentiality, informed consent, autonomy and dignity

- Active involvement of people living with HIV will be ensured at all levels of programme management

- Compliance with national guidelines for the use of ARV drugs in Ethiopia and other treatment protocols based on international and national standards and best practices

- The programme will strive for equitable and universal access to ART

- The programme will be implemented as an integral part of comprehensive HIV care, including HCT, PMTCT, TB/HIV, STI prevention and treatment, palliative care including CHBC, HIV prevention, etc

- The programme should be coordinated and integrated into the health care system to ensure continuity of service delivery and a continuum of care

- Due emphasis will be given to strengthening the health care system

- Standards and monitoring and evaluation systems will established to ensure programme effectiveness and quality of services

- The programme will foster active public-private partnership and national and international networking

- Long term sustainability of the programme and its impact will be paramount,

3. Goals of the ART Programme

The goals of the ART programme are to reduce HIV related morbidity, mortality, and mitigate the impact of the AIDS epidemic. In order to achieve these, the programme will be planned and implemented as a safe, effective, efficient and equitable programme, as an integral part of comprehensive HIV prevention, treatment, care and support interventions, based on a chronic care model, in a way that will strengthen the health sector at all levels.

4. ART Programme Management and Coordination

The ART programme will be managed and coordinated at different levels: national, regional, zonal/woreda, health facility, and community.

The Federal Ministry of Health (FMOH) and regional health bureaus have responsibility to lead and ensure coordination of the Ethiopian ART programme at different levels, and to ensure it is integrated into the existing health care system.

4.1 National level

The FMOH is responsible for policy formulation, developing, updating and standardizing the national programme and clinical guidelines, preparing national plans including target setting, procurement and supply management, capacity-building, monitoring and evaluation, advocacy and operational research, and for overseeing overall national coordination of the ART programme. The MOH employs the following coordination mechanisms to achieve this.

4.1.1 Internal coordination

Within the FMOH, different institutions and departments play key roles in implementation of the ART programme. Coordination of these bodies is crucial for effective and efficient programme implementation and to optimize the quality of services.

At the federal level, a team of experts from relevant institutions and departments, under MOH leadership, will meet regularly to discuss and resolve issues arising from programme implementation.

This team will consist of representatives from the:

- Federal Ministry of Health (FMOH)
- Pharmaceutical Supply and Logistics Department (PSLD) of FMOH
- Federal HIV/AIDS Prevention and Control Office (FHAPCO)
- Ethiopian Drug Administration and Control Authority (DACA)
- Ethiopian Health and Nutrition Research Institute (EHNRI)

Team responsibilities:

- Recommends policy options and programme implementation strategies
- Sets national HIV programme targets
- Monitors HIV programmes performance against set targets
- Develops facility accreditation policy and guidelines
- Establishes standards of care for the ART programme, and ensures these are maintained
- Ensures development of standardized in-service training materials for service providers
- Tracks and ensures timely and uninterrupted availability of HIV supplies
- Compiles, updates, reviews, and disseminates national level HIV programme data

- Recommends, leads, and/or coordinates HIV-related national surveys and operational researches
- Mobilizes local and international resources necessary for the HIV/AIDS programme at national level
- Tracks and coordinates utilization of HIV/AIDS resources at national level
- Reviews the appropriateness of technology transfer and application
- Provides quality control and assurance in ART clinical, laboratory and pharmacy services

4.1.2 National HIV care and treatment advisory committee

At national level, the FMOH will be supported by the National HIV Care and Treatment Advisory Committee. Additionally, this forum will be used to facilitate programme coordination among the different partners of the MOH.

National HIV Care and Treatment Advisory Committee members:

- FHAPCO
- DACA
- EHNRI
- PSLD
- PHARMID
- PEPFAR Ethiopia
- WHO country office representative
- JHU-TSEHAI
- I-TECH Ethiopia
- ICAP Ethiopia
- Tulane University country office representative
- UCSD Ethiopia
- USAID Care and Support Contractor
- IntraHealth International, Inc. Ethiopia
- Family Health International
- JHPIEGO
- Clinton Foundation Ethiopia
- RPM+
- PSCMS
- National universities
- Defence and police health departments
- National network of associations of PLWHA
- The Ethiopian Private Physicians Association

The Advisory Committee will invite additional bilateral and non-governmental agencies when appropriate, and will support establishment of technical sub-committees, as deemed necessary.

Responsibilities of the Advisory Committee:

- Advise/support in the development and revision of the different national policies, guidelines and manuals on HIV/AIDS programmes
- Assist in establishment of standards for HIV prevention, care and treatment services including ART
- Participate actively in setting minimum criteria for expansion of the ART programme
- Assist in developing an accreditation policy and guidelines
- Support ART programme monitoring and evaluation
- Advise on resource mobilization
- Review the appropriateness of technology transfer and application
- Oversee the activities of national ART training and technical support networks

4.2 Regional level

In the decentralized health care system of Ethiopia, regions are the first level programme implementers; regional health bureaus have overall responsibility to lead, manage and coordinate ART programme implementation in the regions by:

- Demonstrating programme ownership
- Providing effective leadership
- Articulating the urgency to act and setting action priorities
- Defining the human resource requirement for effective programme management and coordination, and mobilizing resources to address this need
- Promoting and developing mechanisms for programme coordination at regional levels and beyond
- Ensuring linkages between different HIV services
- Harmonizing and utilizing efficiently available resources

Regional health bureaus should also facilitate an enabling environment for the smooth functioning of ART implementing partners in their respective regions. Besides the public sector, regions should promote involvement of the private sector, faith-based organisations, PLWHA associations, communities, and regional councils to support expansion of HIV prevention, care, treatment, and support services in the region. The regional health bureaus shall promote development of programme leadership and ownership at all levels of the health sector structure in their regions.

In executing such complex responsibilities, regional health bureaus are urged to establish HIV/AIDS committees to facilitate programme coordination:

Regional HIV/AIDS Committee Members:

- RHB (head or delegate, HIV team, regional lab, pharmacy, TB team)
- RHAPCO
- PLWHA Associations

- Implementing partners
- Local universities
- NGO representatives
- Representative of the private sector

The committee can invite additional partners/stakeholders when appropriate.

