

CHAPTER SIX:

SERVICE DELIVERY

Introduction

Most of the time health services are organized primarily to provide episodic acute care. As HIV begins to become a manageable chronic condition, program managers and care providers need to consider how current health delivery systems can be reorganized to provide chronic care.

Once people are diagnosed and enrolled in chronic care, follow-up visits should be scheduled and planned. Waiting until people present with symptoms or preventable complications is costly and inefficient. PLHIV require care that anticipates their needs at different stages of the care continuum. Compared with the acute care model, planned chronic care models provide opportunities for prevention, early identification of issues and timely intervention.

Chronic care requires broad support for PLHIV from their communities and health care teams to stay in care, adhere to treatment and cope with stigma. PLHIV and their families need to be informed about HIV infection and the anticipated side effects of medicines and supported to adhere to treatment. Health care teams play an important role in linking people living with HIV with community-level interventions, resources and support.

This chapter provides broad guidance on four operational and service delivery areas:

6.1. Differentiated care: addressing the diversity of needs of people in care.

6.2. Recommendations to strengthen the continuum of treatment and care:

- Disclosure
- Retention;
- Adherence;
- Task shifting;
- Decentralization;
- Integration;
- Adolescent-friendly health services.
- Improving the quality of HIV services

6.3. Pharmaceuticals supply and management system

6.4. Laboratory and diagnostic services.

6.1. Differentiated HIV service delivery

Differentiated care is a client-centered approach that simplifies and adapts HIV services across the cascade to reflect the preference and expectations of various groups of PLHIV while reducing unnecessary burdens on the health system. Continuing to provide ART to a large and growing number of individuals poses a significant challenge to health systems in resource limited setups where there is a shortage of clinical staff. The challenge is highlighted by substantial rates of attrition reported across ART programs. The pace of ART enrolment will likely further increase in the coming years with recommendations issued by WHO in 2016 to change the eligibility criteria for ART initiation as Ethiopia has also endorsed the recommendations.

The challenges of further scaling up ART to those in need and improving retention in care for those on ART require continued adaptations in the models of healthcare delivery to the reality of people's lives. As national, regional and district teams address the various challenges, lessons from innovative models of ART delivery can help shape the next stages of HIV care and treatment scale-up.

The previous guidance which was adopted from WHO was concerned that Differentiated service delivery for HIV treatment has focuses primarily on people who are clinically stable (established on ART). Subsequently, the need has been recognized to adapt services for those with advanced HIV disease, high viral load and comorbidities through simplified care packages

and differentiated models of service delivery; the principles of differentiating service delivery according to the needs of different groups has also been extended to improving the uptake of HIV testing and prevention.

The New WHO 2021 Guideline defines being established on ART should be applied to all populations, including those receiving second- and third-line regimens, those with controlled comorbidities, children, adolescents, pregnant and breastfeeding women and key populations. It also suggests, considering people's clinical needs, differentiated service delivery for HIV treatment should also consider the specific populations and contextual settings. There is also increasing experience of how such models have been adapted in settings with lower HIV prevalence, acute conflict or other emergency responses.

Differentiated service delivery for HIV treatment is based on four building blocks (Figure. 6.1.). In any given differentiated service delivery model for HIV treatment, the building blocks need to be defined separately for clinical consultations, ART refills and psychosocial support.

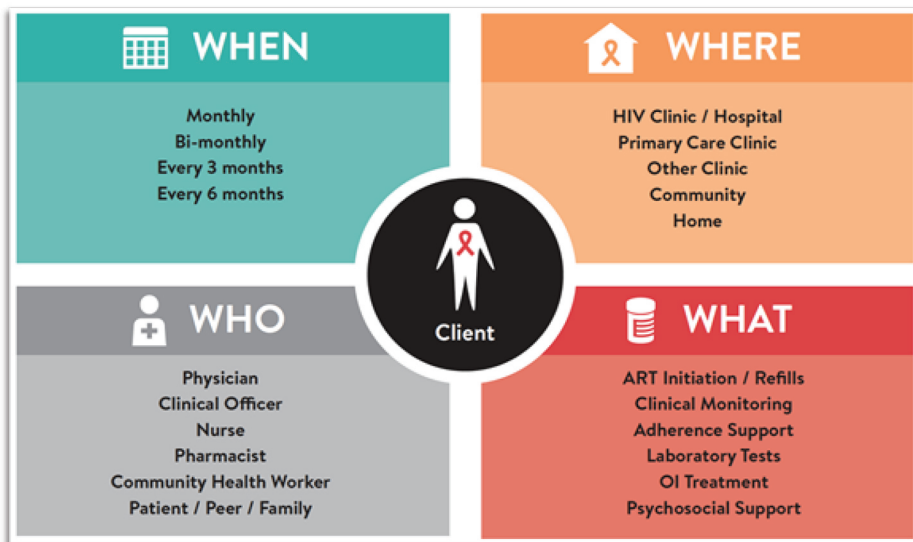


Fig. 6.1. The building blocks of differentiated service delivery for HIV treatment

To accommodate this, our country adopted Appointment Spacing Model/6MMD of HIV care as the first model of differentiated HIV service delivery in 2017. Ethiopia then scaled up other models such as Fast Track ART Refill, 3MMD, Health Extension Professional Managed Community ART groups (CAGs), Peer Led Community ART Group/ Distribution (PCAG/D), Adolescent ART group, Advanced HIV Disease (AHD), MCH and Key Population service delivery models.

All these approaches have reduced the burden for patients (reduced time and cost of travel to clinic and less income loss) and the health system (reduced clinic attendance), while maintaining high retention in care (more than 90% retained in care across multiple time points). Therefore, providers should ensure all required packages of care in the standard

are not missed during the clinical visits of the clients.

Differentiated care applies across the HIV continuum to all the 95-95-95 targets. Differentiated care includes models of testing people unaware of their HIV status to treatment and care to viral suppression of HIV clients enrolled in care. Based on the level of stability of the clients, DSD models can be based in the facility or in the community.

Eligibility criteria for less intensive DSD models

After appropriate classification based on the criteria below, clients should be informed and give verbal consent on the type of the service delivery model they prefer.

The following are the eligibility criteria for less intensive DSD models:

- Patients who are on ART at least six months
- No current illness, which does not include well-controlled chronic health conditions
- Good understanding of life long adherence; adequate adherence counseling provided (a patient with adherence of 95% for the last 6 months)
- Evidence of treatment success (at least one suppressed viral load result (i.e < 50 c/ml) and if no Viral Load result, a patient with rising CD4 cell count or CD4 cell count above 200 cells/millimeter cubes).

- Children with age greater than five years*
- A Patient who doesn't have current Opportunistic Infections
- A Patient with no adverse drug reactions and doesn't need careful clinical monitoring.
- A Patient who is willing or provide consent to get the ART service based on his/her preferred DSD models.

*WHO 2021 guidance did not put age limit for established DSD models but since all children < 5 years are considered to have AHD, age ≥ 5 years is considered for age limit.

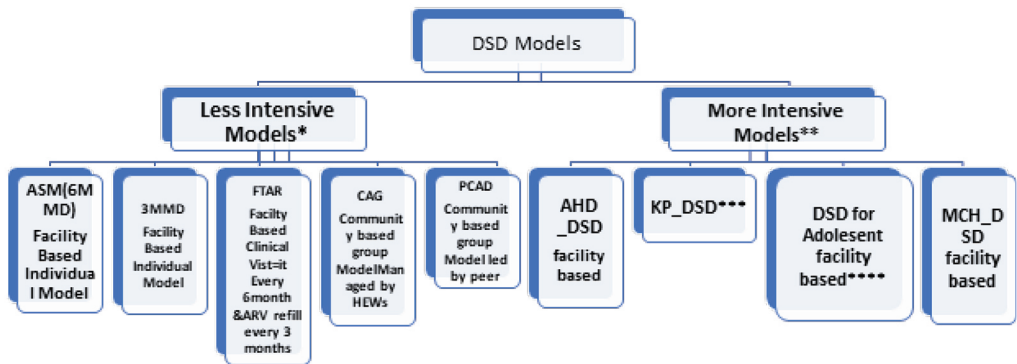


Figure 6.2. Differentiated service delivery model (DSD) framework in Ethiopia

*Less Intensive Model: This individual and group model is intended for clients who are established on ART. It includes both facility and community-based approaches. It requires less frequent clinic visits and focuses on education and empowerment of clients.

**More Intensive Model: This Model is intended for clients who need close follow up and frequent clinic visits. It includes clients with OI, unsuppressed viral load adolescents, pregnant women and those with psycho social barriers to adhere and retention.

