Case Management Toolkit for HIV Antiretroviral Therapy Services to Prevent Interruption in Treatment, Optimize Adherence, and Achieve and Sustain Viral Suppression

2024

fhi360

Suggested citation: Casalini C, Cassell M, Ferradini L, Akolo C, Carpenter D. Case management toolkit for HIV antiretroviral therapy services to prevent interruption in treatment, optimize adherence, and achieve and sustain viral suppression. Durham (NC): FHI 360; 2024.

Acknowledgments

This resource was developed with FHI 360 institutional funds, and FHI 360 is solely responsible for the content. The toolkit was developed and drafted by Caterina Casalini, Michael Cassell, and Laurent Ferradini. We gratefully acknowledge the inputs and comments of FHI 360 and the Meeting Targets and Maintaining Epidemic Control (EpiC) project staff, with particular thanks to Chris Akolo, Deborah Carpenter, Amy Gottlieb, Mary Kariuki, and Michele Lanham. We also thank Natasha Mack for editing the document, Lucy Harber for formatting and design, and Jill Vitick for designing the cover. In addition, without the generous engagement of the bilateral project Enhanced HIV Services for Epidemic Control (EHSEC) in the Dominican Republic and the EpiC project staff in Vietnam, the Philippines, Nepal, Eswatini, and Mali, this work would not have been possible.

Contents

Acronyms and Abbreviations

AHD	Advanced HIV disease
ART	Antiretroviral therapy
ARV	Antiretroviral
CBO	Community-based organization
CSO	Civil society organization
COVID-19	Coronavirus disease 2019
DBS	Dried blood spot
DDD	Decentralized drug distribution
DSD	Differentiated service delivery
DTG	Dolutegravir
#EAWA	Ending AIDS in West Africa
EHSEC	Enhanced HIV Services for Epidemic Control
EpiC	Meeting Targets and Maintaining Epidemic Control
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
IIT	Interruption in treatment
KP	Key population
LAM	Lipoarabinomannan
LINKAGES	Linkages across the Continuum of HIV Services for Key Populations Affected by HIV
M&E	Monitoring and evaluation
MMD	Multimonth dispensing
OVC	Orphans and vulnerable children
PBS	Plasma blood sample
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
SCM	Supply chain management

SDG	Sustainable Development Goal
SOP	Standard operating procedure
TB	Tuberculosis
TLD	Tenofovir-lamivudine-dolutegravir
TLE	Tenofovir-lamivudine-efavirenz
U=U	Undetectable = untransmittable
UIC	Unique identification code
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VL	Viral load
WHO	World Health Organization

1. Introduction to the Toolkit

This toolkit for antiretroviral therapy (ART) case management aims to orient HIV program implementers to principles and practices they can apply to improve the outcomes of individual ART clients and ART programs overall. The case management approach is based on person-centered care, which focuses on individualized services for clients according to their needs and priorities.

1.1 Rationale

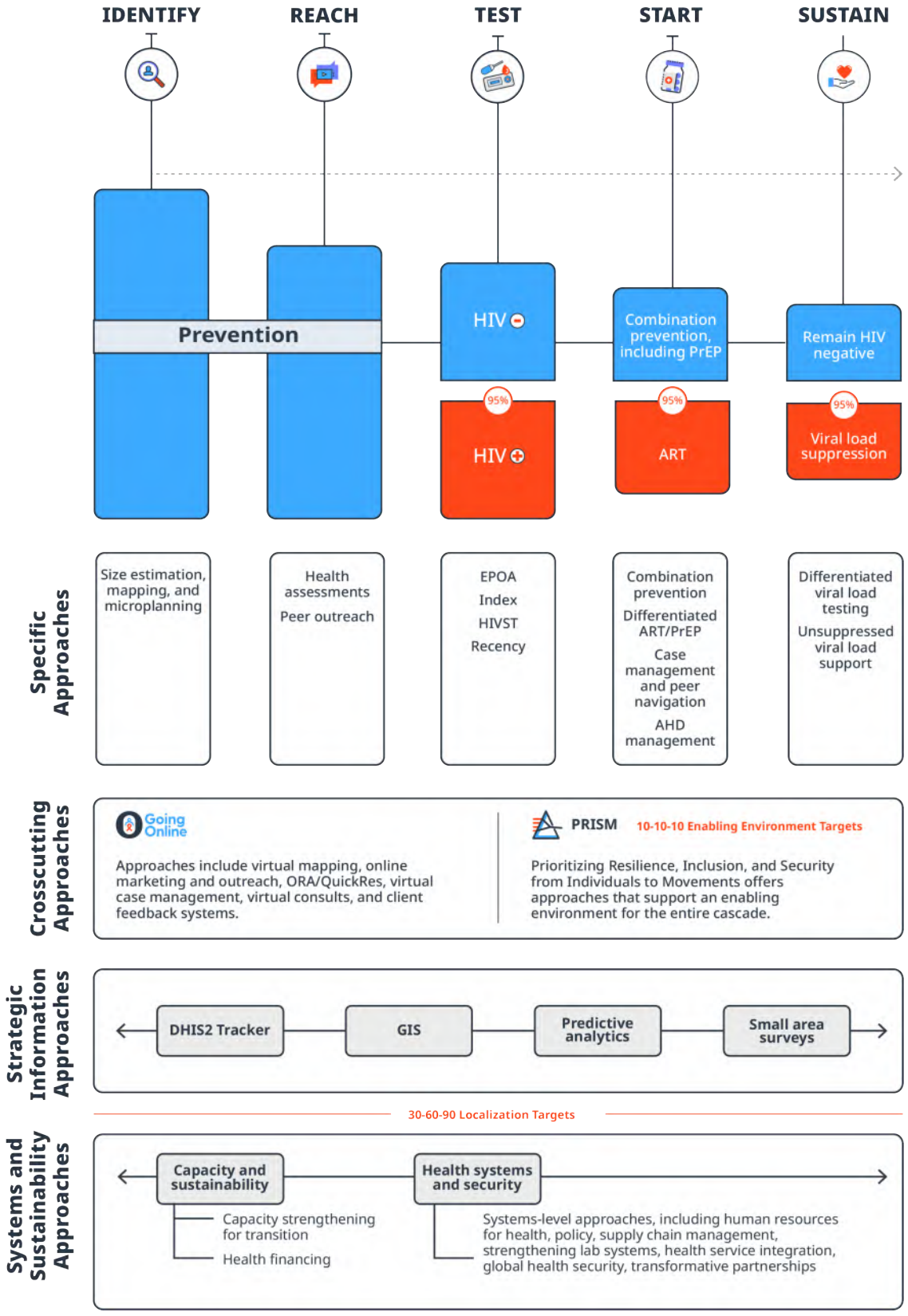
Retention in care and treatment as soon as possible following HIV diagnosis is critical for achieving good health outcomes, preventing increased mortality in public health care settings, and reducing the risk of viral rebound. To close these gaps and achieve and sustain HIV epidemic control, it is increasingly clear that efforts must focus on comprehensive, person-centered ART case management.

An HIV cascade framework such as that developed by the FHI 360-led Meeting Targets and Maintaining Epidemic Control (EpiC) project (Figure 1) can be used to track progress in addressing the HIV epidemic by documenting coverage of proven prevention and treatment services among individuals facing the greatest risks. However, engagement in HIV cascade services is nonlinear, reflecting a dynamic cycle of barriers and facilitators to engagement that are constantly evolving in the face of personal, social, and structural influences.

Globally, HIV programs and their stakeholders and funders have begun to recognize that in the natural course of HIV care, many people will, at some point, disengage from treatment as their preferences, needs, and behaviors change. These same people living with HIV (PLHIV) may later reengage after a brief or lengthy interval, while a small proportion may never re-engage. For this reason, a cascade that documents actual PLHIV behavior—the cycle of engaging and reengaging in care—should inform and prioritize efforts intended to prevent missed clinic visits, overcome barriers to reentry, and minimize onset of advanced HIV disease (AHD).[1]

Scaling up differentiated, person-centered services for HIV, including through case management, is key to ensuring that all PLHIV receive all needed services. In turn, this will help facilitate achievement of the third UNAIDS 95-95-95 target—for 95 percent of people on ART to have suppressed HIV viral load (VL)—by 2030.[2]

Figure 1. EpiC project's cascade of HIV prevention, care, and treatment services for key and vulnerable populations



1.2 Purpose

The purpose of this toolkit is to provide HIV program teams with guidance and resources on ART case management to achieve the following:

- Prevent interruption in treatment (IIT) by identifying clients at high risk of interrupting treatment
- Provide individualized ART services to clients at high risk of IIT to optimize their adherence to ART
- Support ART clients at high risk of IIT to reach and sustain viral suppression

1.3 Contents

The toolkit is a compendium of evidence-based interventions and tools to support discussion, rollout, and monitoring of ART case management programs. Some of the recommended interventions and tools come from the published literature, while others are from FHI 360's HIV programs.

The following topics are covered in the toolkit:

- **Section 2. ART Case Management Model** describes foundational principles, main features, and the ART case management team.
- **Section 3. ART Case Management Interventions** covers risk assessments, peer support, incentives to address structural barriers, adherence support and monitoring, re-engagement on ART, and VL monitoring.
- **Section 4**. **Enabling Policies for ART** includes relevant policies including for rapid ART initiation, optimized regimen, differentiated service delivery (DSD), task shifting and sharing, community engagement and peer-led services, and community-led monitoring
- **Section 5. Enabling Systems for ART Case Management** covers supply chain management, community-facility partnerships, and monitoring and evaluation (M&E) to enhance the use of routinely collected program data to inform person-centered ART case management.
- **Section 6. ART Case Management in the Context of Polycrisis** describes interventions that allow for continued delivery of ART during a polycrisis.

The annexes contain relevant tools programs can adapt as necessary. Throughout the toolkit, we also provide links to published resources from the FHI 360-led EpiC project with information applicable to the context of ART case management.

1.4 How to Use

HIV programs can use the toolkit to gain an understanding of the ART case management approach and how to implement it. The toolkit does not cover all aspects of ART case management that would be needed for every context and population. In addition, new recommendations are likely to emerge as evidence continues to evolve. Therefore, this toolkit is intended as a place to start the conservation on, planning for, and implementation of ART case management, complemented by country- and population-specific epidemiologic and programmatic information.

2. ART Case Management Model

The ART case management approach presented in this toolkit is based on the corresponding model developed by FHI 360 to support clients throughout the continuum of HIV care according to their specific characteristics, risks, and needs (Figure 2). (See FHI 360's Long-Term HIV Treatment Adherence for Key Populations, which describes the diverse needs of PLHIV in key population [KP] subgroups.) The case management model includes both medical and non-medical services intended to address client needs and support clients to remain on ART.