Responsibilities of the regional HIV/AIDS committees:

- Advocate for community involvement and sustained political commitment in support of the ART programme
- Work towards coordinating programme implementation in the region through information-sharing, joint programme planning, supervision and review, and collective programme learning
- Provide technical assistance to the regional health bureau in developing feasible implementation strategies
- Support site readiness assessment for ART facility accreditation
- Sensitize and mobilize members and leaders of community and faith-based organisations and NGOs
- Support adherence to national HIV prevention, care and treatment standards and protocols
- Recommend regional capacity building strategies for ART programme scale-up
- Assist with the regional health bureau response to facilities' and programme needs
- Communicate periodical regional plans, targets, reports, achievements, and issues
- Promote and plan for the integration of community mobilization education/preparedness campaigns with service expansion

4.3. Zonal level

The zonal health desk ensures implementation of HIV/AIDS programme by:

- Coordinating and facilitating overall programme implementation in the zone
- Facilitating linkages between zonal hospitals and health centres in the catchment area (health network model)
- Support the woreda health office in implementing HIV prevention, care and treatment services
- Assessing and selecting ART sites, filling identified gaps e.g. human resource related, in collaboration with the regional health bureau
- Undertake regular supportive supervision to sites for the smooth implementation of HIV programmes at facility level

The zonal health desk is urged to establish a zonal HIV/AIDS committee to facilitate and support execution of its responsibilities.

Zonal HIV/AIDS committee members/representatives:

- Zonal health office
- District hospital
- PLWHA associations
- NGOs and faith-based organizations
- Private sector

The committee can invite additional partners/stakeholders when appropriate.

Responsibilities of zonal HIV/AIDS committees:

- Support the zonal desk office in developing strategies for scale-up of HIV prevention, care and treatment services
- Provide technical assistance through joint programme planning, supportive supervision and review
- Facilitate functional coordination of network of health facilities in catchment areas
- Support and establish linkage with higher health facilities and regional health bureau
- Expedite two-way information flow
- Establish coordination between public-private partners, implementing NGOs and faith-based organisations
- Participate in social mobilization activities
- Support resource mobilization

4.4 Woreda level

Woredas provide training on home-based care, adherence support, social mobilization, and treatment literacy as part of their care and support mandate. Community awareness and capacity building are also conducted at woreda level.

The Woreda Health Office has responsibility to:

- Mobilize the woreda council, kebeles and communities in support of HIV prevention, treatment, care and support services, including ART
- Support ART activities at community level and encourage community mobilization among NGOs, community and faith-based organisations
- Respond to facility needs and report monitoring and evaluation data in a timely fashion

Woredas are urged to establish a woreda HIV/AIDS committee to facilitate support and coordination in execution of the stated tasks.

Woreda HIV/AIDS committee members:

- Woreda health officer
- Health centre representative
- PLWHA associations representatives

- Representatives of NGOs and faith-based organisation operating in the woreda
- Representatives of the private sector

The committee can invite additional partners/stakeholders when appropriate.

Responsibilities of the woreda HIV/AIDS committee:

- Advocate for continued support for HIV/AIDS programmes
- Support community level interventions
- Support HIV prevention, treatment, care and support activities in the woreda
- Organise different events and campaigns to promote service uptake
- Advise the woreda health office how best to ensure access to HIV prevention, treatment, care and support services

4.5 Kebele and community levels

The ART programme should use existing structures as much as possible to reach the community. Moreover, HIV prevention, care and support activities are already taking place at these levels, and can facilitate the integration of ART. Kebeles are a link between the health posts and health centres and between the community and households. The main role of the community is in promoting HIV prevention, care and support, including efforts to reduce stigma and to improve treatment adherence. Through the kebele HIV/AIDS committee, kebeles refer patients to health posts/centres, community-based organizations/NGOs, and support volunteers who conduct home visits. Most voluntary NGOs operate at kebele and woreda levels, and also provide various HIV prevention, care and support activities. The NGO-led home-based care initiatives should be coordinated with the existing government structure, avoiding creation of parallel systems and duplication of efforts. The kebele HIV/AIDS committees are expected to support such efforts.

Kebele HIV/AIDS committee members:

- Kebele representative
- PLWHA associations representative
- Representatives of community-based organisations
- Health extension workers
- Representative of faith-based organizations
- Religious and traditional leaders
- Community leaders

The committee can invite additional partners/stakeholders when appropriate.

Responsibilities of the kebele HIV/AIDS committee:

- Build capacity for care and support at community level

- Provide training on Information, Education, and Behavioural Change Communication (IE/BCC)
- Promote counselling on adherence, risk reduction, and disclosure
- Promote care and support, particularly to vulnerable groups such as orphans, widows, and chronically ill persons
- Promote and support home visits
- Make referrals and linkages with facilities
- Promote community resource mobilization

Key Community Stakeholders

These include:

- People living with HIV groups and associations of which they may be members
- Families and friends of people living with HIV
- NGOs, community and faith-based organisations 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 strengthened to support implementation and scale-up of HIV prevention, treatment, care and support, including ART, in Ethiopia. Successful ART programme implementation requires increased community awareness and support, which can be generated through effective social mobilization, through well-informed mass and mini media and other locally appropriate channels.

Role of the Community:
Community involvement in HIV prevention, treatment, care and support, including ART, will be incorporated within the health extension package and include:

Advocacy: This entails mobilizing political and socio-economic support for scale-up of HIV prevention, treatment, care and support services, including ART. Public advocacy should also target reduction of HIV-related stigma and discrimination, and mobilize community and local resources.

Service provision: This will include prevention, care and support as well as adherence, psychosocial and spiritual, nutritional and home support for people living with and/or affected by HIV/AIDS.

In particular, the kebele, with support of health extension workers, NGOs and community -based organisations, and associations of people living with HIV should:

Identify and utilize existing community capacity to provide:

- Outreach community services to vulnerable populations
- HIV counselling
- Prevention education, including safer sex practices, distribution of condoms, treatment-seeking behaviour during an episode of sexually transmitted infection
- Adherence counselling
- Palliative care including psychosocial, spiritual, and nutritional support
- Home visits
- Referral to health facility
- Linkage and referrals to community-based organizations, and support groups

5. ART Service Delivery

5.1 General

The routine provision of HIV care/ART services rests on health facilities. As part of chronic HIV care/ART, care providers have responsibility for adherence preparation and support, to provide psychosocial support, and ensure the integration of HIV prevention into routine clinical services. Facilities also have responsibility for patient monitoring, data generation, analysis, and reporting to the zonal health departments/woreda health offices or regional health bureaus. Facility-based and community level services will be linked to ensure effectiveness of ART programme implementation.