*** KP _DSD: Can be implemented both at facility and community level

**** DSD for adolescent is categorized under more intensive models assuming that most of the adolescents require close follow up and adherence support. However, for stable adolescents providers may decide based on the above eligibility criteria and additional conditions.

These classification of DSD models are adapted from CQUIN documents

6.1.1 Less intensive DSD models

6.1.1.1 Appointment Spacing Model (ASM/6MMD)

In the appointment spacing care model, stable clients will be appointed every six months for clinical visit and medication refill. Clients in this model should get additional supports like arrangement of treatment supporter at home level among their family members and arrangement of adherence reminders like alarm and education on how to maintain the drug quality at home level. Clients should be counselled and encouraged to disclose their status and to participate in peer support groups or to be a member of PLHIV associations. Those clients who disclosed their status will get adherence support from PLHIV associations via home visits or telephone follow up.

6.1.1.2 Three Months ARV Dispensing (3MMD)

In the three months ARV dispensing model, clients who are eligible but not willing to be enrolled in 6 MMD (ASM) will be appointed every three months for both clinical visit and medication refill.

The MOH interim guidance for provision of HIV Services in the context of COVID-19 Pandemic clearly guides provision of 3 months ARV dose (3MMD) for PMTCT clients, children, newly identified clients including Key Populations (KPs), clients on second or third line ART and any other clients who do not need admission (Advanced HIV Disease, High Viral Load (HVL), those on EAC, etc).

For children taking 3MMD, the caregiver should be allowed to pick up the child's medication without bringing the child unless the child is due for a clinical visit. For clients requiring Co-trimoxazole, a 3-6-month supply should be provided at the same time as ART pickup. TPT should also be given in multi-month intervals at the same time as ART pickup. For children (especially those who are younger) starting a new medication, administration of the first dose should be done before the child and caregiver leave the ART site. At least monthly virtual follow up shall be provided using phone calls and other communications mechanisms for children <30KG body weight for dose adjustment, for clients with co-morbidities, for clients with high viral load and other clients with concerns. In addition, clinicians need to make every effort to align the visit dates and service delivery sites for children and their parents receiving ART.

6.1.1.3. Fast Track ARV Drugs Refill Model

Fast Track ARV drugs Refill (FTAR) is one of the facility based Differentiated Service Delivery Models of HIV care where patients categorized as stable make clinical visit once every six months but collect their medication every three months from pharmacy. The clinical visit at 6 months' interval is meant to ensure the standard package of care is delivered to the clients and to review if the patient still meets the stable criteria. The facility-based fast track system for ART refills can provide an opportunity for those ASM clients who, for various reasons, faced difficulty in taking all of the prescribed six-months of ARV drugs to their home at once from the ART pharmacy as in the ASM framework.

6.1.1.4. Health Extension Professional Managed Community ART refill group (HEP_CAG)

Community ART refill groups (CAGs) are groups comprising of stable clients on ART living in the same community/locality that have a shared understanding. This model is managed by health extension professionals (HEPs) who already have roles in HIV testing and other HIV service provision as one of their packages. The ART refill is for three months and each CAG will have one community refill in between the health facility visits that will happen every six months. Clients can return or referred to the facility at any point in the cycle for any issues that may arise between scheduled health facility visits.

6.1.1.5. Peer lead community based ART distribution/Group (PCAD/G)

The peer led Community based ART distribution (PCAD) groups are groups of PLHIV comprising of stable clients living in the same community/locality. In PCAD, group members will take turns to pick up ARVs at the health facility and distribute among the other group members in the community. Each client will get clinical evaluation and lab monitoring service as per the standard of care package. They will manage their own health and take action with the support of community and facility-based healthcare workers and this will help to align with the clinical consultation visits at health facilities as the recommended, in our set up is every six months.

6.1.2 More intensive DSD models

6.1.2.1. Health care worker managed DSD Model for adolescent living with HIV (DSD for ALHIV)

DSD for adolescents has three core elements which include ART refill, clinical consultation and psychosocial support. This model is coordinated by trained health care workers (HCWs), and regularly meet on weekends and share psychosocial supports. Young adults who already passed through psychosocial support program and transitioned out from Pediatric ART also facilitate the program voluntarily. During this peer session, adolescents interact, learn and share experience among their peers and from facilitators. Understanding the treatment, adherence to treatment and viral suppression are main parts of their discussion. Making the clinical, ARV refill and viral load monitoring service available over the weekends together with the psychosocial support program will make comprehensive HIV service a one stop shopping model for adolescents living with HIV.

Eligibility criteria for Adolescent clients on DSD model:

- Adolescent clients who disclosed their HIV status and willing or provide consent to get the ART service based on his or her preferred DSD models.
- Health care facility where there is functional pediatric psychosocial support program,
- Adolescents, 10- 19 years, fully disclosed, enrolled in the pediatric psychosocial support program,
- No restriction on stability- including both with suppressed and unsuppressed viral load test result

6.1.2.2 DSD for key population (for FSWs)

In Ethiopia there are efforts to make public and private facilities KP friendly by building the capacity of providers and arranging service delivery approach to match their needs. Confidentiality clinics and drop in centers (DICs) were established around hot spot areas in major towns in the country that provide comprehensive HIV services to female sex workers. The KP friendly services delivered at drop in centers have significantly improved HIV prevention, care and treatment service access to FSWs. Therefore, enhancing the coverage and quality of HIV prevention, care and treatment services for KP (FSWs) through initiating DSD for key population is deemed necessary.

6.1.2.3 DSD for Advanced HIV Disease and PLHIV at high risk Disease Progression

For adults and adolescents, and children older than five years, advanced HIV disease is defined as CD4 cell count <200cells/mm³ or 'WHO stage 3 or 4' event. All children under 5 who are not on effective ART are considered to have advanced disease because of high viremia and rapid disease progression with high mortality. For patients with advanced HIV disease, the frequency of clinical visit is recommended every month.

Frequency of visits and MMD for patients with advanced HIV disease in the era of COVID-19 pandemic

Careful consideration should be given to whether persons with AHD should be seen in

person; in some cases, the benefits of being seen in person may outweigh the risks of COVID-19 acquisition in health care facilities. As an alternative to in person visits, close virtual monitoring may also be considered.

Alarming symptoms that support in person clinical assessment include, but are not limited to, fever, cough, shortness of breath, weight loss, severe diarrhea intractable headache and inability to walk unaided. For children, alarming symptoms include fever, tachypnea, cough, lethargy, convulsions, poor oral intake, and persistent vomiting or diarrhea, and warrant in person health facility visit and evaluation by a clinician with pediatric training and experience. Further visits or decision to admit a client to health facility should be done by an experienced clinician and based on clinical and diagnostic evaluation findings.

In addition, extra effort should be taken to ensure that these patients with higher risk of severe outcomes from HIV infection have sufficient medications to avoid interruptions in treatment and unnecessary trips to a health facility. The national interim guidance for continuation of HIV services in the face of COVID 19 pandemic recommends 3 months dispensation of ART (3-MMD) for patients with advanced HIV disease. However, patients should be advised to look for concerning symptoms that warrant in person evaluation. In addition to ART, it is critical to ensure the availability and provision of other medications that have been shown to reduce mortality in Advanced HIV Disease, including cotrimoxazole and TB preventive therapy (TPT) once active TB has been ruled out. The general package of Care is outlined in Table 4.1.

6.1.2.4 MCH_DSD

Mothers living with HIV and their infants are important target population for differentiated service model (DSD). There are various models of care used to support MCH/HIV services. Some of the DSD models in Ethiopia includes family planning service integration to HIV care, point of care (POC) EID testing for HEIs and provision of 3 month ARV dispensing for HIV positive pregnant and breast feeding women during COVID 19 pandemic. For detail information refer to PMTCT guideline 2021.

The role of PLHIV and PLHIV associations in DSD

PLHIV and CSOs are meaningfully engaged in implementation, evaluation and oversight of DSD. Representatives from PLHIV are actively engaged as member of DSD technical working groups. Networks of PLHIV offer a key mechanism for enhancing support to those who are affected, and improving negative experiences of living with HIV. As programs encourage greater involvement of PLHIV, there is increasing engagement of affected communities in national responses to HIV, and PLHIV networks have the potential to maximize stakeholder contributions. In addition, approaches that increase engagement and empowerment can potentially shift the focus of PLHIV's roles from representation to the building of individual and community capacity to promote health.

6.2. Recommendations to strengthen the continuum of treatment and care

6.2.1 Disclosure

Disclosure is a process that involves ongoing discussions about the disease as the child matures cognitively, emotionally and sexually.