Figure 2. ART case management model

The ART case management model aligns with the following principles:

- **Human-centered design,** a collaborative approach that puts end users at the heart of creating solutions. Human-centered design provides creative methods for use with the intended users and clients that apply their deep understanding of behaviors to develop innovative case management solutions to maximize outcomes and impact. (See EpiC Spotlight on Human-Centered Design.)
- **Social and behavioral change and communication,** which uses communication strategies based on behavioral science to positively influence knowledge, attitudes, and social norms among individuals, institutions, and communities. Using a socio-ecological lens and interactive, participatory strategies, case management services can be designed to account for

people's desires, needs, and barriers and facilitators to change. (See FHI 360's A 360-Degree Approach to Social and Behavior Change.)

- **Motivational counseling,** where providers at all levels (both clinical and community/peer workers) use specific skills and techniques from motivational counseling to motivate clients for sustained behavior change. (See EpiC's Motivational Counseling: A Training in Advanced Interpersonal Communication Skills.)
- **Person-centered services,** where the client is the decision-maker, and all participation is voluntary. This builds on human-centered design and uses communication approaches defined by the social and behavioral change and communication strategy, as well as techniques from motivational counseling.
- **Confidential and private services** in which information is collected in a discrete manner and clients are not put at risk during service delivery, including by implementing the following safeguards:
  - Information should be stored in compliance with a data security policy.
  - Informed consent should be obtained from all clients about how to contact them and the sharing of their data.
- **Infection prevention and control,** consisting of services to be integrated into case management to prevent and mitigate the occurrence and severity of epidemics, pandemics, and other emerging infectious diseases (e.g., COVID-19 and mpox screening and linkage to clinical services, social distancing, wearing face masks, coughing and sneezing etiquette, ventilation, disinfection). (See EpiC's Meeting Targets and Maintaining Epidemic Control: Global Health Security Fact Sheet.)

2.1 Implementing ART Case Management

2.1.1 ART Case Management Team, Responsibilities, and Functioning

Supporting client adherence to treatment and client re-engagement following IIT requires strong coordination and collaboration among program staff, clients, and PLHIV networks. Each ART clinic should establish an ART case management team comprised of facility- and community-based teams. The specific composition of the team and the roles assigned will vary according to the cadres in place in each setting, but could include:

- Peer outreach workers, also called peer navigators
- ART counselors
- Psychosocial support officers
- Mental health providers
- Case managers
- Nurses
- Clinicians
- Orphans and vulnerable children (OVC) cadres
- Pharmacists
- Laboratory technicians
- M&E officers

To maximize the benefits of HIV treatment, the responsibilities of the ART case management team should include the following:

- Coordination across the public health care system, civil society, and the private sector, as well as across service locations at the facility, community, and home levels
- Conducting risk assessments with each client to identify and prevent potential IIT
- Customization of services for each client rather than a one-size-fits-all approach
- Personalized counseling and support for treatment literacy and long-term adherence
- Mixed in-person and virtual support across the continuum of care. To ensure that the case management offering is structured to meet client needs, HIV programs can use the EpiC framework on the use of online and mobile platforms to meet HIV education, prevention, testing, and treatment objectives (see the FHI 360-led Linkages across the Continuum of HIV Services for Key Populations Affected by HIV [LINKAGES] project's Going Online to Accelerate the Impact of HIV Programs).
- Appointment reminders and management
- Multimonth dispensing (MMD)
- Flexible schedules and venues for clinical appointments, laboratory testing, and decentralized drug distribution (DDD)
- Linkages to additional relevant services, including those necessary to mitigate AHD
- Coordinated use of data platforms to track client needs and service delivery for effective and efficient case management

A critical skill for providers on the ART case management team is the ability to understand and help clients mitigate the adherence challenges they and their caregivers face—without good adherence, treatment failure is likely, leading to avoidable HIV-related morbidity and mortality. When discussing risks to adherence, providers should seek to establish a relationship of mutual trust to facilitate client involvement in their care plan, ensure optimum cooperation, and improve health outcomes. Although clients value provider recommendations, they still want to be asked what they think about their treatment plans. Insufficient provider engagement with ART clients when providing care may result in poor client involvement in their care plan.

The ART case management model is grounded in peer support. Peer outreach workers/navigators are key to supporting clients to be adherent to treatment, reach and maintain viral suppression, and be retained in care. However, their support must be ongoing, as a single counseling session delivered by a peer worker/navigator, for example, is likely insufficient to help clients address barriers to adherence. We recommend a series of structured meetings between peer workers and clients, with client needs and risk factors dictating the frequency of the meetings and their content.

Annex 1 provides a tool for mapping out cadres to engage on the team and their respective responsibilities in ART case management.

For the case management team as a whole, we recommend weekly, site-level meetings. Responsibility for leading the meetings, taking the minutes, and reviewing the team's progress on action items from the previous meeting can rotate to a different team member each week.

Agenda items and indicators to discuss include:

- Generate and discuss aggregated data and line lists of the following clients:
  - Not yet initiated on ART
  - To be transitioned to dolutegravir (DTG)-based regimen
  - Due for a clinical appointment, laboratory testing (e.g., VL test), ART refill, or other appointment
  - Missed an appointment and interrupted treatment
  - With poor adherence and/or non-virally suppressed
  - Eligible for or in need of MMD and or DDD
  - Eligible for VL testing and with VL test result pending
- Discuss challenges and identify and agree on actionable solutions, responsible individuals, and timelines

2.1.2 Phases of ART Case Management

ART case management has two phases[3]:

- **Intensive phase:** Involves frequent, personalized client support and counseling beginning when the client first enters or re-enters the health care system and lasting until viral suppression is reached. During this time, regular contact and checks between the client and health care personnel can help identify adherence barriers and missed appointments (e.g., drug pick-up, VL tests) and alert staff of the need for active follow-up.
- **Maintenance phase:** Begins once the client has been established in the health system and reaches viral suppression. Check-ins are less frequent (e.g., if clients receive MMD) and event driven (i.e., reminders for VL testing).

Nonetheless, client transition from the intensive phase to the maintenance phase of ART case management may be followed by additional phases of intensive support at some point in the treatment journey. HIV treatment requires lifelong adherence to medication regimens and may involve inconvenient appointment scheduling, adverse side effects, and lifestyle changes—which can lead to treatment fatigue and low adherence, which are inextricably linked. Pill burden and client-provider interaction have also been reported as contributing to the development of treatment fatigue.[4] Of note, treatment fatigue is not a one-time, static experience but may occur multiple times throughout the client's life. As a result, regular assessment and counseling for treatment fatigue are critical, particularly among experienced clients, adolescents who have been on treatment since an early age, and even among those who are virally suppressed and in the maintenance phase. This means that a client can enter, exit, and re-enter the intensive phase of ART case management depending on their risk factors, including as indicated by their VL test results, as being suppressed once does not necessarily imply that the client will sustain viral suppression over time.

2.1.3 Client Option to Opt Out

Clients should be given the opportunity to opt out from case management services or to change their case manager, if feasible, at any point. They should also be informed that any such decision will not affect the quality of the standard of care to be received and that it is possible to opt in later at any time.

2.1.4 Data Integration and Use

ART case management employs a holistic and person-centered approach to support clients throughout their journeys in comprehensive HIV care. To help clients achieve undetectable VL through treatment adherence, integrated data systems or data-sharing agreements between facilities, community centers, and outreach sites are fundamental. Sharing data enables care teams to have a complete picture of client risks and needs that should be addressed through case management, as well as awareness of the services clients receive. In addition, analysis of program data to identify clients facing elevated risks allows programs to provide case management tailored to risk, with enhanced services provided to those with a higher likelihood of not sustaining adherence to treatment and achieving viral suppression.

Incorporating ART case management variables into the routine M&E system and conducting regular data analysis is key to ART case management program improvement. For example, analysis of data at the program level across the cascade allows for calculation of the following:

- Proportion of clients on ART at end of the quarter
- Proportion of ART clients who died, transferred out, interrupted treatment, stopped ART
- Proportion of clients on ART eligible for VL test and tested
- Proportion of clients on ART tested for VL and virally suppressed
- Proportion of clients on ART with MMD, DDD

In addition, the use of such data can guide programs to identify bottlenecks and design specific solutions to address a specific step along the HIV cascade and, in turn, improve ART case management.

3. Interventions for ART Case Management

This section describes the interventions we recommend as part of the ART case management model, building upon EpiC's Long-Term HIV Treatment Adherence for Key Populations.

The interventions presented may be provided either in person or virtually, depending on client preferences, context (e.g., environmental threats), and other operational and program management considerations (described in Annex 2). For instance, when circulation and travel restrictions were in place during the COVID-19 pandemic, most of the interventions were provided virtually. However, even in the absence of pandemic-level challenges, clients may prefer the convenience and flexibility of virtual support services.

Client consent to receive the ART case management interventions should be documented in the client's paper-based or electronic records. In addition, the M&E system should allow for documentation of intervention-specific consent, as clients may accept some of the interventions and not others.

3.1 Risk Assessment for ART Readiness and Interruption in Treatment (IIT)

An initial ART adherence readiness assessment should be conducted with each client at ART initiation, and any barriers to optimal adherence identified should be addressed at every monthly or quarterly follow-up visit or contact, as applicable. Data should also be collected regularly for risk of IIT and integrated into the routine M&E system to inform the case management team's person-centered care for each client.

3.1.1 Risk Factors for Non-initiation of ART and IIT

Known barriers to ART initiation and IIT should be included in risk assessments. For ART initiation, qualitative research has identified feeling healthy, as well as fear of side effects, stigma, unintended disclosure, and being seen accessing HIV services, as barriers.[5, 6]

Major risk factors for IIT include sociodemographic characteristics, including male sex at birth, pregnant and breastfeeding women, older age, being single, and having lower educational status; clinical characteristics such as AHD, low weight, poor functional status, and comorbidities; individual factors, for example, nondisclosure of HIV status, substance use, mobility, perceived lack of benefit of ART, beliefs about medicines, lack of motivation, side effects, lack of access to adequate food, stigma, mental health challenges, lack of family and social support, and poor relationships with health care providers; structural factors including violence, stigma and discrimination, homelessness, work commitments, unemployment, unavailability of transport,

transport costs, and other financial restrictions; and characteristics of health services and systems, such as over-subscribed health care services, long waiting times, prohibitive distance to clinic, and drug stock-outs.[7-11]

3.1.2 Assessing Risk

Programs can assess risk using factors reported in the literature or by conducting a "client risk segmentation" analysis using their own data to identify predictors of delayed ART initiation and IIT. EpiC's A Guide to Client Risk Segmentation to Optimize the Impact of HIV Programming offers guidance on client risk segmentation, including basic principles and practices to improve individual client and overall program outcomes through enhanced use of routinely collected program data to inform client-centered differentiation of HIV services.