5.2 Facility level

At facility level, a client opts to test for HIV and enrols in chronic HIV care through different entry points such as PMTCT, TB clinics, out or inpatient departments, STI services, etc.
Therefore, besides direct service delivery, a facility is responsible to:

- Coordinate different HIV-related services at the facility so patients will not experience difficulty accessing them or endure long waits
- Strengthen referral linkages among different services
- Expand and strengthen entry points for HIV care/ART in the facility
- Ensure appropriate health workers are trained to provide HIV services, and that trained persons are stationed to appropriate posts
- Ensure uninterrupted supply of key commodities (ARVs, opportunistic infection drugs, laboratory reagents and test kits, etc) through proper stock management and timely ordering
- Facilitate task-shifting and distribution among providers in the facility in order to reduce the burden of care on a few staff
- Undertake regular performance review to ensure smooth implementation of different HIV services and quality of care

Facilities are urged to establish HIV/AIDS committees in order to support the tasks stated below.

A. Hospital HIV/AIDS team members:

- Medical director (leads the committee)
- Hospital administrator
- Matron
- ART focal person
- ART nurse
- TB focal person
- PMTCT focal person
- Pharmacy head
- HCT focal person
- Laboratory head
- Data clerk (both HIV care/ART clinic and pharmacy)

Responsibilities of the hospital HIV/AIDS team are to:

- Participate in assessment and preparation of the facility for accreditation
- Provide facility leadership and ownership of the programme
- Assure that service provision complies with national guidelines and treatment protocols
- Conduct facility review meetings, and promptly resolve problems as they occur
- Ensure regular communication on facility stock levels of key supplies, consumption and stock status
- Ensure service delivery is consistent with national standard operating procedures
- Support catchment health centres, especially for ART
- Establish and/or strengthen two-way referrals between health centres and community-based services
- Plan and coordinate on and off-site trainings of service providers
- Assure integration of HIV prevention, care, and treatment services including ART with other routine services provided in the facility
- Ensure quality of facility patient monitoring data, use of available data, and timely submission of reports
- Periodically review selected patient monitoring data to enhance quality of services, ensure referral linkages between different services, etc
- Promote team work at facility level
- Ensure the right people participate in ART trainings and trained personnel are posted to suitable posts
- Ensure continuous learning of providers by facilitating and creating an enabling environment for facility through peer mentoring, regular case conferences, chart and death reviews, periodical meetings, etc
- Assure relevant staff participates in HIV prevention, care and treatment including ART services

B. Health Centre HIV/AIDS team members:

- Head of the health centre
- Health centre administrator
- Physician where available
- Nurses (HIV care/ART, TB clinic, pMTCT, etc)
- Laboratory personnel
- Pharmacy personnel
- Counsellors
- Data clerks

Responsibilities:

- Participate in assessment and preparation of the facility for accreditation
- Provide facility leadership and ownership of the programme
- Ensure service provision is in line with national guidelines and treatment protocols
- Conduct facility review meetings, and promptly resolve emergent problems Ensure regular communication on facility stock levels of key supplies, consumption and stock status
- Ensure service delivery is consistent with national standard operating procedures
- Coordinate HIV prevention, testing, care and treatment services including ART, provided in the facility
- Conduct regular facility service reviews
- Promote uninterrupted supply of key supplies (ARV and opportunistic infection drugs, laboratory reagents, test kits, etc) through proper stock management and timely procurement requests
- Take part in building capacity of the facility to provide HIV services including ART
- Monitor and provide comprehensive support to providers
- Provide support to woreda/kifle ketema and kebeles, particularly in social mobilization in response to the HIV epidemic
- Ensure the right people participate in ART trainings and trained personnel are posted to suitable posts
- Establish and/or strengthen two way referrals between hospitals, health posts, and community-based services
- Build capacity of health posts and communities to carry out suitable HIV prevention, care, treatment, and support services

C. Health post level:

- Promote community level care and support
- Provide TOT on IE/BCC
- Provide counselling on adherence, risk reduction, and disclosure
- Participate and support home visits
- Establish linkage between health centres and community based services
- Assist in establishing the community care monitoring system

- Assist in analyzing and reporting community care data

5.3 The private sector

Associations of professionals and of private health care providers, and others play a major role in HIV care provision, community mobilization, care and support at various levels. Free ART is currently extended to private sector facilities, both for-profit and non-profit. The MOH and regional health bureaus will continue to support expansion of HIV prevention, care and treatment services to the private sector.

The private sector also contributes significantly in drug importation and manufacturing, therefore collaboration with this sector needs to be strengthened and maintained; and best practices adopted for further expansion of HIV services. Members of the private sector are encouraged to participate in HIV/AIDS committees at each programme coordination and management level.

The role of the private sector includes: provision of comprehensive HIV prevention, care, and treatment, including ART, HIV counselling and testing, preparing sites for accreditation, monitoring and evaluating care, submitting periodical reports to regional health bureaus, harmonizing data collection and reporting with the national system tool, and providing training on HIV care, based on national protocols and guidelines.

6. ART Training

In-service training is an essential element that needs to be strengthened and highly coordinated. The main purpose of in-service training is to build capacity of care providers and programme managers to provide a continuum of HIV Care (HCT, ART, prevention and treatment of STIs, OIs, and TB, PMTCT, family planning, palliative care, nutritional support, and other services) at different levels. The FMOH is responsible to ensure standardization of in-service training materials, to define core course content, training methodologies and arrange the training of regional master trainers. National level training will be focusing on TOTs, while the bulk of basic training will be regionalized and, to the extent possible, be on-the-job. Regional health bureaus, in collaboration with regional universities, will lead in-service training of different cadres of health service providers in the region, based on nationally standardized training materials. Regional health bureaus should ensure that training activities are planned, targeted, needs-based, and coordinated in order to systematically build regional capacity.