Commonly used Terminologies in Disclosure:

Full Disclosure to a person who is HIV positive means telling him/her that they have HIV. It can also include the reason for taking medicines. Example: You have HIV and we are giving you ARVs/medicines to help your body fight the virus.

Partial Disclosure to a person who is HIV positive means sharing information about his/ her illness but not using the word "HIV". Example: Your body is sick and we are giving you medicines to help keep your body healthy.

Complete Non-Disclosure to a person who is HIV positive means not telling a person anything about their condition. Example: A HCW may assess the person's health status and give him/ her medications without explaining anything about what the medicines are for or why the person must take them.

Deception is when a person who is HIV positive, is intentionally told something untrue. Example: You are taking medicines because you have TB.

6.2.1.1 Disclosure in Children

Pediatric disclosure is an ongoing process and even in the best of circumstances may be difficult. Adults struggle with the question of where, when or how to tell children that they have HIV, often agonizing over how to find the right words. All families are unique and there are no set rules regarding when and how to disclose to children.

Children react to HIV disclosure in different ways and it is not uncommon for relatives to disagree about disclosing HIV-related information to children. Even amongst the HIV/care team there may be disagreement on the best approach. Disclosure has to be individualized taking into consideration the particular child, parent/s, family, household and community.

HIV disclosure is not a topic that comes naturally for family discussion, especially when children are involved. The best way for a child to learn about his/her HIV status is through age-appropriate information shared by a loving and trusted caretaker. Disclosure to children should never happen casually, inadvertently or in the heat of anger or conflict. A child's maturity and cognitive capacity varies and is not only dependent on age. It is important to tailor the discussion to the child's cognitive level and to the child's personal and individual situation. It is important to assess readiness of the entire family for disclosure and address potential barriers to disclosure. It is also important to discuss benefits of disclosure which have both short and long term impact on the family.

Disclosure can:

- Help create a sense of closeness in the family.
- Help reduce feelings of anxiety and isolation on the part of the parents/ caregiver.
- Relieve the burden of living with the secret of being HIV-positive.
- Help build social support networks.
- Reduce the anxiety children experience when they suspect something is wrong; they will now have information to make better sense of the situation.
- May improve adherence in a non-adherent child.

Assessing readiness for disclosure

The child

- Is the child symptomatic? Taking medications?
- How old is the child?
- Is the child living with a sick parent or family member?
- Is the child asking questions about HIV?
- Does the child appear distressed, anxious or worried?
- Is the child sexually active and at risk of contracting or spreading HIV?

The parent or caregiver

- Has the parent or caregiver been tested for HIV?
- Is the parent or caregiver infected? Symptomatic? Taking medication?
- Is the adult ill? Is s/he in need of help from children in the household?
- Is the infected adult an important attachment figure for the child?

The family or household

- Are there any adults in the household with HIV infection? Who is aware?
- Are other children in the household HIV-infected? Who is aware?
- How many family members are taking HIV-related medications?
- Is the family unit cohesive, or characterized by separations and/or conflict?

The community

- Are testing and treatment generally available in the community?
- Are there people in the community who are open about their own HIV status? Does the child know anyone in the community who is open about his/her HIV status?
- How strong is the stigma surrounding HIV in the community?
- Are there risks to the family (isolation, discrimination) if unintentional disclosure occurs?
- Are there resources within the community for children – a youth group and/or trusted adults they can talk to?

6.2.1.1 Planning for disclosure

Disclosure is not an event or a one-off conversation. It is a **PROCESS** that takes time and constant communication in an age-appropriate manner. It is important to prepare adequately for disclosure. This involves preparation, education, planning and follow-up. Once the decision has been made to disclose to the child, it is important to understand that the topic will have to be revisited over and over again. It is important to give a clear message and listen actively; take clues from the child and avoid lecturing; the emphasis should be on asking directly and indirectly and listening. The following examples can serve as a guide:

Age group of (2-6 years old):

These are too young to comprehend and may still be unable to explain the link between the cause and the illness. Younger children if symptomatic generally want to know what will happen to them. They do not need to know their diagnosis but the illness must be discussed with them. Young children may feel responsible for the parent's illness or just pretend nothing is happening. It is important to give reassurance and take cues from younger children.

- Use visual aids such as drawing, media or puppets in addition to stories to illustrate concepts
- Emphasize the concept of health, wellness and body concrete observation,

School aged children (7-10 years): These age group think systematically about multiple topics more easily. Child's illness descriptions progress from belief that disease is transferred through contact. Hence,

- Use visual aids such as drawings or media
- Emphasize the concept of health, wellness and body

Adolescents 11 years and older: These age groups view body as system, understands illness is within body and caused by external agent

- Visual aids like books
- Use slightly more complex language to convey interactions between health, illness and treatment ("HIV is a type of infection that destroys your immune system's CD4 cells")

Assuring children and adolescents that their HIV status and what they say is confidential, is also very important. Issues of disclosure to others should be discussed while allowing the adolescent to make his/her own decisions about.

6.2.1.2 Stages of disclosure

Stage 1 This is for children around the age of six. If they are symptomatic they want to know what will happen to them. They do not need to be informed of their diagnosis but the illness must be discussed with them.

Stage 2 This stage is for school age children (7-10years). The illness can be discussed as a germ that can weaken their body soldiers without specifying the diagnosis.

Stage 3 Make sure the child and caregiver are ready for disclosure. Some may have difficulty coping with disclosure information leading to

changes in behavior (acting out in school, i.e. fights, low grades, truancy, anger, crying fits, and no expression of emotion). Others may have concerns that other children in the school or community will make fun of them. Encourage them to ask questions; do not be disappointed if they do not react in the manner you expected. At this stage words like HIV and CD4 should be introduced and check the understanding at each visit.

N.B: Full disclosure can be provided to most children over 10 years. Each steps of disclosure should be documented on the patient's chart.

Adolescents 11 years and older

Adolescents should know of their HIV status. They should be fully informed in order for them to appreciate consequences for many aspects of their health, including sexual behavior and treatment decisions. Be supportive and non-judgmental.

6.2.1.3 Post –disclosure assessments and follow-up

Disclosure is a process that does not end with telling an HIV-infected child the name of their illness or diagnosis. After the HIV diagnosis has been disclosed to the infected child, follow-up visits are needed to monitor the child and family's understanding of the illness and their emotional and psychological adjustment.

Once the diagnosis has been explained to a child, it needs to be reinforced or regularly discussed as the child develops because many children will not have understood the full implications of the disease or diagnosis at the time of disclosure. For example, pre-

adolescent children can cognitively understand the concepts about the virus but may be less likely to think of the future implications, such as transmission risks and safe sexual practices. As the child ages and matures, he/she will slowly understand and integrate the implications of the diagnosis into his/her life. Children's perception of self, health, illness, and death evolve as they mature through different developmental stages.

Some children who learn of their HIV status may experience guilt and shame and may isolate themselves as a result of the stigma and secrecy surrounding the disease. Changes in behavior and school functioning may occur in these children and may be symptoms of depression. Patients and families who have a difficult adjustment to HIV disclosure without progress over time should be referred for mental health services and additional support. In young adolescents it will be important to discuss about modes of HIV transmission, sexuality and reproductive health.

6.2.1.3 Disclosure in adults

Among other priorities, testing and counselling programs emphasize the importance of people with HIV disclosing their HIV status, particularly to sexual partners. Informing the sexual partners of an individual's HIV infection is not only an effective means of halting the transmission of HIV, but informing partners allows access to care and support as well as further prevention efforts among the client's partners and family.

Two main processes for informing partners of an individual's HIV infection are disclosure and partner notification. Disclosure refers to actions by individuals themselves to notify their partners of their HIV Sero-status. UNAIDS

and WHO strongly recommend disclosure, when appropriate, as this process is voluntary, respectful of the autonomy and dignity of the affected individuals and mindful of maintaining confidentiality. Providers of testing and counseling prefer that individuals use disclosure to inform those who need to know that they are infected. For the individual, his or her sexual partners, and family, disclosure allows for greater openness about HIV in communities and meets ethical imperatives. To encourage disclosure, it is needed to establish safe social and legal environments in which more people are willing and able to get tested for HIV and are empowered and encouraged to change their behavior according to the results. This can be done by expanding access to counseling, testing, care and treatment services; by protecting people from stigma and discrimination and removing legal barriers.