Clients could be assessed for risk on a monthly or quarterly basis, as feasible, by one case management team member or some combination of the case manager, clinical team, and peer navigator. Alternatively, clients could be offered the option to conduct a self-assessment through digital technologies, if available.

Programs should offer regular assessments and counseling to adolescents who have been on treatment from a young age, as well as to the aging cohort of clients, as these clients might be at heightened risk of IIT and aging contributes to increased multimorbidity. In addition, all clients who are ART-naïve, have AHD, have re-engaged in care, or are not virally suppressed should be considered at high risk of IIT. Programs should offer these clients more frequent support and in-depth counseling for at least the first 60–90 days and, ideally but depending on available resources, until they reach viral suppression, as determined during the first VL test performed at 90 days or 180 days.

Understanding a client's individual profile for known adherence barriers is invaluable to minimize the risk of IIT.* To offer customized care, the provider needs to understand the client's individual circumstances and preferences and incorporate these through a shared decision-making process. The Risk Assessment Tool for IIT (Annex 3) is only the starting point for engaging in a broader, honest conversation with the client according to client-centered care and motivational counseling principles.

3.1.3 Tasks to Assess and Manage Risk Factors for IIT

Case managers are recommended to engage in the following tasks to assess and manage the risk factors of ART clients to prevent IIT:

- Conduct the risk assessment using a standardized tool (see Annex 3) that has been translated in local languages and field tested to ensure cultural appropriateness. In the tool in Annex 3, population type was purposely not included as a "risk" to avoid stigmatizing particular groups. However, pregnant and breastfeeding women and their HIV-exposed infants, children (particularly those under five years who are considered to have AHD according to the World Health Organization [WHO] classification),

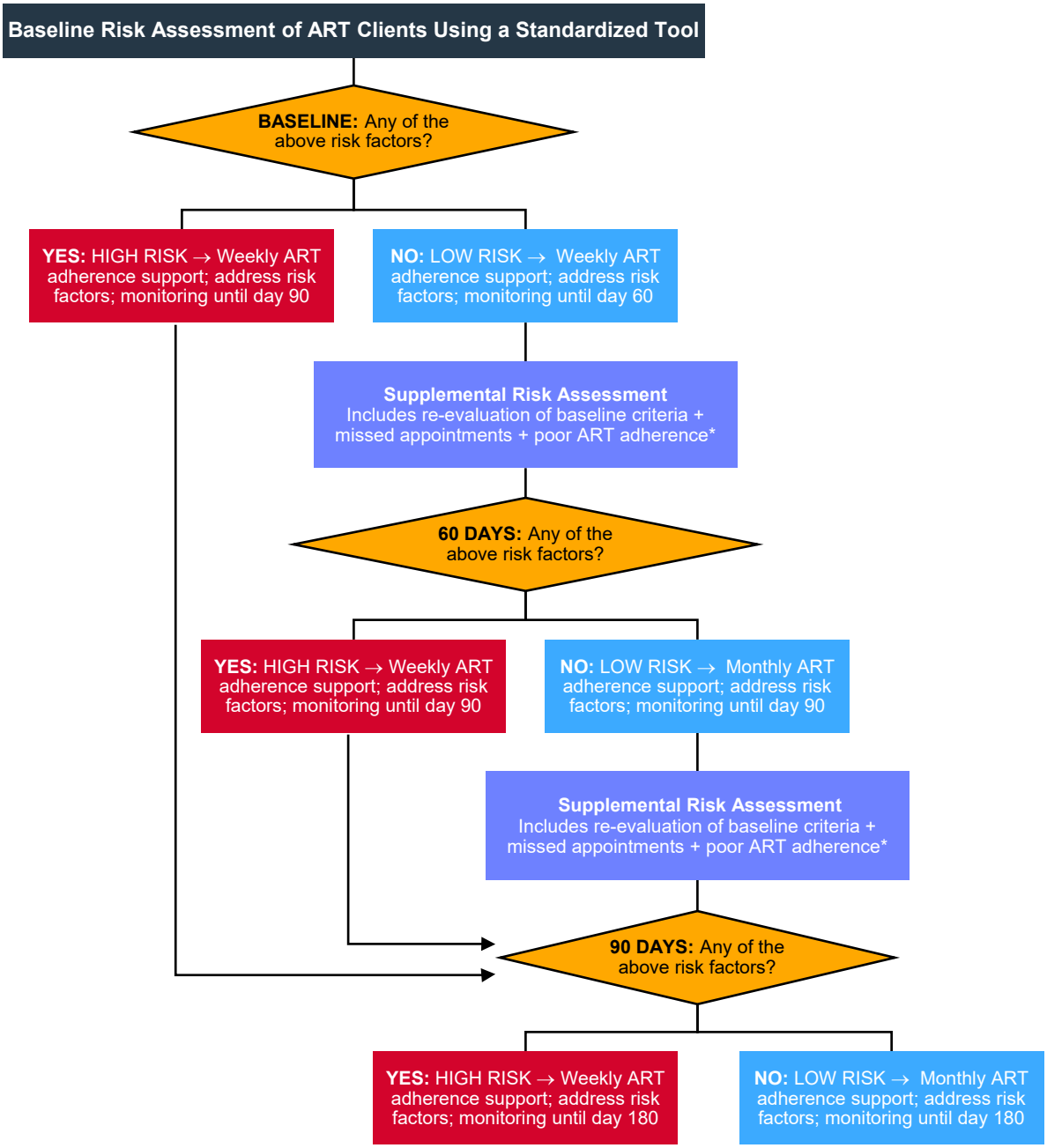
* In 2020, PEPFAR defined IIT among ART clients as having had no clinical contact for at least 28 days after the last clinical appointment or expected clinic visit. IIT is comparable with the concept of loss to follow-up as defined by WHO —with the distinction that the latter is defined as the client having had no clinical contact for at least 90 days after the last expected clinical visit. In that regard, the PEPFAR definition of IIT supports more timely identification of clients interrupting treatment.

adolescents, men, and KPs are groups often reported as having poor clinical outcomes and to whom programs might pay specific attention.

- Categorize clients as at high risk of IIT if at least one risk factor is reported.
- Offer CD4 testing.
- Use a standardized tool to assess for AHD (Annex 4), and manage AHD as per national policy as applicable. Other resources for case management around risk of IIT for AHD clients include FHI 360's Advanced HIV Disease Management and Care Toolkit and the Package of Services and Interventions for Advanced HIV Disease: A Community Guide.
- Offer relevant or appropriate services to mitigate the risk factors (Annex 5).
- Use information about the client's most frequent risk factors to develop retention protocols and interventions.
- Support and monitor clients at high risk of IIT more frequently, e.g., weekly or biweekly.
- Continuously assess risk factors after ART initiation—monthly or quarterly—to identify new clients at high risk of IIT and to assess whether high-risk clients have shifted to low risk.
- Following completion of 60 days of treatment, clients at high risk of IIT should continue being followed up and supported on a weekly basis through 90 days from ART initiation. They may be switched to monthly follow-up if adherence and appointment compliance have been good, while in cases of poor adherence and/or poor compliance to appointments, follow-up should continue weekly until 180 days following ART initiation. Clients at low risk, with good adherence and compliance to appointments, can switch to monthly monitoring beginning on day 60; otherwise, follow-up should continue at a weekly frequency and be re-evaluated at 90 days.
- If the client is evaluated as being at high risk of IIT at any time, return to more frequent support and monitoring.
- At day 90 or 180 (depending on national policy), the client should receive VL testing.
- If virally suppressed and at high risk of IIT, continue with or switch to monthly support and monitoring. If virally suppressed and at low risk of IIT, switch to quarterly support and monitoring.
- If non-virally suppressed, regardless of risk category, offer weekly enhanced support and monitoring and repeat VL test after three months. If non-virally suppressed at this VL test, move on with individualized case management.

An example of a risk assessment flow chart is provided in Figure 3.

Figure 3. Flow chart for ART case management based on risk factors, missed appointments <28 days, and VL test result



*Based on most recent ART compliance score

Documentation of reasons for refusal to start ART should also be considered and, if feasible, responses for pre-coded reasons entered in the M&E system. For example, factors could include:

- Pill burden
- Stigma and discrimination
- Lack of disclosure
- Long distance or lack of transportation to ART service location
- Unable to cover the travel cost to the ART service location
- Cannot miss work to attend ART appointments
- Feeling healthy
- Belief that ART cannot help
- Use of traditional medicine
- Mobility, migration
- Displacement, detention, living in unsecure/conflict-affected area
- Lack of peer, family, partner support
- Mental health challenges
- Substance use
- Violence
- Food insecurity
- Homelessness
- Unemployment
- Other, please specify _____

Project Example

The FHI 360-led Enhanced HIV Services for Epidemic Control (EHSEC) project in the Dominican Republic offers peer-led risk assessment and individualized support to Haitian migrants and individuals of Haitian descent living with HIV who have some risk factors like being new to HIV treatment, non-virally suppressed or have AHD, and to those who have reported violence or are unemployed and do not have housing.

3.2 Peer Support

WHO has emphasized the critical role of peer support in HIV prevention, improving retention in care, and achieving viral suppression.[12] Peers are defined as individuals who share common characteristics or experiences, including the experience of living with HIV, with those they support.[13] Peer-led programs integrated in existing HIV services are effective in engaging and supporting PLHIV by enhancing mutual trust, social support, and knowledge, and reducing perceived stigma. For example, HIV-positive mentor mothers might support other mothers living with HIV to adhere to ART through home visits. Other peer activities shown effective for increasing ART adherence and viral suppression among pregnant and breastfeeding women living with HIV and their HIV-exposed infants include flagging and tracking clients who miss appointments, actively documenting prevention of mother-to-child transmission (PMTCT) and early infant diagnosis outcomes, and a daily feedback session with supervisors.[14]

3.2.1 Peer Navigation

Peer navigation promotes access to and engagement in the HIV care continuum, including by navigating clients to clinics for check-ups, providing counseling interventions, supporting treatment adherence, and providing referrals to care. Peer navigation should be offered for ART refills, clinical assessments, VL testing, and any

other referral relevant to the well-being of the client. The navigation service should be revisited upon completion of the first 180 days and depending on the VL test result at that time. Non-virally suppressed clients should continue to be offered navigation to the ART clinic, while for those who are virally suppressed, navigation can be paused and re-evaluated later based on risk.