The following outlines the responsibilities of FMOH and regional health bureaus concerning ART in-service trainings:

National level:

Train national and regional HIV/AIDS teams of trainers (training of trainers)

- Support regional HIV/AIDS training teams

- Develop strategies and frameworks for continued education, pre-service training, and continuous learning
- Work with health care training institutions to upgrade HIV and ART curricula
- Develop standardized training materials at national level
- Develop certification programmes
- Assist in regularly updating national clinical and ART guidelines
- Mobilize sufficient resources for training at national level
- Monitor and evaluate performance of the national HIV/AIDS training and give technical support

Regional level:

- Identify regional level HIV-related training needs, in partnership with implementing partners
- Ensure the roll-out of in-service training in the region
- Identify participants of regional master trainings in collaboration with regional implementing partners
- Plan and coordinate trainings at regional level
- Identify cadres of trainees at programme management and service delivery levels
- Ensure right persons are trained, and are placed in the right posts
- Ensure nationally standardized training materials and approaches are used
- When relevant, lead translation of training materials to the local language
- Keep track of HIV-related trainings accomplished in the region

HIV care/ART should be integrated into pre-service trainings, which is more cost-effective, sustainable and ensures routine service provision. The FMOH in collaboration with relevant partners will work towards this end.

7. ART Programme Requirements

Successful implementation of the ART programme, based on a public health approach, requires well-defined and standardized arrangements, processes, service delivery, and monitoring. This entails:

- Adhering to national ART policies, guidelines and protocols
- Using clinical tools and monitoring
- Defining minimum requirements for facility accreditation
- Developing and enforcing standard operating procedures
- Standardizing training curricula and materials
- Developing and applying a standardized health management information system

7.1 Policies and guidelines

These ART implementation guidelines, which address the public health approach to ART, are guided by the national HIV/AIDS policy on supply and use of ARV drugs. Guidelines for use of ARVs, PMTCT, OIs, STIs, HCT and infection prevention serve to standardize the national approach to ART programme planning and implementation.

7.2 Protocols

HIV clinical care is standardized with the help of protocols, especially when care is dependent on a multidisciplinary team and is decentralized to peripheral health units with limited staffing. Protocols are also instrumental in delegation of care to the appropriate level, and in guiding smooth task-shifting between members of the clinical team. Protocols cover wide ranges of clinical activities: intake processes-including patient identification, diagnostic steps, treatments, and follow-up and referral systems.

7.3 Clinical tools

The skill, competence and capacity of health care providers are directly proportional to the degree to which 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. Simplified and standardized checklists will be used for clinical documentations to obviate writing.

7.4 Clinical monitoring

Programme adequacy, service access, treatment outcomes, clinical process monitoring and reporting are expected of each facility providing ART. Ethiopia has one system of routine patient monitoring,. The referral system includes:

- A two-way system between clinical service sites (hospitals, health centres and posts), community, and home-based care and support programmes
- Standardized referral/transfer forms
- A patient will be automatically given a unique ART number at the health facility, where they are initiated on ART. Patients should maintain the same unique number, even after referral or transfer out

7.5 Facility accreditation for ART

Facilities are required to be accredited before starting to provide ART services. Accreditation is often designed to stimulate continuous improvement in quality of services, and signifies the systematic assessment of an entire facility, against an explicit set of standards. In accreditation, a multidisciplinary team of professionals evaluate compliance of a facility at least to the minimum set of criteria to deliver ART service (Tables 1, 2 and 3). Accreditation should be perceived as a process where there is assessment, supervision, monitoring and support to improve the quality of services continuously. A similar process may continue after a facility is accredited to provide ART.

7.5.1 Roles and responsibilities in facility accreditation for ART

Regional health bureaus carry overall responsibility in accreditation of facilities for ART provision. The FMOH is responsible to develop national implementation guidelines, facility assessment checklists, to define standards for accreditation, and develop Standard Operations Procedures (SOP) for service delivery. The regional health bureaus shall ensure the involvement of professionals with a multi-disciplinary background; notably

clinical, pharmacy and laboratory services, in the pre-accreditation assessment process. The accreditation decision will be based on nationally set standards, assessment tools and checklists. Once a facility is accredited to provide ART services, regular supportive supervision and reviews will be made in order to further enhance quality of services. The regional health bureaus, together with FMOH, EHNRI, FHAPCO, PSLD DACA and in collaboration with partners, should carry-out post-accreditation monitoring in order to ensure service quality. The FMOH and regional health bureaus, in collaboration with partners, will support a high quality of services through supportive supervisory visits, operational researches, periodical facility surveys, clinical mentoring, routine monitoring, and facilitation of site level support. Similar accreditation standards and processes will be followed for private health facilities, except they will not be required to have the pharmacy and laboratory components on site.

Once a facility is accredited to provide ART, and the minimum criteria are met, regional health bureaus and partners providing site level assistance should plan and work collaboratively. Additionally, corrective action needs to be taken promptly if a setback occurs. For instance, the facility and regional health bureau should ensure the appropriate cadres and individuals are trained, that trained individuals are assigned to appropriate positions, and that staff reorganisation (intra or inter-facility) is done when needed.

The following tables identify the minimum clinical, pharmacy and laboratory criteria for facility accreditation to provide ART.

TABLE 1: Clinical Service Minimum Package by level of facility

<table>
<tr><th></th><th>Special/Referral Hospital</th><th>Regional/Zonal Hospital</th><th>District Hospital</th><th>Health Centre</th></tr>
<tr><td>Infrastructure</td><td colspan="4">Examination room
One private counselling room</td></tr>
<tr><td>Equipment and supplies</td><td colspan="4">Exam Tools and supplies (otoscope, stethoscope, blood pressure cuff, reflex hammer)
Supplies (infection prevention materials, tongue blade)</td></tr>
<tr><td>Human Resources</td><td colspan="3">1 MD trained on ART for special/referral hospital and
1 health officer for regional and district hospitals
2 ART trained nurses
1 data clerk</td><td>1 ART trained health officer and 1 ART trained nurse, or
2 post-basic ART trained nurses
1 data clerk</td></tr>
<tr><td>M&E/MIS</td><td colspan="4">Log book
Recording/reporting forms
Special ART prescription</td></tr>
<tr><td>Services</td><td colspan="4">Comprehensive HIV services
(VCT, PITC, pMTCT, TB, STI and OI Services, palliative care)</td></tr>
<tr><td>Referral Systems</td><td colspan="3">Referral slip, feedback forms</td><td>Referral slip and feedback forms</td></tr>
</table>