Disclosure can be difficult as people may be afraid of the consequences: for example, the threat of rejection and violence by partners and family or discrimination in the community and workplace. In some cases, people may have limited knowledge of their partners and how to locate them, or may not know the identity of their partners or where they can be located. Although evidence of effectiveness of partner notification is limited in resource-limited settings, it is advised that partner notification or ethical partner counseling be based on the informed consent of the source client, and maintain the confidentiality of the source client, and where possible, protect individuals from

physical abuse, discrimination and stigma that may result from partner notification. Ideally, partners of infected individuals should be encouraged to seek HIV testing and counseling, as this is a critical prevention and treatment tool in the control of HIV.

How to discuss disclosure in adults

- Ask the patient if he/she has disclosed his/her HIV test result or is willing to disclose the result to anyone.
- Discuss concerns about disclosure to partner, children, other family and friends.
- Assess readiness to disclose HIV status and to whom.
- Assess social support and needs (refer to support groups).
- Provide skills for disclosure (rehearsal can help).
- Help the patient make a plan for disclosure if now is not the time.
- Encourage attendance of the partner to consider testing and explore barriers. As couples may have different HIV status, partner testing is important.
- Reassure the patient that you will keep the result confidential and that disclosure is voluntary.

If the patient does not want to disclose the result:

- Reassure that the results will remain confidential.
- Explore the difficulties and barriers to disclosure. Address fears and lack of skills (help provide skills).
- Continue to motivate the client.
- Advise the client not to harm others.
- Offer to assist in disclosure (for example, talk with spouse).
- Offer another appointment and more help as needed (such as peer counselors or trained counselors).

For women, discuss benefits and possible disadvantages of disclosure of a positive result and involving and testing male partners. Men are generally the decision makers in most families and communities. Involving them will have greater impact on:

- Increasing acceptance of condom use, practicing safer sex and making appropriate reproductive choices.
- Helping to decrease the risk of suspicion and violence.
- Helping to increase support to their partners.
- Motivating to get tested.

- **Anticipated consequence of involving and testing the partner:** danger of blame, possible violence, abandonment. Health worker should assess the risk of violence or suicide and discuss possible steps to ensure the physical safety of patients. Health worker should try to counsel the couple together, when possible.

6.2.2. Retention

Ensuring retention for people living with HIV across the continuum of care is essential for optimal health outcomes. For people living with HIV who are receiving treatment, uninterrupted ART and continual monitoring are essential for sustained viral suppression and optimal treatment outcomes. Retention in ART program is more challenging in pediatric populations, postpartum women. Multiple factors may play a role in lost to follow-up, including distance to health facilities, lack of transport or inability to cover travel expenses, stigma and disclosure-related issues, being too sick and lack of understanding of the need for lifelong care.

6.2.2.1 Good practices to optimize retention

Optimizing retention in HIV care requires interventions at multiple levels of the health care system. Given the broad array of challenges and heterogeneity of barriers across settings, no single approach is likely to work for everyone in all settings. Improving the understanding of barriers and innovative strategies to address them are important.

Related transport costs and loss of income while seeking care serve as discouragements when health facilities are located far from the person's home. Bringing services closer to communities, where feasible, reduces the indirect costs of care for the PLHIV and their families and improves retention.

Waiting times at the facility during consultation are frequently high, especially in settings with a high burden of HIV infection. Reorganizing services, such as systems for appointment, triage, separating clinical consultation visits from visits to pick up medicine, integrating and linking services and family-focused care may reduce waiting times at the health facility.

Interventions harnessing social support have emerged as a promising approach to counteract the structural, economic, service delivery and psychosocial constraints that affect retention.

6.2.2.2 Specific population considerations

1) Pregnant and breastfeeding women

For pregnant women living with HIV, the transition between ART care and antenatal care/MNCH services is a potential point for lost to follow-up.

Interventions include:

- Monitoring approaches to ensure that registers are aligned and that women are tracked and followed across different ART service delivery points;
- Peer support, such as mothers-to-mothers program, may improve transition across service delivery settings, and

- Peer adolescent support groups for adolescent pregnant women living with HIV.
- They should have the choice to continue receiving their ART through the differentiated ART delivery model or to have their ART delivery integrated within their maternal, newborn and child health care.

2) Children

Caregivers are responsible for understanding the importance of ensuring retention for children in care, especially younger children. Disclosure to children typically occurs late, making it challenging to discuss the importance of follow-up. WHO recommends age appropriate disclosure to children. This is based on their judgement of the overwhelming benefits of the intervention in increasing retention in the testing to treatment cascade.

Interventions include:

- Supporting caregivers to attend for regular follow-up.
- Reinforcing to the caregivers the importance of the process of disclosing to the child; this can begin early with age-appropriate messaging and tools.

3) Adolescents

Frequent clinic visits, time spent waiting for services and having to miss school discourages adolescents' engagement in care. Negative health care provider attitudes, concerns regarding privacy and confidentiality and limited opportunity to discuss their concerns also act as barriers to retention for adolescents. Distance to facilities and out of pocket expenses may restrict their engagement.

Interventions include:

- Strengthen the adolescent DSD based at Health Facility level.
- Implementing adolescent friendly health service approaches to improve quality;
- Providing adolescent services at specific times or in separate areas with flexible appointment systems that accommodate school hours;
- Comprehensive services that address multiple needs, including psychosocial support and sexual and reproductive health, and

- Close monitoring of adolescents' engagement in care, rapid proactive follow-up and implementation of strategies for re-engagement.

4. Key populations

Specific consideration, especially in settings in which people are criminalized because of their behavior or identity, requires delivery community and peer-based options to support people to retain in care.

Table 6.1. Factors related to the health system and people receiving ART influencing retention and adherence with respective potential interventions.

Factors	Possible interventions
High direct and indirect costs of receiving care.	<ul style="list-style-type: none"> ■ ART and related diagnostics and services free of charge at the point of care. ■ Decentralize ART where feasible. ■ Scheduled facility visits ■ Reduce waiting time at the facility level. ■ Client centered appointment system. ■ Separate clinical consultation visits from appointments for picking up medicines. ■ Link, integrate and coordinate care.
Stock-outs of ARV drugs.	<ul style="list-style-type: none"> ■ Optimize pharmaceutical supply management systems to forecast, procure and deliver ARV drugs. ■ Ensure regular & accurate reporting and requisition system using RRF. ■ Use fixed-dose combinations to simplify forecasting and supply management systems.
Lack of a system for monitoring retention	<ul style="list-style-type: none"> ■ Implement systems for patient monitoring across the continuum of care, including cohort analysis and patient tracking systems.

Factors	Possible interventions
Lack of a system for transferring people across different points of care.	<ul style="list-style-type: none"> ■ Interlinked patient monitoring system across services for HIV, TB, maternal and child health and PMTCT; system for transitioning from pediatric to adolescent and adult services and from maternal and child health and TB services to chronic HIV care.
Pill burden and complex ARV drug regimens.	<ul style="list-style-type: none"> ■ Use fixed-dose combinations to reduce the pill burden and simplify the regimens.
Lack of accurate information for patients and their families and peer support.	<ul style="list-style-type: none"> ■ Engage and integrate community health workers, case managers, adherence supporters, volunteers, PLHIV in peer support, patient education and counseling, and community-level support.
Adherence support	<ul style="list-style-type: none"> ■ Task shifting for involving case managers, adherence supporters and community health workers. ■ Linking with community-level interventions and resources such as peer adherence support (community adherence support groups). ■ Using known effect reminder methods ■ Peer support also provides opportunities for in-person reminders.
Gaps in relationship between patient and care provider.	<ul style="list-style-type: none"> ■ Train health workers on how to reduce stigma; improve treatment preparedness, adherence and retention; provide adherence support and care for key populations; and provide simplified approaches for educating patients and their families.
Lack of time for educating people in HIV care.	<ul style="list-style-type: none"> ■ Task shifting and sharing among clinic team members. ■ People living with HIV as expert patients and peer supporters. ■ A team approach to care.
Adverse drug effects	<ul style="list-style-type: none"> ■ Preparedness and knowledge of how and when to self-manage adverse effects and when to return to the clinic. ■ Implement monitoring and report of adverse drug reactions through implementing pharmacovigilance system.

Factors	Possible interventions
Forgetfulness, life stress, stigma and discrimination.	<ul style="list-style-type: none"> ■ Using reminder to keep patients engaged. ■ Peer and family support. ■ Link to community support group.
Comorbidity, substance and alcohol use disorders and mental health disorders.	<ul style="list-style-type: none"> ■ Manage HIV with mental health disorders, alcohol and other substance use disorders and link with community and social support.
Patient knowledge and beliefs related to HIV infection, its course and treatment.	<ul style="list-style-type: none"> ■ Integrate the education of patients and their families and counseling, broader community literacy and education and community engagement.
Trust in faith and other herbal remedies	<ul style="list-style-type: none"> ■ Implement strong counseling system and engage faith based organizations in providing education in adherence and retention.