Peer Navigation for Key Populations: Implementation Guide provides guidance for programs implementing peer navigation as part of a core package of HIV-related interventions for KPs. Although this document focuses on specific populations, the principles and strategies it includes can be adapted for other groups.

3.2.2 Peer Support Groups

In the community peer support model, PLHIV are invited to form peer support groups, typically comprised of clients living in close proximity and led by a trained peer outreach worker or a nurse, who provides HIV prevention and treatment education. These support groups are intended to facilitate greater awareness and understanding of the importance of ART adherence and/or to actively promote it. Typically, one member collects the antiretroviral (ARV) refills on behalf of the whole group on a rotating basis, the group receives their ARVs at the meeting venue, and members provide one another with peer support. They are also used as platforms to offer index testing, pre-exposure prophylaxis (PrEP) to serodiscordant couples, condoms and lubricants, and HIV educational materials. In addition, peer support groups present an opportunity to nest economic empowerment services and additional interventions (e.g., mitigating stigma and discrimination, screening for violence, psychosocial support for mental health) that can further contribute achieving optimal clinical outcomes.

Maintaining confidentiality is critical to peer support groups. Venues where they meet are typically selected by the members and ensure safety and privacy. Personal information members share within the group is to be kept confidential. For example, if a client's clinical files are brought to the venue for documentation of clinical services, they should be kept in lockable containers. The medications for each client should be pre-packed at the health facilities, and personal identifiers should not be visible on the outside of the package.

Research has shown participation in peer support groups as beneficial at multiple levels, including the following:

- Facilitated information sharing among group members about disease progression and the importance of daily drug intake[15]
- Provided an opportunity for support group participants to encourage one other to continue attending clinical appointments[16]
- Facilitated treatment adherence by establishing a sense of connectedness and belonging to a wider community of those living with HIV[17]
- Promoted healthy lifestyle and HIV treatment adherence[18]
- Enabled individuals to speak openly with others in the same situation, facilitating an improved sense of self and greater acceptance of one's HIV status[12]
- Improved peace of mind and diminished shame and stigma[19]
- Improved mental and physical health among support group members[20]
- Facilitated access to mutual savings funds, allowing support group members to pool funds when needing assistance with food, transportation, or health care costs[21, 22]

- Decreased transportation costs, work absences, and concern about unintended disclosure given that employers and co-workers were reported to be less likely to wonder and inquire about an individual's health given fewer work absences[23]
- Provided the support group members with an opportunity to help other members, potentially boosting their own psychosocial health[19]
- Supported spiritual healing and/or spiritual connections, pointing to an important role for spirituality and faith communities to recruit group members, which should be considered for the composition, functioning, and effectiveness of the support group[19]

3.3 Mobile Phone Technologies

Globally, the number of mobile phone subscriptions has been increasing, with the fastest growth seen in resource-limited settings due to a reduction in the cost of mobile phones and subscription plans.[24] Growing evidence that mobile technologies can play a significant role in health systems strengthening has led to expanded use of these technologies in this context. In particular, short message service (SMS) messages and interactive voice response systems (IVRS) for mobile phones are promising to support ART adherence and retention in care in resource-limited settings.[25] In addition, the technologies can greatly reduce the burden on care providers and clients by automating functions that previously required ongoing human attention, for example, appointment reminders,[26] and reducing the effort associated with participation.

However, country projects should first carefully assess smartphone coverage to establish the feasibility of using different platforms—for example, mHealth (SMS and phone call) versus eHealth (internet-based)—in the local context. A 2017 systematic review of the perceived feasibility of various digital platforms found that mHealth (SMS and phone call) interventions were rated as highly feasible in 75 percent of studies, whereas eHealth (internet-based) interventions were highly feasible in just 45 percent of studies,[16] although we would note that the technology landscape is rapidly changing. In addition to assessing smartphone coverage, projects should conduct an assessment to understand client preferences for appointment reminders (e.g., SMS versus IVRS), as well consider using these platforms to deliver other messages to strengthen clients' ART adherence and communicate messaging around treatment literacy (e.g., see EpiC Spotlight on Treatment Literacy), VL monitoring, and the concept of undetectable=untransmittable (U=U).[27]

3.4 Incentives to Address Structural Barriers

Incentives can play a role in addressing the ART client's challenges and needs. Incentives aim to reinforce and shape healthier behavior through the provision of a reward to accomplish a specific task or behavior. Individuals frequently weigh present costs and benefits relative to those in the future, and incentives can act as a "nudge" toward adopting a healthy behavior by increasing its immediate benefits. Incentives may also provide households "social protection" to maintain health care when income is uncertain.

When considering incentives as part of the HIV program, projects should conduct an assessment to understand incentive preferences among the target audience, develop a safety framework and tools to avoid abuse and/or misuse of the incentives, develop specific criteria for determining who is eligible to receive incentives, set up systems to electronically transfer incentives, and consider linking incentives to specific behaviors, e.g., attendance at clinic appointments, ART refills, ART adherence, VL testing uptake, and viral suppression.

Incentives can take multiple forms beyond cash transfer. For instance, an incentive could consist of a nutrition assessment and counseling plus food baskets[28] or food vouchers to support ART adherence; transport allowance to facilitate ART refills; SIM cards and airtime to ensure regular communication between the client and peer navigator, case manager, or other member of the ART team; or small prizes awarded through a drawing conditional, for example, on attending scheduled clinic appointments or achieving at least 90 percent adherence to ART.[29]

Project Example

The FHI 360-led EHSEC project in the Dominican Republic uses an integrated case management approach designed to be responsive to client needs. As part of this approach, the project offers food vouchers, a SIM card, airtime, and transport allowance to Haitian migrants and individuals of Haitian descent ages ≥15 years and living with HIV. From baseline to endline, following implementation of the incentives, ART initiation increased from 38 percent to 98 percent.

3.5 ART Adherence Support and Monitoring

Poor adherence to ART has been associated with missed appointments to pick up medication refills and, in turn, IIT. According to one study in Uganda,[30] missing clinic appointments was associated with poor adherence to treatment among ART clients and increased risk of poor immunological outcomes. Discontinuation or interruption of ART may result in viral rebound, immune decompensation, and/or clinical progression. It is important to assess an individual's barriers to adherence to ART and to compliance with clinic or ART refill appointments before or shortly after ART initiation and regularly thereafter. This can help identify specific indicators that influence adherence to ART.

To improve adherence to and retention on ART, current DSD models must be modified to better accommodate individual-level client needs and preferences. That is, the DSD

model only decentralizes services, which is not sufficient to ensure good adherence and retain clients in care. At the individual level, barriers to adherence include beliefs about medicines, lack of motivation, side effects, lack of access to adequate food, stigma, lack of social support, and poor relationships with health care providers.[31] Common mental health disorders such as depression are highly prevalent in PLHIV and have consistently been associated with worse adherence to ART in lower- and middle-income countries.[32] Conducting client risk segmentation is key to understanding each client's barriers, identifying support needs, and providing enhanced support to ensure that high-risk clients have good adherence and reach and maintain viral suppression. The provision of people-centered care such as individualized adherence counseling can support shared decision-making and planning for ART, facilitate behavior change, and improve HIV treatment outcomes.[33]

Various health interventions have been implemented with the intention of improving adherence and retention among clients on ART. However, rather than using a one-size-fits-all approach, careful consideration should be given to understanding the settings where different interventions work best and what interventions are effective for high-risk groups, including youth, pregnant women, those with comorbidities, individuals with mental health disorders, and KPs.

For many clients, ART adherence patterns can change over time. They may struggle with adherence at some point in their lifetime due to issues such as nondisclosure, internalized HIV stigma, substance use, and mental health disorders such as depression that negatively affect adherence.

Although self-reported pill intake, pill counts, and prescription refills are proxy measures for ART adherence, versus VL which is an objective biological marker of adherence, we suggest integrating these adherence monitoring methods into ART counseling with clients. As part of case management, clients should be offered adherence counseling during in-person or virtual meetings, the frequency of which should be determined through risk assessment. Health care providers trained on motivational counseling and ART adherence support, monitoring, and counseling, such as nurses, clinicians, the case manager, or peer navigators, should use a standardized job aid to guide the conversation (e.g., EpiC's HIV Treatment Adherence Counseling and Retention Guide: A Job Aid for Counselors and Providers Working with People Living with HIV).

3.5.1 Tasks to Identify and Mitigate ART Adherence Barriers to Reach and Sustain Viral Suppression

The following tasks are recommended to support and monitor ART adherence and ensure that clients reach and maintain viral suppression. The case manager may either implement the tasks directly or delegate them to the peer navigator, except where indicated.

- Document and ensure that the contact information of the client and their backup contact are regularly updated in the client files; this can be done during any encounter with the client.
- Obtain consent to contact the client in person and virtually across the continuum of care.

- Initiate treatment-naïve clients on ART and switch follow-up clients to an optimized regimen (e.g., DTG-based regimen). *(Task cannot be delegated to peer navigators with no clinical background.)*
- Offer DSD, DDD, and MMD as per national guidelines.
- Regularly assess the client's risk using a risk assessment tool (e.g., Annex 3). Based on the client's risk category, determine the frequency of support and types of services that should be offered to the client.
- Ensure that continuous risk assessment informs changes in the frequency of support provided to the client and that these changes are communicated to the client.
- Offer linkage to the client's preferred peer navigator and explain the purpose of peer navigation support.
- Offer in-person and/or virtual support (see FHI 360's Going Online to Accelerate the Impact of HIV Programs resources) to monitor and document the client's ART adherence through a standardized job aid, reassess client risk monthly or quarterly using the risk assessment tool, and offer services as appropriate according to the client's risk category and risk factors.
- Send appointment reminders (manually or automatically) to the client, such as one week before and again 48 hours prior to the appointment.
- Offer enhanced ART adherence counseling to clients who report poor adherence.

3.6 Re-engagement on ART

Re-engagement is part of the HIV care cascade, given that individuals may move in and out of care following diagnosis and across their lifetime. Studies estimate that 25 percent to 75 percent of disengaged patients who have been on ART with 6 months to 15 years of follow-up return to care, with a higher return rate closer to initial disengagement.[34] In Tanzania, clients who interrupted treatment and then successfully re-engaged in care described having typically leveraged social support networks during the treatment interruption but also feeling guilt and shame for having disengaged.[35] Community outreach and re-engagement programs should target clients with a recently missed appointment rather than waiting until the client is categorized as IIT. These early re-engagement efforts may be particularly important given evidence that the longer an individual is absent from HIV care, the higher the chance of virological rebound and the less invested they may become in their care and treatment.[34] Developing strategies to facilitate early re-engagement through flexible attendance policies, improved client-provider interactions, and outreach and support for disengaged clients is strongly recommended.