TABLE 2: Pharmacy Service Minimum Package by level of facility

<table>
<tr><th></th><th>Special/Referral Hospital</th><th>Regional/Zonal Hospital</th><th>District Hospital</th><th>Health Centre</th></tr>
<tr><td>Infrastructure</td><td colspan="4">On-site pharmacy
Secure storage space
Private counselling room or space</td></tr>
<tr><td>Equipment & Supplies</td><td colspan="4">Refrigerator</td></tr>
<tr><td>Human Resources</td><td colspan="3">2 ART trained pharmacy personnel</td><td>1 ART trained pharmacy personnel</td></tr>
<tr><td>M&E/MIS</td><td colspan="4">Drug supply and management system (bin card, stock card, receiving voucher, models, prescription forms, registration book, report forms)
Lockable drawer</td></tr>
</table>

TABLE 3: Laboratory Service Minimum Package by level of facility

	Special/Referral Hospital	**Regional/ Zonal Hospital**	**District Hospital**	**Health Centre**
Infrastructure	Specimen collection area and 1 additional room		Specimen collection area and laboratory	Laboratory
Onsite or networked laboratory services	All tests done at District Hospital **Plus** CD4 Count		All tests done at Health Centre **Plus** Clinical Chemistry (BUN, Creatinine, LFT, Indian ink)	Full blood count (Hb, WBC and Diff.) AFB smear Gram smear Ova & Parasite Malaria smear Pregnancy test Serology for HIV RPR / VDRL
Equipment & Supplies	Equipments & Supplies included under District Hospital **Plus** CD4 Count Machine		Equipments and supplies included under Health Centre **Plus** Haematology auto-analyzer Clinical chemistry auto-analyzer	Sterilizing equipment Microscope Refrigerator Centrifuge Test Kits IP supplies Reagents
Human Resources	2 trained laboratory personnel		2 trained laboratory personnel	1 trained laboratory personnel[1]
M&E/MIS	Log book Recording/reporting forms			

7.6 Integration and coordination of different levels of care

The Ethiopian health care system is organized around regional/referral hospitals, district hospitals, health centres, health posts and community health services. Coordinating the different levels of this system is important in order to ensure smooth flow of patients and appropriate access to laboratory services, drugs and other supplies. A network approach for health care delivery should strengthen linkages between the different levels of services in order to ensure comprehensive care.

[1] A second lab technician should be trained at the same time.

7.7 Standard operations procedures (SOPs) for ART services

There must be Standard Operations Procedures (SOPs) on clinical processes and procedures, laboratory services, and pharmacy practices. The FMOH will lead development of the different SOPs in collaboration with its partners, practitioners and the programme management team. Clinicians, laboratory and pharmacy supervisors must ensure adequate supplies for patients, and health provider safety in their respective practice areas. The supplies will be identified in the SOPs.

7.8 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. Efforts are currently underway to integrate training into pre-service education, as it has proven more cost-effective, does not compete with time of service providers, maximizes task-shifting and sharing of responsibilities among providers, and in addition increases the pool of trained providers. Training a large number of health care providers will also assist rapid scale-up of HIV services and their integration into routine health services eventually.

Trainings, materials and curricula must:

- Reflect the comprehensive nature of the ART programme
- Be discipline-tailored (physicians, nurses, pharmacists, laboratory technicians, data managers and clerks, adherence counsellors/patient educators, and programme managers)
- Be standardized (core national training content and duration per discipline)
- Be coordinated and decentralized to regions
- Conducted collaboratively with regional health bureaus and health facilities
- Certification is automatic when the national content and trainers' credentials are satisfied

Training needs and responsibilities at the various levels are:

- **Community level**: People living with HIV, CHA, TBA, community and faith-based organisations and NGOs, should be trained in adherence, supportive counselling, treatment literacy and preparedness
- **Health post level**: Health extension workers will be equipped to lead, plan, implement, coordinate and monitor community level HIV prevention, treatment, and care and support interventions
- **Health centre level**: A team of care providers (physicians/health officers, nurses, pharmacy and laboratory personnel) should be trained to provide comprehensive primary HIV care. Clinicians (physicians, health officers, and nurses where available) should be trained to provide HIV care including ART in stable patients as defined in the national SOP for HIV care/ART services. As ART is decentralized to selected health centres, the capacity of nurses will be upgraded to prescribe first-line antiretroviral medications, provide primary chronic HIV care, and to recognize when to refer a patient, through post-basic HIV care/ART trainings and clinical mentoring. National clinical mentoring guidelines will be developed to direct and monitor clinical mentoring.

- **Hospital level**: A team of care providers (physicians, health officers, nurses, pharmacy and laboratory personnel) should be trained to provide comprehensive HIV care. Physicians will be trained to prescribe first and second-line antiretroviral drugs and provide comprehensive primary care . The capacity of nurses will be upgraded to prescribe first-line antiretroviral drugs, provide primary chronic HIV care, and to recognize when to consult through post-basic HIV care/ART trainings and clinical mentoring. National clinical mentoring guidelines will be developed to direct and monitor clinical mentoring.
- **Regional, zonal and woreda levels**: Programme managers and coordinators at different levels will be capacitated to lead, manage, and coordinate the ART programme. Such trainings will be comprehensive HIV/AIDS programme management, including monitoring and evaluation.
- **National level**: The FMOH, FHAPCO, EHNRI, and DACA, in collaboration with partners, will coordinate and assure standardized content and delivery of HIV prevention, care and treatment including ART trainings. Programme managers at national level will also be trained in HIV/AIDS programme management.

7.9 Monitoring and evaluation

7.9.1 HIV care/ART management information system

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 programme implementation, access to patient care and treatment outcome, as well as logistical capacity and performance. Regions must assure that reporting materials, tools and systems follow national standards in support of this system.