6.2.3. Adherence to ART

WHO defines treatment adherence as “the extent to which a person’s behavior – taking medications, following a diet and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider”. For ART, a high level of sustained adherence is necessary to suppress viral replication and improve immunological and clinical outcomes; decrease the risk of developing ARV drug resistance; and reduce the risk of transmitting HIV.

6.2.3.1. Barriers to adherence

Multiple factors related to the health care delivery systems, the medication and the individual taking ARV drugs may affect adherence to ART.

Individual factors: may include forgetting doses; being away from home; changes in daily routines; depression or other illness; a lack of interest or desire to take the medicines; and substance or alcohol use.

Medication-related factors: may include adverse events; the complexity of dosing regimens; the pill burden; and dietary restrictions.

Health system factors: may include requiring people with HIV to visit health services frequently to receive care and obtain refills; travelling long distances to reach health services; and bearing the direct and indirect costs of care. Lack of clear information or instruction on medication, limited knowledge on the course of HIV infection and treatment and adverse effects can all be barriers to adherence to ART.

Specific population groups face additional challenges to adherence, and these should be considered when implementing the recommended interventions.

Pregnant and postpartum women

The pregnancy and postpartum period presents significant biological, social and economic challenges that may affect treatment adherence. Pregnancy-related conditions such as nausea and vomiting may negatively affect treatment adherence. Other individual factors include suboptimal understanding of HIV, ART and PMTCT, lack of partner disclosure and support, and fear of stigma and discrimination. Service delivery barriers include poor-quality clinical practices, gaps in provider knowledge and training, poor access to services and health worker attitudes

Adolescents

Adolescents face specific challenges, including psychosocial issues such as peer pressure, the perceived need to conform and inconsistent daily routine. Adolescents are often left out of decisions and have limited opportunities to discuss their concerns, and there is limited availability of adolescent-specific treatment literacy and adherence counselling tools. For adolescents who are transitioning from pediatric to adolescent care, additional challenges may include assuming increased responsibility for their own care, issues relating to disclosure to peers or partners, difficulties in navigating the health-care system, lack of links between adult and pediatric services and inadequately skilled health workers.

Infants and young children

Successfully treating a child requires the commitment and involvement of a responsible caregiver. Parents and other family members of CLHIV may themselves be living with HIV, and suboptimal HIV care and treatment for family members could result in suboptimal care for the child. Other challenges include lack of nutrition support, limited choice of pediatric formulations, poor palatability of liquid formulations, high pill or liquid volume burden, large pill size, frequent dosing requirements and difficulties in swallowing tablets.

People with mental health conditions and substance use

People with HIV with uncontrolled depressive symptoms are more likely to have poor adherence to ART. Adherence is complicated by mental health comorbidity that results in forgetfulness, poor organization and poor comprehension of treatment plans. Similarly, use of alcohol and other substances may also contribute to poor adherence to ART. Alcohol and substance use can lead to forgetfulness, poor organization and diversion of monetary resources.

6.2.3.2. Supportive interventions

Several interventions may also be of value in addressing specific challenges that impact on adherence and/or viral suppression. Interventions to optimize adherence to ART includes using fixed-dose combination regimens for ART and strengthening drug supply management systems to reliably

forecast, procure, and deliver ARV drugs and prevent stock-outs. Efforts to support program-level interventions for improving adherence to ART include: avoiding imposing and maximize adherence should begin before ART is initiated. Developing an adherence plan and education are important first steps. Initial patient education should cover basic information about HIV, the ARV drugs themselves, expected adverse effects, preparing for treatment, and adherence to ART.

Patient education, counseling and peer support

Patient education and counseling are essential both when ART is initiated and throughout the course of treatment. Informing and encouraging people receiving ART and their families and peers are essential components of chronic HIV care.

Substance use and mental health interventions

Studies indicate that improving well-being by treating depression and managing substance use disorders improves HIV treatment outcomes.

Nutritional support

Nutrition assessment, counseling and support are essential components of HIV care. HIV programs should ensure that existing national policies on nutritional support are observed when it is necessary and feasible to maximize adherence to ART and achieve optimal health outcomes in food-insecure settings.

Reminder and engagement tools

Mobile phone calls can be considered as a reminder tool for promoting adherence to ART as part of a package of adherence interventions. Other patient reminder tools include alarms, phone calls, diaries and calendars can be used to as a reminders about the timing of ARV drugs, drug dosage and appointments.

6.2.3.3 Monitoring adherence to ART in routine program and care settings

Objective monitoring of adherence to ARV drugs is necessary for effective and efficient treatment planning and ongoing support. Each facility visit brings opportunity for assessing and supporting treatment adherence. Effective monitoring of adherence requires a combination of approaches based on human and financial resource capacity, acceptability to PLHIV and to health workers and the local context.

Viral load monitoring

Viral load monitoring is considered as a gold standard and recommended to diagnose and confirm treatment response and failure. Although treatment failure is often caused by lapses in adherence to ART, it may also result from other factors such as drug resistance, drug stock-outs, drug interactions or malabsorption. Viral load monitoring must therefore be combined with other approaches to monitoring adherence. These approaches should also be considered as a way to provide additional information about possible causes of virological failure or to support adherence monitoring in settings where viral load testing is not available.

Following an initial viral load result (>50-1000 & >1000 copies/ml), enhanced adherence intervention should be carried out prior to conducting a second viral load test. Viral load monitoring also has a high potential to motivate adherence.

Pharmacy refill records

Pharmacy refill records provide information on when PLHIV pick up their ARV drugs. When people obtain pharmacy refills at irregular intervals, this may indicate non-adherence to ART; however, in many routine care settings, people may pick up their medications when receiving care irrespective of their adherence level. This behavior could lead health care providers to overestimate adherence by solely using pharmacy refill records. In many settings, pharmacy refill records are already a part of national monitoring and evaluation frameworks and can also provide additional information on adherence to ART when used in combination with other tools.

Self-report

Asking people living with HIV or their caregivers how many doses of medication they have missed since the last visit (or within a specified number of days in the past) can help to estimate non-adherence.

However, although this method is commonly used, people may not remember missed doses accurately or may not report missed doses as they may want to be perceived as being adherent and to avoid criticism. Counselling on the importance of remembering and/or documenting ARV drug doses and an

environment that promotes and enables honest reporting of non-adherence are critical components of monitoring adherence to ART in routine care settings.

Pill counts

Counting the remaining pills in bottles may help to assess adherence. Pill counts usually take place at routine health care visits. However, some people may throw away tablets prior to health care visits, leading to overestimated adherence. Although unannounced visits at people's homes could lead to more accurate estimates, this approach poses financial, logistical and ethical challenges. Counting pills also requires health care personnel to invest significant time and may not be feasible in routine care settings. Pill count can perform better when combined with self-reported adherence.

6.2.4. Task shifting for HIV treatment and care

Reorganizing, integrating and decentralizing HIV treatment and care will require re-examining the roles and tasks of teams of health care providers involved in delivering chronic HIV care. Task shifting involves the rational redistribution of tasks among health workforce teams. With this approach, specific tasks are reassigned, where appropriate, from highly qualified health workers to health workers with shorter training and fewer complementary qualifications to efficiently and effectively use the available human resources. Task shifting should be implemented alongside other strategies designed to increase the total numbers and capacity of all types of health workers.

The quality of care in task shifting should be ensured by;

- a) Providing training, mentoring, supervision and support for nurses, non-physician clinicians and community health workers;
- b) Stating clear indications for patient referral;
- c) Implementing referral systems and
- d) Implementing monitoring and evaluation systems.

Both initial and ongoing training and mentoring, supportive supervision and administrative planning have been critical to the success of program that has implemented task shifting. Program need to train and establish a system for routine supportive supervision of health workers, including lay providers.

6.2.5 Decentralizing HIV treatment and care

Although rapidly scaling up HIV programs has significantly improved access to ART and increased the health and survival of PLHIV, it also poses significant challenges to health systems. Decentralizing ART to primary care settings will ease the burden of routine management on other parts of the health system and will improve equity by promoting access to ART in rural areas. Decentralizing HIV care and treatment could reduce the workload for health care personnel, thereby reducing waiting times for people with HIV and people receiving care at hospitals for other conditions and bring HIV services closer to people's homes. Decentralization and scale-up of HIV care and treatment services will continue based on need assessments to address community groups with high HIV prevalence.