Effective re-engagement support requires an understanding of individual client experiences both while clients were on ART and during their IIT, and how these translate into their return to care. It also requires building strong client-provider relationships up front, regularly updating contact information in the client files and, if the client agrees, ensuring that the client is linked to a peer outreach worker or peer navigator who has regular contact with the client.

Evidence suggests that poor client-provider communication negatively affects ART client retention in care. Clients have reported valuing the establishment of rapport as a

foundational aspect of effective client-provider communication, while providers have described "responding to emotional needs," "eliciting patient conflicts and perspective," and "partnering to mitigate conflicts" as ways to address barriers to engagement.[36] Clients who have disengaged have described feeling that providers' communication of their "reacceptance" prompted them to re-engage sooner and that tailored "partnering to mitigate conflicts" would be more effective in sustaining re-engagement than the standard adherence education providers typically offer.[37]

3.6.1 Tasks to Manage Missed Appointments and IIT

The following tasks are recommended to manage missed appointments and IIT. The case manager may directly implement all tasks.

- Monitor compliance to appointments (e.g., for ART refills, clinical assessment, VL monitoring) on a daily basis.
- Contact clients via phone within 24–48 hours of a missed appointment on three different occasions (on different days and times of day) within one week.
- Create a weekly line list of clients who missed an appointment and have not yet rescheduled, and of those who have interrupted treatment.
- Conduct up to three community or home visits (on different days and times of day) within three weeks.
  - If the client is not found through calls and home or community visits, reach out to the contact person via calls and home or community visits using the same protocol as for the client.
  - Clients who are reported as dead or as transferred out are not eligible for further tracing.
  - Clients who are detained should be linked to the specific program offering HIV services to prisoners.
  - Clients who refuse ART and those who are undecided should be offered psychosocial support through a specialized cadre, e.g., a mental health professional, psychosocial support officer, or psychologist.
- Within four weeks, the outcome of the client follow-up should be documented and discussed by the case management team.

Further tracing of clients who could not be located within the four-week cutoff should be decided according to operational issues and on a case-by-case basis.

If it is not possible to trace all clients, priority should be given to those with missed appointments and those with the most recent IIT—as they carry a higher chance of being located and re-engaged—as well those with AHD and those not virally suppressed.

An important bottleneck in the tracing activities is missing or unreliable client contact information. For this reason, it is important to document and regularly update contact information in monitoring systems and engage peer navigators to ensure regular contact with ART clients.

- It is recommended to identify clients who periodically miss appointments and interrupt treatment to offer them enhanced ART adherence counseling and reinforce motivating messages about reaching and maintaining undetectable VL; otherwise, with IIT, clients will have increased risk of HIV disease progression and opportunistic infections.
- Clients who interrupt treatment and return to care should be assessed for AHD through CD4 testing and offered the AHD package, as appropriate. For clients with suspected treatment failure and AHD, CD4 cell count and VL testing should be carried out in parallel. Where VL testing is not available, the decision to switch regimens should be assessed according to individual clinical presentation.
- Clients re-engaging in care after treatment interruption should be rapidly reinitiated on ART on the same day.

After the client is re-engaged on ART, their reasons for IIT should be documented and used to create a personalized adherence support plan that meets the client's needs. During this process, the case management teams should welcome clients back with a nonjudgmental approach, which is critical to supporting re-engagement. Providers, case managers, and peer navigators should reinforce the motivational messaging that an undetectable VL is the goal of ART for all PLHIV, both to benefit their own health and prevent onward transmission.

Project Example

In Eswatini, the FHI 360-led EpiC project engaged a dedicated case manager and a pool of ART peer navigators to support adherence and help prevent IIT. This case management team offered regular ART adherence counseling and support to clients, as well as provided DDD through mobile outreach services at community hot spots and clinics led by civil society organizations (CSOs). Using this case management approach, EpiC Eswatini reduced IIT from 5 percent in 2022 to 0.8 percent in 2024.

In Mali, ART case management included engaging peer navigators to trace clients with IIT as part of a series of back-to-care campaigns. Through these campaigns, EpiC Mali doubled the proportion of clients returned to treatment from 2022 to 2024.

Project Example

As part of ART case management in two FHI 360-led projects—Ending AIDS in West Africa (#EAWA) in Burkina Faso and Togo, and the USAID HIV Support in PNG project in Papua New Guinea—back-to-care campaigns were implemented to trace and support clients disengaged from care. Tracking and tracing lists were developed from facility records, and clients were followed up through phone and home-based tracing. Re-engagement interventions included identifying and addressing barriers, providing social support, conducting motivational interviewing, and providing MMD. As a result of these efforts, among those identified as having IIT, 67 percent of 10,362 clients in Burkina Faso, 55 percent of 9,299 clients in Togo, and 15 percent of 1,126 clients in Papua New Guinea re-engaged in care. Through the back-to-care campaigns, some clients originally categorized as having IIT were found to have transferred to other ART clinics for treatment without advising the tracing clinic (10 percent in Burkina Faso, 31 percent in Papua New Guinea, 16 percent in Togo).[38, 39]

For caregivers of children living with HIV, the assessment and counseling should include a check on the caregiver's well-being (including HIV and ART status) and mental health, asking whether HIV status has been disclosed to the child, and encouraging participation in caregiver support groups.

Discussion of IIT with the client should also include exploring whether the client used any buffer stock or treatment sourced elsewhere to cover the period following the missed appointment(s).

Reasons for IIT should be documented in the M&E system, including using the following pre-coded reasons, among others:

- Side effects
- Pill burden
- Stigma and discrimination
- Lack of disclosure
- Poor quality of ART service, e.g., breach of confidentiality, long waiting time, lack of empathy among providers
- Long distance or lack of transportation to ART service location
- Unable to cover travel cost to the ART service location
- Cannot miss work to attend ART appointments
- Feeling healthy
- Belief that ART cannot help
- Use of traditional medicine
- Mobility, migration
- Displacement, detention, living in unsecure/conflict-affected area
- Lack of peer, family, partner support
- Mental health challenges

- Substance use
- Violence
- Food insecurity
- Homelessness
- Unemployment
- Other, please specify _____

Upon returning the client to care, the following outcomes can be used to categorize and document client status:

- Active on ART (if no prior IIT)
- Missed appointment, if <28 days have passed since the last appointment
- Returned to ART (if prior IIT)
- Transferred out
- Died
- IIT, if ≥28 days has passed since the last appointment (disaggregated by on ART <3 months, 3–5 months, >6 months)
- Refused or stopped ART

The outcome of clients previously categorized as IIT and who have been located (directly or indirectly) should be updated in client records and in reports.

Project Example

The EHSEC project in the Dominican Republic engages peer navigators to gain a better understanding of the circumstances that affect clients' ability to attend appointments and continue treatment. In 2024, 32 percent of the clients reported feeling healthy as the main reason for IIT, followed by inability to miss work (16 percent); fear of deportation (11 percent); mobility, care by traditional healers, and stigma and discrimination (8 percent each); distance and family issues (5 percent); and ARV side effects, long waiting time at the clinic, and being detained by immigration (3 percent each). A psychologist supported clients to address their barriers to ART adherence. The information was also used to design specific interventions to strengthen overall program retention and viral suppression.

3.7 HIV Viral Load (VL) Monitoring

Reduction in VL has a strong impact on community HIV prevention, not only since PLHIV with undetectable VL cannot sexually transmit HIV, but also with regard to improving maternal health and preventing vertical transmission as countries approach epidemic control. Critical elements to sustain epidemic control include routine VL monitoring through timely line listing of eligible clients, decentralized sample collection through dried blood spot (DBS)/plasma blood sample (PBS), improved supply chain management and equipment maintenance, reduced turnaround time for results, accurate documentation of test results, and strengthened U=U literacy (e.g., the LINKAGES resource U=U | Undetectable=Untransmittable) among clients and within communities at large.

3.7.1 Tasks to Ensure Timely Blood Sample Collection for VL Testing of Eligible Clients

The following tasks are recommended to ensure that clients receive timely VL testing. The case manager may either implement the tasks directly or delegate them to the peer navigator, as appropriate.

- Track VL test commodities monthly and coordinate with the laboratory point person to ensure uninterrupted availability.
- Generate weekly line list of ART clients eligible to receive a VL test:
  - ART clients who have completed six months of treatment and not yet had VL test
  - ART clients not virally suppressed and who have completed three sessions of enhanced ART counseling, three months after last VL test date
  - ART clients who are virally suppressed 12 months after last VL test date
- Plan weekly for VL sample collection, as follows:
  - Using line list of individual clients as a reference
  - Marking the files of ART clients due for an appointment within the following one month in order to collect the VL sample at the next appointment
  - Contacting ART clients whose next appointment is more than one month away to plan VL sample collection as soon as possible; tracing any clients who cannot be contacted (see Tasks to Manage Missed Appointments and IIT)
- Offer VL sample collection at the ART clinic or in the community, depending on client needs.
- Collect VL samples (daily) by allocating staff for sample collection; prioritize sample collection using DBS instead of full blood whenever possible.
- Store samples (daily).
- Transport samples to VL testing laboratory (daily or multiple times each week).
- Synchronize date of the next appointment to the date when VL testing is due.
- Contact the clients due for VL testing to remind them of the importance of attending the appointment.
- Inform clients of laboratory hours of operation for sample collection.
- Plan for transporting the sample to another laboratory if the machine is faulty or has reached capacity, reagents are not available, the on-site refrigerator is not available or has reached capacity, or VL test samples cannot be stored for processing beyond the day of sample collection.

From a programmatic perspective, optimizing diagnostic networks can significantly enhance HIV VL testing coverage by improving accessibility, efficiency, and integration of testing services. For instance, analysis of the geographic distribution of health facilities and clients can help identify optimal testing locations, while assessment of sample transportation can result in more efficient systems that ensure timely sample collection and delivery of test results, such as through the use of integrated sample referral systems and decentralized point-of-care diagnostics. Multiplex testing also represents an opportunity to improve VL monitoring by tapping into existing platforms that support diagnostic testing for other pathogens like tuberculosis (TB) and human papillomavirus (HPV), and to reduce costs associated with reagents, labor, equipment. The engagement of private laboratories could expand testing capacity, allowing for more samples to be tested in a shorter time; address shortages of reagents or equipment breakdown in the public sector; and contribute to sustainability of the program.

3.7.2 Tasks for Timely Tracking of Pending VL Test Results

The following tasks are recommended to ensure timely tracking of pending VL test results. The case manager should be responsible for directly implementing the tasks.