7.9.2 Programme review

Regular review meetings assist timely learning, experience-sharing, and monitor performance and achievements. These should be organized at different programme management levels to:

- Review and track status of key programme inputs (human resources, drugs, laboratory supplies etc)
- Track resource and fund utilization
- Monitor performance and achievements
- Identify emerging issues and propose recommendations

Such regular meetings will facilitate learning among regional programmes, facilitate national coordination, and will also be used to discuss issues and forward recommendations, to facilitate timely learning and problem solving.

7.9.3 Supportive supervision

Regular supportive supervision is critical to direct and support staff to enable them to perform their duties effectively. With decentralization of service provision, the need for supervision becomes more critical. Supportive supervision includes observation, discussion, onsite problem identification, support, guidance and problem solving; and is an important tool in programme management, ensuring quality of services and timely corrective actions. Supervision of HIV prevention, care and treatment services will be integrated as functions of federal, regional, zonal and woreda health sector offices.

7.10 Drugs and supply management

- **Selection of ARV Drugs and Related Supplies**[2]

  The National List of Drugs for Ethiopia describes the antiretroviral drugs and related supplies for use in Ethiopia. This list will be updated as required. Forms containing information about strength and dosage of individual drugs will also be made available.

- **Procurement of ARVs and Related Supplies**

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

  Procurement of ARVs will be done according to national and international regulations and 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, ARV procurement should be limited to suppliers which meet the World Health Organization standards. Procurement will be based on national aggregated consumption and forecasting of ARV drugs needs.

- **Distribution of ARVs and Related Supplies**

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

[2] Drugs for Opportunistic Infections & Sexually Transmitted Infections, and Infection Prevention and control supplies

Proper storage of ARVs, including refrigeration, is critical to maintain the quality of the drugs 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 drug use, increasing the risk of drug resistance. Therefore security in the supply chain must be assured at all levels.

ART implementing organizations (governmental and non-governmental, and the private sector) can contract the services of pharmaceutical businesses for specific tasks such as procurement, clearance, storage, distribution, and delivery. Concurrently, efforts will be undertaken to strengthen the logistical capacity of the public sector health system. Existing mechanisms of the drug and supply management system will 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, antiretroviral drugs should only be dispensed after proper adherence counselling in a private and confidential setting has taken place. In addition, patient and public education to enhance drug adherence, proper handling and storage at home and to avoid 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. The national laboratory must have the capacity to assure the quality of ARV drugs. Quality assurance of drugs and supplies will be maintained using simple visual methods: a First-In-First-Out (FIFO) system will be used to avoid expiration and ensure fresh supplies at all levels.

7.11 Sustainability

Ethiopia launched free antiretroviral treatment in January 2005; therefore long-term programme sustainability is a legitimate concern for the country. A successful ART implementation plan should be cost-conscious and attempt to address programme sustainability.

7.11.1 Resource mobilization

Different mechanisms will be employed to mobilize local and international resources for HIV care including ART services. Some of these will:

- Establish workplace AIDS funds
- Advocate for employer-assisted workplace initiatives
- Encourage workplace ART, PMTCT and PEP initiatives
- Establish tax levies and provide tax exemption
- Approach local groups and persons in the Diaspora for support
- Utilize generic ARV drugs where applicable
- Mobilize international support
- Access international initiatives
- Promote public-private partnerships
- Mobilize community level resources

7.11.2 Cost-saving strategies

- Realization of national ART implementation plan
- Harmonization and enforcement of standardized national guidelines in diagnosis and treatment
- Integration of services, activities and programmes
- Promotion of local production of ARV drugs
- 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
- Exploitation of networks and partnerships within and outside the service
- Promotion of community/family participation and awareness in cost-effective care

8. Approaches to Implementing the ART Programme

In order to provide ART services, several important steps must be followed:

- Assess site/facility readiness for ART
- Identify and make recommendations to bridge gaps
- Provide resources and build capacity to fill identified gaps
- Accredit the facility to provide ART services
- Initiate ART service
- Perform follow-up supportive supervision, monitoring and evaluation
- Provide support; and
- Collect monitoring data for ART programme and ensure findings are used to improve quality of services continuously
- Perform periodical evaluation of the ART programme and improve quality of care accordingly

Capacity building and infrastructure improvement are major priorities. Other basic health care services including testing and counselling, psychosocial support, positive prevention, diagnosis and treatment of common HIV-related illnesses will be strengthened. Referral systems for higher level care must be established; support and provider groups (other than facility-based health workers), including PLWH, must be recruited and involved; existing

health care providers must be trained adequately, allowing expansion of services and maintenance of service quality.

9. ART Rollout

Rollout of the ART programme in Ethiopia employed a phased approach. In the initial phase the focus was to prepare sites already providing fee-based ART services to meet the accreditation criteria by correcting identified gaps. In the second phase, treatment rolled out to public and private hospitals and selected health centres following a similar process: facilities were assessed and supported to meet the minimum accreditation criteria before they were allowed to prescribe. In the third phase, there will be consolidation of ART services at hospital level, while at the same time ART programme management will be further decentralized to selected health centres and corresponding programme management structures. The details of the ART programme rollout plan will be articulated in detail in national and regional plans.

10. Planning for ART Service Delivery

10.1 Programme management level

- Develop plans for the expansion of ART services in the region
- Lead the selection and assessment of facilities to provide ART
- Coordinate the preparation of facilities for accreditation
- Develop individual implementation plans to meet the minimum facility accreditation criteria
- Coordinate and support implementation of the plans
- Map resources to optimise their allocation and use

10.2 Facility level

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

Competent and proactive leaders
A plan for what services are to be provided and how to deliver them
Infrastructure that matches the plan
Adequate number of trained staff
Systems to facilitate and support care
Monitoring systems

10.2.1 Leadership

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

- Have capacity at the facility to deliver comprehensive HIV care including ART

- Identify a practice model that matches capacity
- The care model is that of chronic illnesses
- The presence of trained staff willing to support comprehensive HIV care
- The leadership has or plans to invest in staff recruitment and retention to meet the minimum necessary staff requirements
- Access to this comprehensive HIV care is equitable, taking women and children into full consideration
- ART resource allocation is patient care centred

10.2.2 HIV care models

A. Family-centred care model:

HIV is rarely an illness of an individual alone; in most cases, multiple family members are involved due to the route of transmission. Therefore when one person is diagnosed with HIV, it should be seen as an opportunity for a partner, children, or siblings to access care. Clients should be informed of the possibility of other family members already being infected with HIV, encouraged to disclose their status to family members and to bring them for testing.