6.2.6 Integrating and linking services

Chronic care requires integrating and linking related services to ensure comprehensive and consistent patient management over time including provision of related services in single settings, systems to share information and effective referrals across settings and providers.

Integrating and linking services are likely to reduce missed opportunities for initiating ART, enhance long-term adherence support and optimize patient retention. Programs for HIV, sexual and reproductive health, maternal and child health, mental health, non-communicable diseases, viral hepatitis and TB need to collaborate to successfully implement ART and related services at different levels of the health system.

Delivering HIV services in antenatal care, maternal and child health settings

HIV testing should be offered to all pregnant women through provider-initiated approaches as an essential component of MNCH services. It is also recommended to provide couple and risk screening based partner HIV testing for all pregnant women and their partners in maternal and child health care settings.

ART should be initiated and maintained in all pregnant and postpartum women and in infants at maternal and child health care settings, with linkage and referral to ongoing HIV care and ART, where appropriate.

Delivering HIV services in TB treatment settings

All confirmed and presumptive tuberculosis patients should be offered HIV testing services in TB clinics. TB patients co-infected with HIV should be initiated with ART through linkage to HIV care and ART services. All PLHIV enrolled to HIV care need to be screened for TB and those with no sign and symptoms of active TB should be provided with TPT. PLHIV who develop TB after the initiation of ART, should be linked to TB clinics for TB treatment.

Sexual Transmitted Infection, family planning and cervical cancer screening services in HIV care settings

Sexually transmitted infections, family planning and cervical cancer screening services should be integrated within HIV care settings. WHO recommends routine offer of HIV testing services for persons with an STI in all epidemic settings and for family planning clients in generalized epidemic settings. Likewise, all PLHIV should be screened for STIs and treated as per the National Guidelines for Syndromic Management of STI. Family planning services should be provided in HIV care/ART clinics to avoid unintended pregnancy among women living with HIV. Women living with HIV aged 15 years should be screened for cervical cancer as per the National Guidelines for Screening and Management of cervical cancer.

6.2.7. Adolescent-friendly health services

There is a growing cohort of adolescents living with HIV, which includes those infected from birth and those who have acquired HIV later in childhood and adolescence. While there is still a

lack of health outcome data for this age group, emerging evidence indicates that adolescents living with HIV are underserved by current HIV services including access to ART. Adolescents are at high risk of lost to follow-up both before and after ART initiation. Adolescents and youths aged 15–24 years and those attending services for the PMTCT of HIV are particularly at risk.

All adolescents, including those living with HIV, face significant barriers to accessing health services, due to inadequate health literacy, limited ability to navigate health services, legal requirements for parental or caregiver consent, and insufficient resources to pay direct and associated service costs. Adolescents face significant levels of stigma and discrimination.

Poor quality of services also limits adolescent engagement in health care. Adolescents often perceive health services as unacceptable due to concerns about confidentiality and negative health provider attitudes. Services are often not organized to accommodate adolescent needs, have inconvenient service schedules, inflexible appointments and unwelcoming environments. Without sufficient consideration and support, adolescents can be lost between paediatric and adult services. The rapid developmental and social changes that occur during adolescence exacerbate the impact of such barriers and can have a profound impact on the way adolescents engage with health services.

Due to their unique needs, adolescents living with HIV require quality and comprehensive services. These includes care & support access, continuity in treatment, adherence, psychosocial support, sexual & reproductive health and mental health care. According to the WHO quality of care framework, adolescent

friendly health service is defined as follows:

- Equitable: all adolescents, not just certain groups, are able to obtain the health services they need.
- Accessible: Adolescents are able to obtain the services that are provided.
- Acceptable: Health services are provided in ways that meet the expectations of adolescent clients.
- Appropriate: The right health services that adolescents need are provided.
- Effective: The right health services are provided in the right way and make a positive contribution to the health of adolescents.
- Adolescent-friendly HIV prevention, care and treatment service implementation considerations include:
 - Aligning approaches for HIV service delivery with national adolescent-friendly health service standards, protocols and activities;
 - Including implementation of adolescent-friendly approaches in HIV health service supervisory and monitoring systems;
 - Ensuring training, research and personal development opportunities for health service providers on adolescent HIV treatment and care;
 - Engaging service providers, adolescents and other key stakeholders to identify acceptable and feasible activities;
 - Implementing adolescent-friendly health service approaches in all HIV services used by adolescents, including antenatal care for pregnant adolescents living with HIV; and

Establishing linkages and referral pathways to ensure a comprehensive continuum of care, especially for the transition from paediatric to adult HIV services.

6.2.8. Improving the quality of HIV care services

HIV program should be innovative in addressing local challenges and aim to strengthen programme monitoring and the routine use of programme data to improve the quality of services. Quality of care emphasizes that services should be effective in achieving desired health outcomes and that health-care practices should be people-centred and safe. Strategies to improve the quality of HIV care services are needed both at the programme management level and at health facility and community levels where HIV care services are provided. If an intervention is to achieve the desired health outcomes, it needs to be evidence based, of high quality and achieve a level of coverage that brings desired outcomes at the population level.

Quality care means that people living with HIV receive the care they require to maintain their health and quality of life. For HIV program and health-care providers, quality HIV care optimizes programme effectiveness and efficiency. For policy-makers and funding agencies, quality care is an important requirement for maintaining health at the population level and ensuring the optimal use of available resources.

Quality of care should not be seen as an additional activity to routine HIV services or a short-term project to address implementation issues and gaps; it should be incorporated into daily activities at all levels, from service delivery to national programme management.

6.3. Pharmaceuticals Supply Management System

6.3.1. Supply Chain Management

The overarching objective of pharmaceuticals supply management system is to support national policy with the adequate and continuous availability of the most safe, effective, quality-assured ARVs and related pharmaceuticals at service delivery sites in the right quantity, at the lowest possible cost and in a timely manner.

The new recommendation that ART should be initiated in all PLHIV regardless of CD4 cell count will require an integrated national strategic response that considers the resources available and enables strong supply chain management systems at all levels of the health system. MOH, EPSA and other stakeholders need to work together to ensure that the national supply system is functioning well in accordance with the increasing national demand and achieve the 95-95-95 targets.

Ethiopian Pharmaceuticals Supply Agency (EPSA) is responsible for quantification, procurement, storage and distribution of pharmaceuticals to health facilities. Health facilities obtain HIV pharmaceuticals primarily through the Integrated Pharmaceutical Logistics System (IPLS), a single reporting and distribution system managed by EPSA. Pharmaceuticals used for HIV programs are also managed through IPLS.

Selection of ARV drugs and related supplies

Product selection is done based on existing national policies and ART guidelines. Products are selected from or become part of a National Essential Medicines List (EML) and are based on standard treatment guidelines. If a selected ARV drug is not on EML and/or not registered in the country, HIV program managers should coordinate with Ethiopian Food and Drug Administration (EFDA) and request that these drugs be put on the list and registered.

Quantification

National quantification of ARV and related pharmaceuticals is conducted by EPSA in collaboration with MOH, FHAPCO, other stakeholders and development partners. The national quantification is done every year covering a three-year forecast. Based on the forecast produced, supply plan for one year consumption will be prepared considering stock for procurement lead time and safety stock which can allow sufficient flexibility to accommodate minor consumption fluctuations due to unforeseen events.

Procurement

All ARV and related pharmaceuticals for use in the public and private sector should be procured at affordable prices, with assured quality and adequate shelf life, from a reliable supplier. ARVs and related commodities are procured by EPSA.

The procurement process follows the national and international procurement regulations, which is a competitive approach through international bidding.

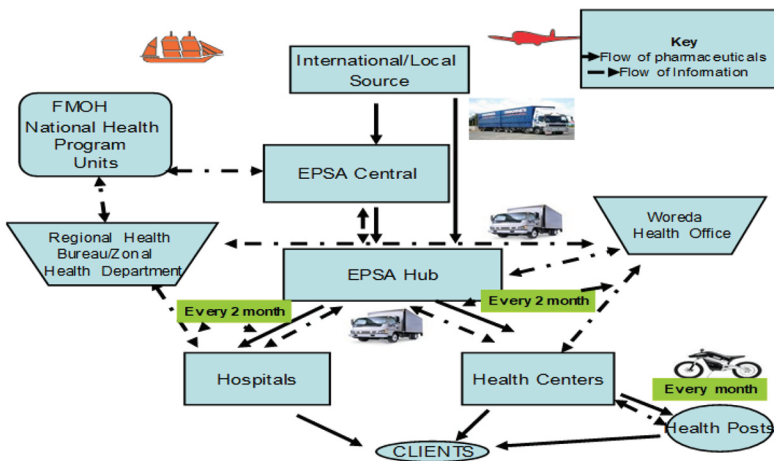
Storage and distribution

Proper storage facilities, including refrigeration, is critical to maintain the quality of the drugs and related supplies. Since the commodities required for HIV program are increasing, there should be adequate storage space, warehouse material handling equipment and distribution facilities need to be ensured at various levels.