- Create weekly line list of ART clients whose VL test result remains pending more than two weeks after the sample was sent to the VL testing laboratory.
- Collaborate with the VL testing coordinator/manager to obtain the VL test results.

Table 1 provides an example of pre-coded VL outcomes based on laboratory feedback which could be documented in the M&E system and marked for follow-up action.

Table 1. VL testing outcomes and corresponding follow-up actions

Viral Load Testing Outcome	Follow-up Action
Sample for VL test not received by laboratory	Contact client and collect new VL sample within one week.
Sample for VL test not yet processed by laboratory	Follow up with laboratory weekly.
Sample for VL test not valid	Contact client and collect new VL sample within one week.
Sample for VL test processed but result not available	Follow up with laboratory weekly.
Sample for VL test processed, result available, and viral suppression achieved	Document VL test result and inform client on the same day.
Sample for VL test processed, result available, and non-virally suppressed	Document VL test result, inform client on same day, plan enhanced ART counseling, and repeat VL test in three months.

3.7.3 Tasks for Management of Non-Virally Suppressed Clients

The following tasks are recommended to manage non-virally suppressed clients. The case manager may either implement all tasks directly or delegate them to the peer navigator, except where indicated.

- Create weekly line list of all ART clients not virally suppressed at last VL test.
- Screen for AHD.
- Create weekly plan for offering enhanced ART counseling to ART clients who have not yet started ART and those with IIT, by:
  - Marking the files of ART clients due for an appointment within the following one week, to offer enhanced ART counseling
  - Contacting ART clients whose appointment is more than one week away to offer enhanced ART counseling; engaging peer navigators to trace clients who cannot be contacted (see Re-engagement on ART)
- Track progress weekly on completion of the three enhanced ART counseling sessions; line list ART clients who have completed it and plan for VL sample collection.
- On a weekly basis, line list all ART clients not virally suppressed at the second VL test.
- On a weekly basis, discuss with ART case management team whether to switch clients with two consecutive non-suppressed VL test results to second-line regimen.
- Contact ART clients whose appointment is more than one week away to inform them of the plan; trace clients who cannot be contacted (see flow chart in Figure 4).

Emerging evidence shows that VL “blips” above 50 copies per mL are associated with increased risk for subsequent virological failure. Given this, when resources permit, close monitoring and enhanced adherence support may be useful as part of the differentiated case management package for these individuals.[40]

Importantly, ensure that non-virally suppressed clients are supported by a peer navigator or member of the case management team with extensive experience in ART adherence counseling and, if available, offer these clients psychosocial support services by specialized cadres.

Project Example

The EpiC Nepal and EpiC Mali projects led by FHI 360 developed a VL dashboard for site-specific weekly tracking of the number of clients eligible for VL testing and clients whose samples were collected and tested. The project also provided technical support to the public laboratories to ensure that VL testing equipment was in functional condition and that the supply of reagents was uninterrupted. From 2020 to 2024, VL testing coverage increased from 54 percent to 73 percent in Nepal and from 45 percent to 95 percent in Mali.

3.7.4 Interventions to Improve VL Testing Coverage and Viral Suppression

The following resources present evidence-based interventions that have improved VL testing coverage and suppression:

- Targeted Solutions to Increase Dolutegravir Coverage, Viral Load Testing Coverage, and Viral Suppression among Children Living with HIV in Togo
- Decentralizing Viral Load Testing through the Private Sector: A Promising Strategy for Expanding Testing Coverage among Key Populations in Botswana
- Liberia's Multipronged Strategy to Improve Viral Load Testing among People Living with HIV
- Strategies for Improving Viral Suppression among CLHIV in Nigeria

3.7.5 Interventions for Other Health Services

Other services should be offered to ART clients, including the following:

- **Self-care,** by educating clients on how to maintain health and cope with illness, including disease prevention and control, seeking hospital/specialist care when needed, self-hygiene (general and personal), nutrition (healthy choices about the type and quality of food eaten), lifestyle (e.g., sports activities, leisure), environmental factors (e.g., living conditions, social habits), socioeconomic factors (e.g., income level, cultural beliefs), and self-medication.[41]
- **Integration of HIV and primary health care,** e.g., nutritional support, screening and services for hepatitis, asthma, diabetes and hypertension other noncommunicable diseases, as feasible and appropriate.[42-44]
- **Mental health services,** as having HIV is linked to greater risk for developing mental health conditions like depression, anxiety, personality disorders, and cognitive disorders. Clients should be educated about and assessed for mental health conditions and offered services as needed. FHI 360's The 8Cs Model of Collaborative Consultation for Mental Health and Psychosocial Support Programs guidance document describes the 8Cs Model, which provides a roadmap of the resources available for technical advisors and program managers to integrate mental health and psychosocial support into development, humanitarian, and public health programs.
- **Sexual and reproductive health services**, including contraception and syphilis testing and treatment. FHI 360's Integrating Family Planning into HIV Programs: Evidence-Based Practices provides technical guidance with recommendations for institutionalizing and scaling up integrated family planning and HIV services. Use of a dual HIV/syphilis rapid diagnostic test, a simple, proven, and cost-saving test,[45] is recommended, particularly in antenatal care and in the context of KP programs.
- **Cervical cancer screening for females living with HIV**. FHI 360's Cervical Cancer Screening in Nigeria describes an integrated approach that can be used to raise awareness and increase access to cervical cancer screening and treatment in the context of integrated delivery of HIV services.

- **Index testing to elicit sexual and injecting partners and biological children** should be offered as part of the HIV post-test counseling; periodically, as clients might acquire new partners; and particularly when clients are not yet virally undetectable. FHI 360's Index Testing and Risk Network Referral: Program Implementation Orientation and Training Package provides guidance for HIV programmers to train on and develop, adapt, or revise index texting services for PLHIV and their children, sexual and drug-injecting partners, and peers in their risk and social networks.
- **Violence prevention and response** should be mainstreamed into HIV services and **screening for intimate partner violence** should be integrated into index testing.
- **PrEP services** should be offered to HIV-negative partners of non-virally suppressed clients living with HIV. PrEPWatch: The One-Stop Clearinghouse for Global PrEP Resources offers a wide range of information and tools to effectively provide PrEP services, for example, among serodiscordant couples.
- The following **vaccines** are recommended for PLHIV: mpox (if risk of exposure),[46] COVID-19,[47] hepatitis A and B, HPV, influenza, meningococcal disease, pneumococcal disease, diphtheria-tetanus-pertussis, and zoster for those ages 18 years and older.

4. Enabling Policies for ART

Developments in HIV policies in the past several years have had a major influence on the need for and ways case management should be supported for treatment success. In the context of ART case management, the key policies described here should be in place.

4.1 Test and Treat or Same-Day ART/Rapid ART Initiation

Prior to WHO's "Treat All" policy, 23 percent of people on ART in sub-Saharan Africa were thought to have poor adherence.[48] Evidence that immediate initiation of ART after a positive HIV test result could contribute to epidemic control prompted the updating of WHO's 2013 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach and the launch of the second edition in 2015, Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach. This strategy has brought about considerable changes in many African countries, with test-and-treat policies implemented in almost all countries.[49] Following the advent of universal test and treat and same-day/rapid ART initiation, findings from a review from sub-Saharan African countries suggest that adoption of the policies described below for optimized ART, DSD, MMD, and DDD to expand ART uptake and reduce HIV transmission at the population level may improve early (within the first six months) retention in HIV care.[50]

4.2 Optimized ART

In 2019, WHO's Update of Recommendations on First- and Second-Line Antiretroviral Regimens recommended DTG, if available as fixed-dose combination, as the preferred ARV drug in first-and second-line regimens, including safety and efficacy among pregnant women and people coinfected with TB. The availability of safer and more efficacious ART regimens has increased as integrase inhibitors have become more affordable for lower- and middle-income countries. FHI 360 has also an informational sheet, Tenofovir, Lamivudine, and Dolutegravir (TLD) Transition: General Information for Clients, Clinicians, Counselors, and Other Service Providers, with information about transitioning clients from tenofovir-lamivudine-efavirenz (TLE) to TLD.

4.3 Differentiated Service Delivery (DSD)

DSD models respond to diverse needs and preferences of clients—for example, KPs, children and adolescents living with HIV, pregnant and breastfeeding women, and HIV-exposed infants, among others—through in-person and/or virtual case management services offered at the client's home, preferred community venues, or a facility. It is

designed according to client concerns around structural barriers such as stigma and discrimination, violence, mental health, privacy, and confidentiality. In addition, it ensures continuity of care and treatment services beginning soon after HIV diagnosis, a critical component to achieve good health outcomes, prevent increased mortality in a public health care setting, and reduce the risk of viral rebound. Services may be provided through community-based organizations (CBOs), civil society organizations (CSOs), or public or private clinics, depending on client preferences and needs, project operational requirements, and threats such as security or public health emergencies.[51-53]

In 2021, WHO's Updated Recommendations on Service Delivery for the Treatment and Care of People Living with HIV recommended DSD as an approach that simplifies and adapts HIV services to better serve the needs of PLHIV and optimize the available resources in health systems. Recent innovations in DSD for HIV treatment for clients established on ART can be categorized into four models: groups managed by health care workers, client-managed groups, facility-based individual models, and out-of-facility individual models.[54] DSD for HIV treatment has focused primarily on people who are clinically stable/established on ART. More recently, there has been recognition of the need to adapt services for those with AHD, poor adherence, high VL, and comorbidities through simplified care packages and differentiated models of service delivery. Multiple models can work in parallel, and clients can move across models as their needs change during their lifetime. The models are also flexible to accommodate clients who may want to be referred.

4.4 Multimonth Dispensing (MMD)

WHO recommends dispensing ART every three to six months for people established on ART,[†] since this appears to be associated with improved outcomes compared to monthly schedules. The organization's 2021 Updated Recommendations on Service Delivery for the Treatment and Care of People Living with HIV encourages clinical visits and/or ART refills every six months, if feasible, and extends the criteria of "stable on ART" to those on ART for at least six months with at least one VL test showing suppressed VL in the past six months. FHI 360's Multi-Month Dispensing of Antiretroviral Medications for Adolescents and Children Living with HIV offers tools to educate and encourage discussion about MMD of ARVs among providers, case workers, counselors, caregivers, and children and adolescents living with HIV.

4.5 Decentralized Drug Distribution (DDD)

Effective and sustainable delivery of ART to a growing number of PLHIV requires innovative approaches to make services more convenient for the clients and reduce the burden on health systems. One innovative approach to ART provision includes transitioning clients currently receiving ART in public high-level facilities to obtain their refills from the private sector (e.g., community pharmacies, private hospitals, and automated dispensing models), CSO/CBO-led clinics, and satellite lower-level public facilities. Guidance on this model from the EpiC project is available at Meeting Targets and Maintaining Epidemic Control (EpiC): Decentralized Drug Distribution.