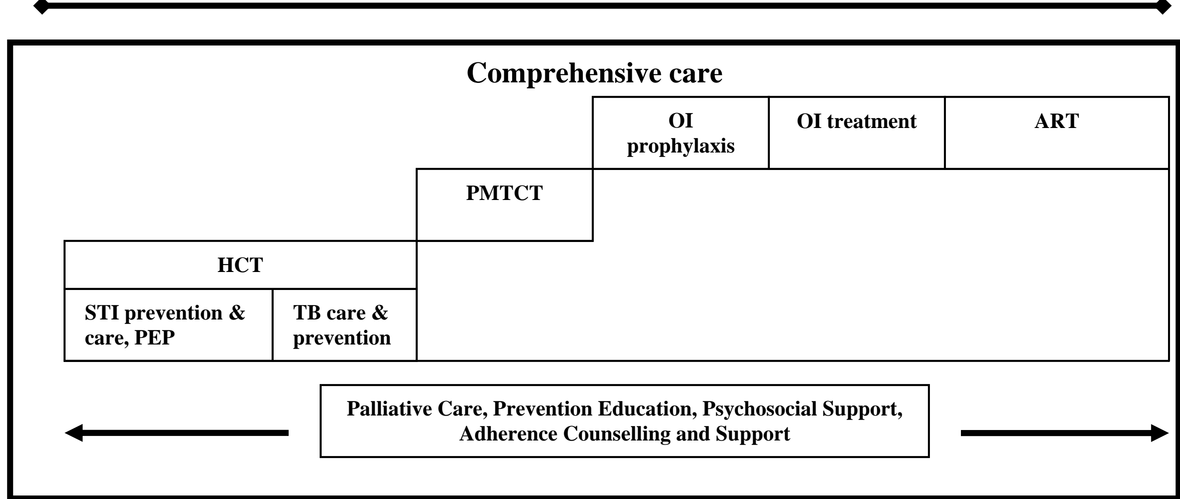
HIV care/ART services should also be organized to address needs of the family as a unit, though central to any decisions are the needs of the individual; providers should:

- Care for the whole family as far as possible, e.g. mother, father, children cared for by one clinical team
- Schedule follow-up appointments for the family or couples as units
- Consider transferring out the family as a unit to another health facility if/when relevant
- Use same ARV drug regimens for family members when possible
- Organize family/group education and adherence counselling

B. The continuum of care model:

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

Figure 2: The Continuum Care Model



HIV is not yet curable, and the advent of antiretroviral treatment has created a growing recognition that it is a chronic health condition. As in most chronic illnesses, adherence to treatment regimens and self-care by the patient is crucial. HIV infection bears persistent stigma, making it hard to handle openly. Adherence to ARV regimens are often complex due to multiple factors. Therefore linkages to community support, routine patient education, and planned care are extremely important.

10.2.3 HIV care/ART patient flow

The following are points of entry for ART services:

- VCT
- TB clinic
- STI clinic
- MCH/pMTCT services
- Private providers
- Self referred
- Outpatient clinics
- Inpatient services
- Prisons, orphanages and other closed settings
- 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 can delegate roles that can be safely and legally handled by an adequately trained nurse and/or a pharmacist. It is highly advisable that patients are *not* started on ART on the first clinic visit. Patient flow at a facility varies depending on the facility type (e.g. health centre versus hospital), number of patients and available human resources. The detailed guide should be incorporated in the SOP for HIV care/ART services.

10.2.4 Staffing needs

Facility leaders, supported by regional health bureaus, must staff their respective sites commensurate to the facility level of care. Staffing levels must be determined by the clinical workload. A multidisciplinary team approach to ART is recommended for the sake of efficiency, but more importantly, for better adherence and treatment outcomes.

10.2.5 Clinical services

Facilities must review their respective patient flows in order to identify gaps before ART scale-up is attempted. Provision of ART services must be part of continued comprehensive HIV services; in isolation ART is not effective. Patient intake processes and referrals as well as care systems must be reviewed, improved and expanded in order to allow comprehensive care. Programmes and different services must be linked and integrated to reduce patient waiting times, and to assure follow-up and a continuum of care. The role of community must be recognized and community members mobilized to support continuity and home-based care, reduce HIV- related stigma, and encourage HIV testing. Community peers, PLWH associations, faith and traditional leaders, clubs all serve different purposes in provision of care, support, stigma reduction, and reinforcement of adherence.

10.2.6 Laboratory services

Accurate patient care monitoring is dependent on competent laboratory 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, recorded and visibly mounted. There must also be internal and external controls as part of laboratory quality control. Referral linkages between district hospitals and regional referral laboratories will ensure this. In turn, the referral laboratories must be linked with the national lab. Each laboratory should closely follow the national standard operating procedures.

10.2.7 Pharmacy services

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

10.2.8 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 among care providers on patient flow tract. This system is the foundation, not only for patient care but also for monitoring, evaluation, and patient referrals.

11. Information Management and Communications

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

- A complex and fairly new treatment programme is being scaled up rapidly
- Treatment has to be lifelong and requires a high rate of adherence, allowing no room for supply interruption
- The programme requires specific skills and resources in a resource-limited setting

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

Communication within and outside the programme will:

- Create awareness about ART
- Clarify the roles of various stakeholders in ART implementation
- Enable experience sharing and adaptation of best practices
- Facilitate coordination and integration
- Standardize delivery of ART across the nation
- Disseminate standard treatment protocols, procedures and guidelines
- Distribute monitoring and evaluation findings to participants

Maximum effort should be exerted to establish two way communications, to ensure the programme meets the people's needs and at the same time to disseminate information on the continuum of care, including prevention and ART, to a much wider audience.