Pharmaceuticals and health products distribution will follow the existing delivery

system and it extends from the central level to health facilities. Central EPSA will have a major role of delivering the products to its Hubs; subsequently the hubs distribute the commodities to health facilities based on orders placed by health facilities to EPSA hubs.

Figure 6.3 Flow of pharmaceuticals and information in the integrated pharmaceutical logistics system.



Inventory Control

Inventory control system is mandatory to maintain an appropriate stock level of products at all level of the supply chain to avoid shortage and wastage (due to overstock and/or expiry) of products. IPLS dictates the implementation of max-min inventory control system where there is a set of maximum and minimum months of stock to be kept at each level of the supply chain. Health Commodity Management

Information System (HCMIS) is an electronic inventory control system which is currently utilized at EPSA central, hubs and some health facilities whereas the remaining health facilities are utilizing a paper based system. HCMIS need to be strengthened to improve inventory control and data visibility at all levels of the supply chain. EPSA is responsible for collecting, validating, analyzing, and utilizing product information to ensure an uninterrupted supply of health products.

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 pharmaceuticals is developed and implemented by EFDA. Quality standards should also define storage conditions at EPSA warehouses and health facility stores. The national laboratory must have the capacity to assure the quality of ARV pharmaceuticals. Quality assurance of drugs and supplies will be maintained using simple visual inspection methods and a First-Expiry-First-Out (FEFO) system to avoid expiration and ensure fresh supplies are available at all levels.

6.3.2. ART Pharmacy Services

The ART Pharmacy unit is determined to take responsibility and make all the necessary follow up to improve the ART pharmacy services. Pharmaceutical care provider who is working in ART Pharmacy is expected to play an important role in the follow-up of adherence, monitoring treatment outcomes, monitoring and preventing drug interactions, detecting and reporting ADEs, and other medication related issues. There is also a need for strict pharmacovigilance of ARVs since new ARVs are constantly entering the market.

Key activities and processes in ART pharmacy

The pharmacist assigned to provide ART pharmacy unit should minimally accomplish the following:

- Filling of patient information sheet for specific patient

- Confidential documentation system of patient information sheet
- Identifying ADR, drug interactions, adherence of ART clients using patient information sheet
- Record patient appointment date for easily tracking of patients for follow up
- Timely trace lost for follow up patient and make adherence support
- Register basic patient data on daily basis to summarize the data for informed decision making.
- Summarize data from registers to consumptions summary
- Generate monthly report and share to respective bodies.
- Analyze and interpret monthly report for decision making purpose
- Properly provide services for PEP and Emergency clients

Pharmaceuticals Management Information Systems

The management of patient related data serves two basic purposes among others: it enables the Pharmaceutical care provider to follow-up adherence, treatment outcomes, prevent adverse drug reactions, drug interactions and other medication related issues; and the information obtained is crucial for decision-making on the selection and quantification of ARVs. Accordingly, the system will allow

the effective and efficient documentation and reporting that is important in the management and monitoring of patient uptake and regimen profile at national, regional and health facility levels. Moreover, the overall prescribing and dispensing practices at facility level will be improved. It will also contribute to the identification of discrepancies in treatment protocols in an effort to improve adherence to latest ART guidelines. Hence, the information generated at health facilities is being utilized for decision-making throughout the drug supply management cycle of the country.

Tools and systems in ART pharmacy Services:

- Patient information sheet (PIS)
- Patient tracking chart (PTC)
- ARV drugs dispensing registers (Adult, Pediatric, PEP, Emergency)
- Drug Therapeutic Problem (DTP),
- Monthly consumption summary and
- Monthly activity report.

Medicine Use Evaluation

In order to sustain the benefits of ART, continuous availability of ARVs should go hand in hand with rational medicine use practices of prescribing, dispensing, and patient use. However, there are reports of non-adherence to treatment protocols. Irrational use of medicines contributes to drug resistance, treatment failure, and resource wastage. In

recent years, to optimize ART and achieve national treatment targets, new regimens and service delivery models have been introduced. Hence, ensuring the proper use of new regimens using methodologies such as drug use evaluation (DUE) should be given a priority. DUE is an ongoing, systematic, criteria-based program of medicine evaluations that helps ensure appropriate medicine use is provided. If therapy is determined to be inappropriate, interventions with providers or patients will be necessary to optimize pharmaceutical therapy. The drug and therapeutics committee (DTC) is responsible for identifying medicine use problems and implementing strategies to alleviate these problems. All DTCs should ensure that medicines are being used correctly so that patients receive the maximum benefit from their pharmaceutical therapy.

ARV drugs safety monitoring and reporting (Pharmacovigilance)

Pharmacovigilance is the science and activities relating to detecting, assessing, understanding and preventing adverse effects or any other possible drug related problems. Pharmacovigilance is a key component of comprehensive patient care and the safe use of medicines. Failure to monitor, understand and manage these events can result in poor adherence and treatment failure and can reduce confidence in antiretroviral therapy among both PLHIV and the care providers. Pharmacovigilance is required not only for long term antiretroviral therapy but also for the antiretroviral drugs used for PMTCT, PrEP and PEP.

Even though there are advances in HIV treatment, adverse drug events (ADEs) associated with antiretroviral medicines (ARVs) still poses a challenge to patient safety. Usually, ADEs occur in the context of comorbidities and pill fatigue due to the lifelong treatment regimens. Advances in HIV treatment would also mean continuous introduction of newer regimens whose safety profiles have not been well studied and established in various settings and population groups such as children, elderly, pregnant women, people with co-morbid conditions (TB, hepatitis and others). These facts call for strong prevention, early identification, management, and reporting of adverse events. And WHO recommends enhanced monitoring and surveillance of toxicity on transition to new ARV drugs in HIV programs. EFDA has established and coordinates a national pharmacovigilance center to strengthen this effort. Professionals involved in prescribing and dispensing as well as patients are encouraged to monitor and report ADEs to the center. The information obtained through the national pharmacovigilance system enables the HIV program to make informed decision on the safety profile of ARVs. Therefore, EFDA will avail reporting tools and build the capacity of providers through trainings and face to face discussions as appropriate.

The main pharmacovigilance methods include spontaneous reporting, cohort event monitoring and targeted spontaneous reporting.

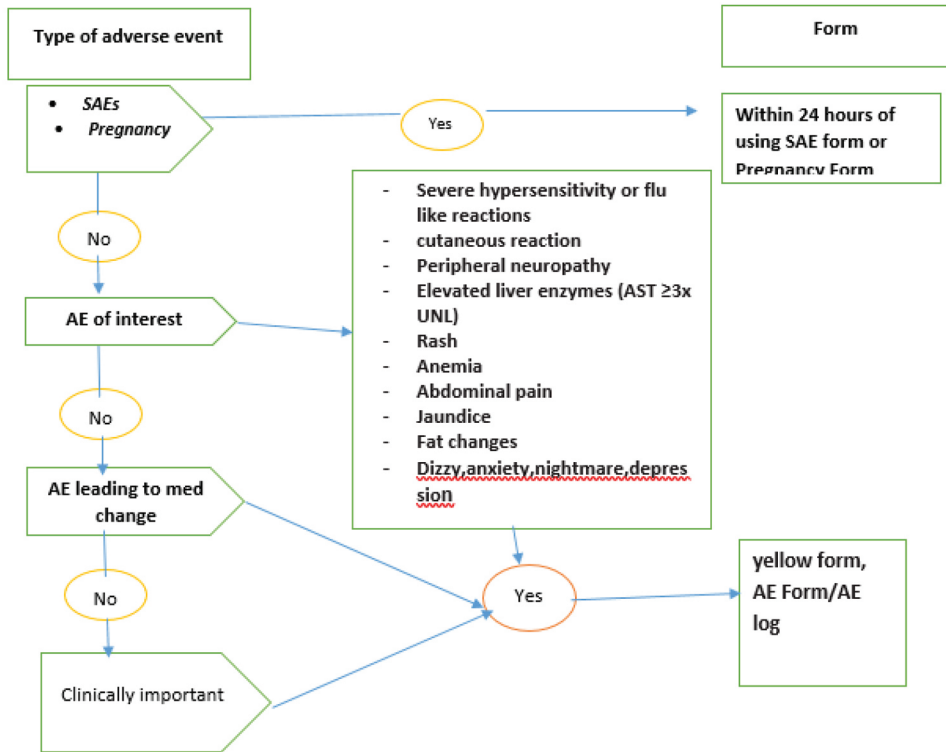
- Spontaneous reporting system is the most widely used system. Health professionals and pharmaceutical manufacturers voluntarily submit suspected adverse drug reactions to the national regulatory authority. A serious limitation here is underreporting.
- Cohort event monitoring is a prospective observational cohort study of adverse events associated with one or more medicines. All adverse events occurring to a person taking antiretroviral drugs are collected regardless of the causality or relationship with the antiretroviral drugs.
- Targeted spontaneous reporting is a method that builds on the principles of both spontaneous reporting and cohort event monitoring. Targeted spontaneous reporting enables focus on a specific drug of interest (such as DGT, Tenofovir), a specific population of interest (such as women, children) or a specific adverse drug reaction (such as anemia).