[†] Defined as receiving ART for at least six months; no current illness, which does not include well-controlled chronic health conditions; good understanding of lifelong adherence; adequate adherence counseling provided; and at least one suppressed VL result within the past six months (if VL is not available, CD4 >200 cells/mm3 or weight gain, absence of symptoms, and concurrent infections); for children 3–5 years, CD4 cell count >350 cells/mm3).

4.6 Task Shifting and Task Sharing

Human resources for health is an essential health system building block. WHO's 2010 Monitoring the Building Blocks of Health Systems: A Handbook of Indicators and Their Measurement Strategies advises that health systems have adequate human resources for health engaged in service delivery to improve population health. However, there is a chronic shortage of health workers globally.[55] Task shifting and task sharing were initially recommended by WHO in the context of the HIV epidemic but are used in a variety of public health settings to meet demand for health services and address workforce shortages.[56]

4.7 Community Engagement and Peer-led Services

Communities are recognized as a "critical catalyst" to achieving the health-related targets in United Nations Sustainable Development Goal (SDG) 3 ("Good health and well-being"). Similarly, the HIV sector is increasingly recognizing that communities living with and disproportionately affected by HIV should play a prominent role in the global response.[57] The comparative advantage of community-led HIV responses is predicated on several factors, including credibility with community members, ability to adapt to changing contexts and policy priorities, maintaining influence both within the community and at the policy level, community ownership, and iterative interactions and alliances with authorities resulting in accountability gains.[58, 59] Likewise, several studies have reiterated the point that having interventions that are community based is insufficient for producing improved outcomes—instead, interventions must be peer-led, of high quality, and strengthen capacity through skill building to ensure stronger, community-endorsed outcomes. Peer-led responses are not only feasible but also effective in producing higher service-related yields.[60, 61] Peer support for PLHIV has gained increasing traction and is considered to be one way to take an active role in self-management. There is also increased recognition that peer-led interventions and Community–Led Monitoring Tools — PEPFAR Solutions Platform complement general health care services and contribute to meeting consumer health care needs.

4.8 Community-led Monitoring

Community-led monitoring should be conducted to regularly inform case management. In addition, empowering clients and the local community through monitoring enables them to improve the quality of HIV services. (See EpiC's Community-led Monitoring Resources).

5. Enabling Systems for ART

5.1 HIV Supply Chain Management

Procurement and supply chain management (SCM) are critical processes required to move HIV-related supplies from manufacturers to clients. Procurement is the country-level process of ordering ARVs and other HIV-related supplies for laboratory testing (e.g., CD4, HIV VL, lipoarabinomannan [LAM], TB Xpert, Ag cryptococcus) and opportunistic infection prophylaxis and treatment (e.g., TB, cryptococcus), while SCM is the mechanism by which supplies are delivered to health care facilities. Effective and efficient communication between central, regional, and local health facility levels, quantification, secure transport, and quality assurance of medical products are all required parts of a functional supply chain. Tools already exist with measurable indicators across various aspects of the supply chain, and such tools should link across central-, regional-, and facility-level indicators. The following summarizes SCM best practices from the literature[62]:

- Calculate the minimum and maximum levels of pharmaceutical stock needed over a specified period, taking into consideration buffer stock, stock used during lead time, and order quantity for one supply period.
- Use electronic systems to assist with tracking services and products delivered to clients, fulfilling new monthly orders, maintaining stock records, and reporting these records to higher-level offices.
- Use guidelines in inventory control to improve performance of logistics systems.
- Recheck the medications and labs requisition request (verifying calculation, order, and inventory stock) before an order is sent to the central or regional level to reduce order verification errors.
- Calculate the order fill rate to cut down the number of emergency and/or unfilled orders, and ensure staff are consistently aware of order dates to avoid late orders.
- Document any newly received or issued products in stock-keeping records. Further update the entries either when stock is counted during a physical inventory or as soon as a loss is noticed.
- Use security, monitoring, and auditing as methods to prevent stock-outs and losses.
- Good inventory control includes appropriate storage space, stock rotation, stock arrangement, cleanliness, security, and fire prevention.

- Assess the stock status of each product in the storeroom regularly (monthly) by staff, comparing the quantities on hand with the quantities entered in inventory control cards.
- Use standard operating procedures (SOPs) for the prescribing process in the event of stock-outs to standardize actions among prescribers.
- Ensure active communication between pharmaceutical and nonpharmaceutical staff regarding shortages and stock-outs to increase consistency and accurate recording of prescriptions.
- Account for national policies and new product introduction to ensure accurate ordering, e.g., MMD and DTG-based regimen.

5.2 Community-Facility Partnership

The partnership between community and facility ART teams is crucial to ensure a continuum of HIV care. Tracking the continuum of care is important for individual-level clinical care to achieve and maintain viral suppression through treatment using ART. At the population level, it provides a framework to analyze the proportion of PLHIV in a community engaged in each step of the continuum. It also allows policymakers and service providers to identify gaps in services and develop strategies to support individuals in improving health outcomes for those with HIV. The use of the client's unique identification code (UIC) is essential to track the continuum of care across community- and facility-based services.

To facilitate the continuum of HIV care for PLHIV, it is critical that all providers involved in a client's care regularly communicate and share client information in alignment with confidentiality protocols. To this end, facility-based and community-based providers at all levels should form part of the ART case management team and participate in regular meetings, including with the team from the OVC program. The latter should provide the opportunity to enroll eligible clients (e.g., PLHIV <19 years and their caregivers) into OVC programs.

5.3 Monitoring and Evaluation (M&E)

The case management team should work closely with the M&E team responsible for generating the aggregated reports and clients line lists for clinical follow-up.

5.3.1 Data Documentation and Use for ART Case Management

Documentation of risk factors for IIT (e.g., ART-naïve, AHD, re-engaged in care, not virally suppressed, pregnant, unemployed, high mobility), reasons for refusal to start or continue ART, and reasons for IIT are critical to inform and improve programming by prioritizing support of clients and offering client-centered care. Data can be used automatically through an electronic M&E system that generates line lists of clients having these risks for use by case managers, for example, but also for multivariate analyses and to continue learning about the predictors of poor adherence, missed appointments, or IIT.

Program data can also be used in machine learning. For example, machine learning models can be developed using routinely collected service delivery data and then integrated into routine health management information systems.[63] Such models can improve the targeting of interventions through differentiated models of care before HIV clients interrupt treatment, resulting in increased cost-effectiveness and improved patient outcomes.

5.3.2 Indicators

Table 2 provides the key indicators that should be monitored on a regular basis, monthly at minimum, using aggregated data. The benchmarks represent the percentage goals for the program.

Table 2. ART indicators and benchmarks to be monitored regularly

Indicator	Definition	Program Benchmark
ART initiation	Number of clients living with HIV who have started ART	≥95% of clients living with HIV have started ART
Same-day ART initiation	Number of clients living with HIV who started ART within 7 days	≥95% of clients living with HIV started ART within 7 days
New on ART with CD4 test coverage	Number of clients living with HIV who started ART and received CD4 test	≥95% of clients living with HIV who started ART received CD4 test
New on ART with CD4 ≤200 receiving AHD care	Number of clients living with HIV who started ART and had CD4 ≤200 and received AHD care	≥95% of clients living with HIV who started ART and had CD4 ≤200 received AHD care* **As defined by national policy*
Retention on ART	Number of clients living with HIV and currently on ART (attended their last appointment)	≥95% of clients living with HIV who started ART are currently on ART
Risk of IIT	Number of clients living with HIV, currently on ART (attended their last appointment), and received risk assessment for IIT at last visit	≥95% of clients living with HIV who started ART, are currently on ART, and received risk assessment for IIT at last visit
DTG coverage	Number of clients living with HIV and currently on DTG-based ART regimen	≥95% of clients living with HIV and currently on ART receiving DTG-based regimen
MMD coverage	Number of clients living with HIV and currently on ART receiving MMD (dispensing of 3–5 months or 6 months of ARVs)	≥95% of clients living with HIV, currently on ART, receiving MMD* **Depending on eligibility criteria for MMD as defined by national policy*
Missed appointment	Number of clients living with HIV and currently on ART who missed their last ART appointment (<28 days from last appointment)	≤95% of clients living with HIV, currently on ART, and missed their last ART appointment
Interruption in treatment	Number of clients living with HIV who interrupted treatment (>28 days from last appointment), disaggregated by <3 months on ART, 3–5 months on ART, >6 months on ART	≤2% of clients living with HIV and currently on ART interrupted treatment
Good adherence	Number of clients living with HIV and currently on ART who reported good adherence at last visit (good adherence defined as ≥6 doses within last week)	≥95% of clients living with HIV and currently on ART, reported good adherence at last visit
VL testing coverage	Number of clients living with HIV and currently on ART who have a documented VL test within last 12 months	≥95% of clients living with HIV and currently on ART have a documented VL test within last 12 months

Indicator	Definition	Program Benchmark
Virally suppressed	Number of clients living with HIV and currently on ART who have a documented suppressed VL (<1,000 copies/mL) within last 12 months	≥95% of clients living with HIV and currently on ART have a documented VL test showing viral suppression within the last 12 months
TB screening	Number of clients living with HIV and currently on ART who received TB screening* **According to national policy*	≥95% of clients living with HIV and currently on ART have received TB screening
TB testing	Number of clients living with HIV, currently on ART, and with presumptive TB received a TB diagnostic test* **According to national policy*	≥95% of clients living with HIV, currently on ART, and with presumptive TB have received TB diagnostic test
TB preventive therapy coverage	Number of clients living with HIV and currently on ART who did not have presumptive TB or reported a negative TB diagnostic test started TB preventive therapy	≥95% of clients living with HIV, currently on ART, did not have presumptive TB or reported a negative TB diagnostic test started TB preventive therapy
TB preventive therapy completion	Number of clients living with HIV and currently on ART who did not have presumptive TB or reported a negative TB diagnostic test started and completed TB preventive therapy	≥95% of clients living with HIV, currently on ART, did not have presumptive TB or reported a negative TB diagnostic test started and completed TB preventive therapy
TB therapy coverage	Number of clients living with HIV and currently on ART who had a positive TB diagnostic test and started TB therapy	≥95% of clients living with HIV, currently on ART, and reported a positive TB diagnostic test started TB therapy
TB therapy completion	Number of clients living with HIV and currently on ART who had a positive TB diagnostic test and started and completed TB therapy	≥95% of clients living with HIV, currently on ART, and reported a positive TB diagnostic test started and completed TB therapy

5.3.3 Program Data Analysis for IIT

Whenever possible, a granular analysis of the new clients no longer on ART in the reporting quarter should be conducted, and analysis of the total "lost" should be disaggregated into IIT (also referred to as "lost to follow-up"), death, refusal to continue treatment, and transferred out. This analysis would facilitate understanding of issues related to late client access to treatment, AHD, client treatment barriers, quality of services, and ART decentralization, among others.