12. Strategic Information

This section is an expanded version of the traditional monitoring and evaluation and includes surveillance, operational research and health management information systems, all critical in the planning and follow-up of programme implementation. Planned and systematic data gathering, analysis and interpretation are essential for:

- Monitoring clinical care
- Tracking patient treatment outcomes

- Ensuring logistical appropriateness
- Ensuring programme cost-effectiveness
- Measuring and improving performance

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

• Clinical monitoring:

Demographics
Patient monitoring (laboratory data)
Clinical status and progress
Weight gain
Functional score
Occurrence of opportunistic infections
Rate of hospitalization
Adverse drug reactions
Ratio of first to second- line regimens
Trends in CD4
ARV selection and changes
Adherence
Drug resistance monitoring
Mortality

• Supplies and commodities:

Tracking storage, expiry dates
Tracking stock-outs of drugs and supplies
Performance of distribution system

• Human resources:

Staffing levels
Skills
Gaps and plans to meet them
Recruitment and retention
Incentives and investment to minimize turnover

Management of strategic information will require at minimum :

• Trained staff:

To collect, enter and analyze data

• Standardized tools:

Paper-based and/or electronic system
Standardized clinical records
ART unique numbers
Hospital patient card numbers
Standardized data collection forms

• Confidentiality:

Health care confidentiality must be assured
Confidentiality of data gathered for monitoring and evaluation purposes must be legally protected

• Operational research:

At a minimum operational research will examine the following critical areas:

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 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-centred 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 they are captured as part of clinicians' routine clinical documentation.

The process of data management involves:

- Clinical documentation by physicians, nurses, counsellors, and pharmacists
- Data entry and report compilation by data clerk
- Aggregation
- Data analysis
- Reporting by programme coordinator (paper and/or electronic based)

Information will be collected at all HIV care/ART sites:

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

Data collected locally should be aggregated on time, analyzed and interpreted for well-timed intervention and action plans at all levels, and distributed to stakeholders on a need-to-know basis in order to protect confidentiality.

Reports required by different organizations will be passed up the national monitoring reporting channels. Monitoring and evaluation data, analyzed or raw, must be utilized and reported to the section responsible for corrective action. The principles of continuous quality improvement dictate that monitoring and evaluation data is not used for punitive action nor be accessible for anything else, including the courts, other than performance and quality of care improvement.

Facilities will report on selected indicators to regional health bureaus where the report is aggregated for the region. The regional health bureaus will report to MOH and HAPCO, the aggregated data of the region.

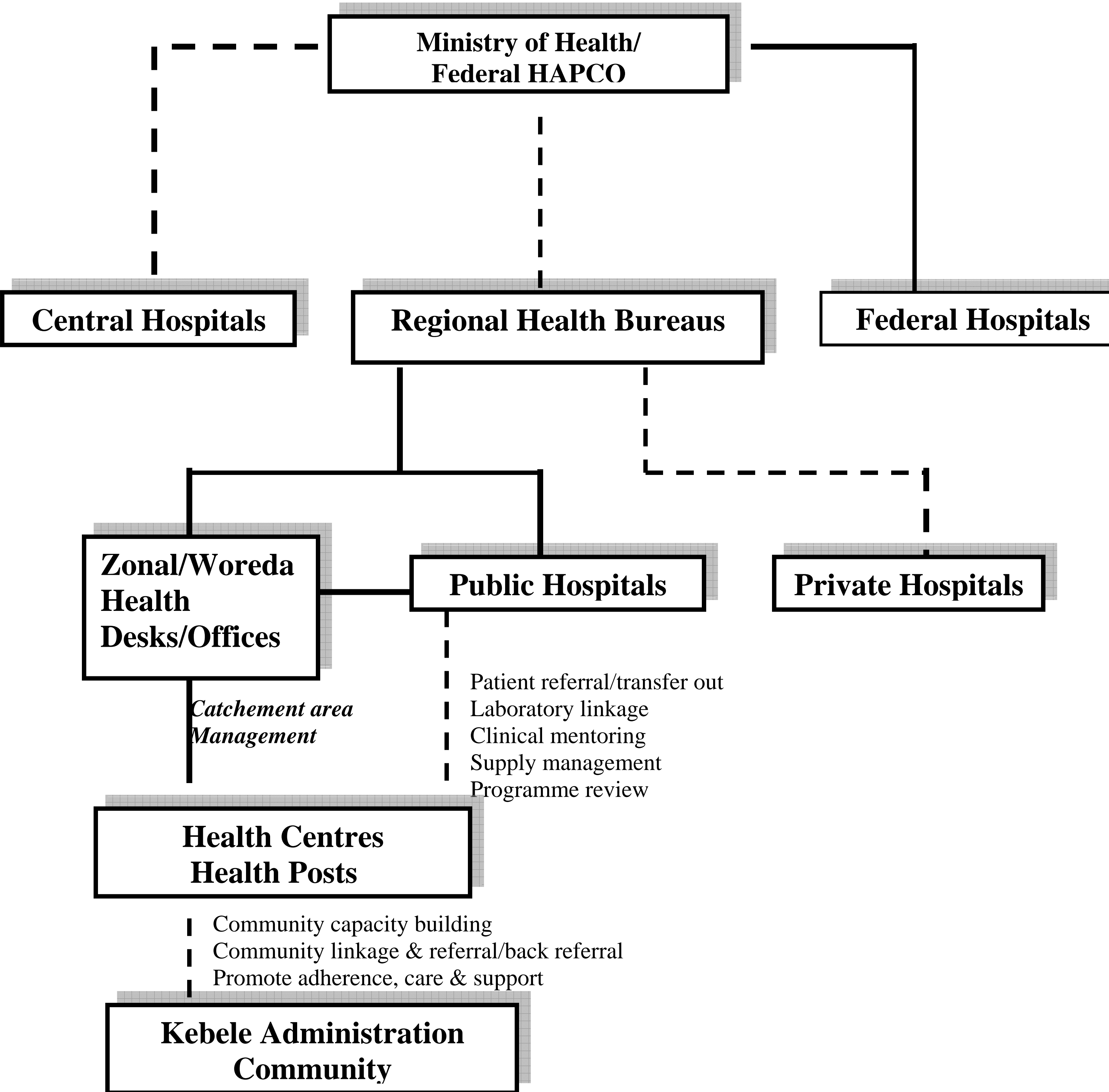
Other indicators not included in the national report are:

- Performance of the supply system to support ART
- Community preparedness
- Programme targets

Interwoven into some activities are monitors that are programme-specific, e.g. quality assurance and quality control of pharmacies and laboratories are integral parts of these programmes and must be included in the overall monitoring and evaluation.

Annexes

Figure 1: ART Management and Coordination Structure



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