Reporting of adverse events

Adverse drug events should be reported to the responsible authority body, Ethiopian Food and Drug Authority (EFDA). The adverse events that need to be reported includes medicine-related injuries, with at least a reasonable possibility to be caused by the direct pharmacological mechanism of a medicine, an individual's particular vulnerability, drug interactions, unexpected therapeutic ineffectiveness (e.g. resulting from drug interactions, product quality, problems or antimicrobial resistance), medication errors, and product quality defects.

In line with this, adverse events associated with the drugs should be reported using either the standardized adverse event reporting format (yellow form), using hot line 8482 (toll free line) or Telephone 0115523142(direct) or 0115524122(via operator), electronically on e-reporting of ADR available on the apps or website of EFDA (www.fmhaca.gov.et) and Using a mobile app Medsafety by health care providers and public health programs.

General Reporting approach and Timeline for active DSM



6.4. Laboratory and diagnostic services

The consolidated national HIV guidelines support an increased access to HIV care and treatment and laboratory diagnostic services. To ensure that laboratory services are accurate and reliable, relevant quality assurance systems need to be strengthened in multiple HIV diagnostic settings, as well as other laboratory testing services (eg. Viral Load, CD4 chemistry, CBC etc.). Therefore, strategic planning for proper placement and harmonization of HIV screening platforms and other laboratory

services should be carried out to ensure appropriate use and cost-effectiveness. To enhance implementations of essential and timely patient care, minimum packages of laboratory tests need to be provided as per the schedule or as needed. Minimum laboratory testing services packages for people with HIV are: treatment monitoring tests, HIV drug resistance tests, OI screening/co-infection assessment monitoring test and toxicity monitoring test.

Table 6.4. Summary Components of minimum Laboratory service packages for PLHIV

Laboratory tests	Period
Complete Blood Count	Baseline and every 6 months
CD4 cell count	Baseline and as needed
Kidney Function Tests: (Blood Urea Nitrogen and Creatinine)	Baseline and as needed
Liver Function Tests: ALT (alanine aminotransferase), AST (aspartate aminotransferase), Bilirubin, Alkaline Phosphatase, GGT (gamma glutamyl transpeptidase), LDH (lactic dehydrogenase)	
Blood Sugar: High blood sugar can be a side effect of the HIV protease inhibitors.	Baseline and as needed
HIV Viral Load tests	See ART monitoring section
HIV drug resistant testing	For second line treatment failure
AFB/MTB/RIF	As needed
LF-Urine LAM	For patients with ≤ 200 cells/mm ³ (inpatient) ≤ 100 cells/mm ³ (outpatient) Or any CD4 count with TB symptoms or if seriously ill At baseline and as required
Cryptococcal Antigen (CRAG) tests	for patients with CD4 cell count < 100 cells/mm ³
Others STIs (HBsAg, HCV, HPV)	As needed, for HPV DNA refer CxCa HPV DNA PCR testing

This guidance emphasizes the importance of leadership and governance to ensure implementations of minimum laboratory service packages, strengthen high-quality laboratory services, expanding testing services and developing the health workforce:

- To strengthen and expand laboratory testing services;
- To support a dedicated specimen referral system;
- To increase access to HIV viral load testing;
- To support the expansion of diagnostic services to include testing at the point of care;
- To train and certify health workers who perform the testing;
- To ensure high-quality laboratory services and plans for implementation, including quality assurance; and
- To ensure appropriate deployment of laboratory diagnostic technologies to increase their efficient and optimal use.

1) Strengthening and Expanding Laboratory Testing Services

The following areas are important to strengthen the network of laboratory services for implementing the national guidelines:

- Expanding and strengthening current laboratory networks with efficient specimen referral mechanisms to support and monitor the decentralization and integration of laboratory services or to provide access to laboratory tests which are available at limited number of sites (e.g. HIV viral load testing, DNA PCR, CD4 count etc.).
- Standardizing testing methods to streamline procurement, quality assurance and training.
- Incorporating new testing approaches and systems into national laboratory strategic plans and policies.
- Evaluating diagnostics for their performance and operational characteristics to validate testing algorithms (with back-up options) before introduction.
- Carrying out strategic planning for properly placing and harmonizing testing platforms to ensure appropriate use and cost-effectiveness.
- Allocating appropriate resources to ensure the availability of testing services, including human and financial resources.

2) Strengthen a dedicated Specimen Referral System

Laboratory referral systems and procedures for collecting and processing specimens need to be strengthened to increase access to viral load testing and other laboratory testing (for example, CD4 and early infant diagnosis). Providing for and strengthening a dedicated, efficient, safe and cost-effective specimen referral system requires reliable specimen transport with adequate conditions for whole blood, plasma and dried blood spot specimens (DBS) and rapidly and dependably reporting test results back to the referring sites to support for timely patient care.

3) Increasing Access to HIV Viral Load Testing

The guideline recommends the use of viral load testing to monitor treatment response and diagnose treatment failure and the use of dried blood spot samples for hard-to-reach sites for viral load testing. This will require strengthening the existing laboratory services and phased expansion of monitoring services into peripheral facilities and can include:

- Strengthening and leveraging existing specimen transport and result receiving networks;
- Ensuring that laboratories have adequate infrastructure, technical testing expertise and quality assurance and quality improvement programs;

- Ensuring an appropriate mix of high-volume centralized laboratory testing and point of care testing technologies. Point-of-care Viral load testing prioritized for the following populations groups:
 - Pregnant and breastfeeding women
 - Infants, children and adolescents
 - People requiring a repeat viral load after a first elevated viral load
 - People for whom treatment failure is suspected
 - People presenting sick, living with advanced HIV disease or having a known opportunistic infection (TB, cryptococcal infection, etc.)
 - First scheduled viral load test for people re-entering care
 - The use of dried blood spots as a tool to increase access to viral load testing.

4) Planning for appropriate use of CD4 count testing as access to viral load testing increases

The country has formally quitted CD4 count-dependent treatment initiation thresholds and viral load monitoring replaces monitoring with CD4 cell count. However, CD4 cell count testing will continue as part of HIV programs for baseline assessment, monitoring OI prophylaxis and other clinical assessments, even in settings with full access to viral load testing.

5) Expanding point-of-care(POC) testing Technologies

Decentralizing laboratory services requires that all aspects of testing be in place before implementing services, including:

- Using only high-quality, evaluated and reliable diagnostic tests;
- Supervising and monitoring POC testing for quality and reliability;
- Implementing a strategy for managing supply chain and equipment service; and
- Establishing data management systems for timely identification of quality issues at regional and national data reporting.

6) Implementing Comprehensive Quality Management Systems

Implementing comprehensive quality management system including quality control, External Quality Assessment (EQA) and quality Improvement project is essential. The quality management system should:

- • Be implemented within the laboratory network and all remote testing sites
- Be incorporated into the routine testing procedures and periodically monitored
- Ensure that testing sites undertake quality control, as appropriate
- Ensure that testing sites are enrolled in

an external quality assessment scheme (proficiency testing program and on-site evaluation)

- Ensure the use of standard operating procedures for all processes, including specimen collection and processing, test methods, interpreting results and reporting
- Ensure the use of standardized logbooks or electronic data management and identifying errors and potential misclassification and
- Ensure the implementation of preventive and corrective measures for equipment

7) Providing guidance for developing health workers' capacity, including staff training and certification

Supplementing guideline for developing health care worker capacity building includes; qualification of personnel who will perform the laboratory tests, training requirements for specific tests and the process for certification and re-certification. The guideline also indicating that, all health workers assigned to perform POC and other laboratory testing services must be trained, proficient on the testing procedure, specimen collection and quality assurance before implementing these services.