IIT should be disaggregated by time on ART (≤3 months; 3–5 months; ≥6 months). If, for example, the majority of clients with IIT fall into the category of ≤3 months on ART, case management teams should consider assessing barriers for this specific group and intensifying support to clients who are within the first three months of treatment. Alternatively, if the majority of clients with IIT have been on ART ≥6 months, case management teams should disaggregate by those with VL test and virally suppressed, and then by time on ART, as treatment fatigue might also play a role in IIT.

5.3.4 Waterfall Analysis

Figure 5 shows an example of a "waterfall analysis," which estimates the potential number of clients on ART in the reporting quarter. The estimate is based on the number of clients on ART in the previous quarter, those returned to ART, those new on ART, and losses (IIT, death, refused to continue ART, transferred out), versus the actual number of clients on ART reported in the quarter.

This analysis allows for calculation of the return-to-ART rate and loss rates by outcome (e.g., percentage of IIT, death, refused to continue, transferred out) among those currently on ART.

It also allows for assessment of the quality of the data, given that any difference between current on ART this quarter and potential current on ART adjusted for "loss"[‡] reflects an unattributed loss or gain. The unattributed value can refer to transfers in (+), data completeness (-/+), errors or corrections (-/+), aging in (+), and aging out (-). To better understand these positive and negative categories, further investigation is recommended, including patient-level data analysis if available.

Some examples of reasons for unattributed gain or loss include:

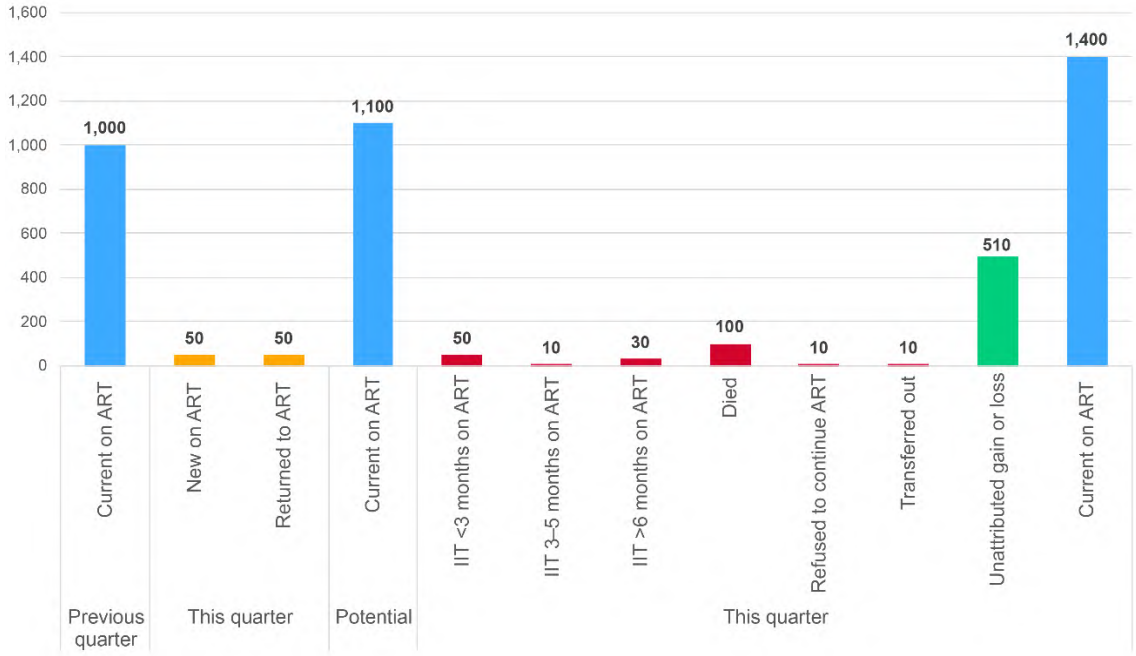
- Duplicate client records can lead to patients being counted more than once.
- Incomplete reporting, i.e. missing site data, can reduce the count of clients on treatment.
- Acquisition of new sites can result in a higher number of clients reported on treatment.

In the example in Figure 5, the formula would be populated as follows:

- Potential current on ART:
  - 1,000 current on ART previous quarter + (50 new on ART this quarter + 50 returned to ART this quarter) = 1,100
- Lost to ART this quarter:
  - 50 IIT <3 months on ART + 10 IIT 3–5 months on ART + 30 IIT >6 months on ART + 100 dead + 10 refused to continue ART + 10 transferred out = 210
- Potential current on ART adjusted for losses:
  - 1,100 potential current on ART - 210 lost to ART this quarter = 890
- Unattributed value:
  - 1,400 current on ART this quarter - 890 potential current on ART adjusted for losses = 510 unattributed gain

[‡] Loss defined as the sum of IIT, death, refused to continue treatment, and transferred out

Figure 5. Example of a waterfall analysis on continuity of treatment



5.3.5 Line Listing for Clinical Follow-up

Line listing of clients is critical to improve client care in ensuring that they receive timely and necessary HIV services, which can result in better health outcomes. From a programmatic perspective, it helps to effectively allocate resources by prioritizing client needs. It also facilitates systematic follow-up of clients, reducing the risk of missed appointments or overlooked services. In addition, line listing offers programs an opportunity to make data-driven decisions by looking at trends, identifying bottlenecks, and discussing new solutions.

On a weekly basis, the ART case management team should review the line list of clients who need clinical follow-up, such as those listed in the categories in Table 3. If available, an individual-level electronic database should be programmed to automatically generate the line lists.

Table 3. Categories of clients to line list for clinical follow-up

	Line-List Categories
1	Clients living with HIV who have an ART visit (to start/continue) in the next week
2	Clients living with HIV who did not start ART within 7 days
3	Clients living with HIV who were not tested for CD4 within 7 days of ART initiation
4	Clients living with HIV with CD4 ≤200
5	Clients living with HIV, currently on ART, and at high risk of IIT at last appointment
6	Clients living with HIV, currently on ART, and reporting poor adherence (defined as <6 doses within last week) at last appointment
7	Clients living with HIV, currently on ART, and not on DTG-based regimen
8	Clients living with HIV, currently on ART, not on MMD (3–5 months or 6 months), and eligible for MMD
9	Clients living with HIV who missed their last ART appointment (<28 days from last appointment)
10	Clients living with HIV who interrupted treatment (>28 days from last appointment)
11	Clients living with HIV, currently on ART, who did not report good adherence at last visit (good adherence defined as ≥6 doses within last week; poor adherence defined as <6 doses within last week)
12	Clients living with HIV, currently on ART, who do not have a documented VL test within last 12 months
13	Clients living with HIV, currently on ART, whose VL test has been pending ≥1 month
14	Clients living with HIV, currently on ART, who do not have a documented suppressed VL (<1,000 copies/mL) within last 12 months
15	Clients living with HIV, currently on ART, who do not have a documented suppressed VL (<1,000 copies/mL) within last 12 months and did not complete the minimum 3 sessions of enhanced ART counseling
16	Clients living with HIV, currently on ART, who do not have a documented suppressed VL (<1,000 copies/mL) within last 12 months and who did complete the minimum 3 sessions of enhanced ART counseling but did not repeat the VL test
17	Clients living with HIV, currently on ART, who were not screened for TB at least twice within last 12 months
18	Clients living with HIV, currently on ART, with presumptive TB, whose TB test was not done
19	Clients living with HIV, currently on ART, with presumptive TB, whose TB test result has been pending >1 month
20	Clients living with HIV, currently on ART, whose TB test was positive, and TB treatment was not started within 7 days
21	Clients living with HIV, currently on ART, with TB, who did not complete TB treatment
22	Clients living with HIV, currently on ART, without presumptive TB or with negative TB test, who were not started on TB preventive therapy
23	Clients living with HIV, currently on ART, without presumptive TB or with negative TB test, who did not complete TB preventive therapy

The line list of clients should allow for tracking of the clinical follow-up outcome. This outcome should be documented in the client's paper-based file and in the national and/or project database.

To document the risk assessment, adherence assessment, CD4, DTG, MMD, VL, ART status, and tracing activities, among others, the case management team could

use a longitudinal paper-based or electronic M&E tool (Annex 6). Depending on feasibility, the tool could document the risk category only or also the specific risk factors, whether the client has been traced, how the client has been traced, and the outcome of the specific tracing activities, e.g., dates of calls, home visits.

Project Example

The FHI 360-led EpiC Mali project uses an electronic individual-level data tracker based on DHIS2, through which case managers at public and CSO-led clinics can automatically generate line lists of clients due for a follow-up appointment, those eligible for VL testing who need to be tested, and those who missed an appointment, interrupted treatment, and need to be contacted, among others. Electronic data systems programmed to deliver this information represent a critical tool to enhance ART case management.

6. ART Case Management in the Context of Polycrisis

Environmental and climate crises affect health in complex ways. This can happen directly, such as through exposure to higher temperatures or increased mobility due to flooding, but also indirectly such as through the effects of crises on physical and psychological safety, mental health, and loss of income, thereby increasing an individual's risk of HIV infection. Like climate change disasters, violent conflicts also affect HIV services by forcing migration and internal displacement; increasing sexual activity among migrants; driving the scarcity of basic medical supplies; causing loss of electricity, communication, and interruption of transportation services; and making it necessary to reallocate providers to war-related services.

Critical priorities during polycrises include ensuring continuity of treatment and support for viral suppression among PLHIV, continuing to identify undiagnosed individuals, ensuring their prompt enrollment on treatment, and helping those who are at risk of HIV acquisition to remain HIV negative.

6.1 Interventions to Continue ART Delivery during a Polycrisis

The following interventions can be implemented to continue delivery of ART and HIV care services during a polycrisis:

- Advocate for and support revision of government policies to permit and/or expand MMD and DSD strategies so that clients on ART can benefit. The expansion could include relaxing the criteria for eligibility for MMD and DSD (e.g., established on treatment versus not established on treatment).
- All clients on ART should continue to receive adherence support, if possible and safe, at the community level as well as from service providers using virtual platforms (see Annex 2 and FHI 360's Going Online to Accelerate the Impact of HIV Programs).
- Clinics and/or community programs should rapidly scale up MMD of ART and other comorbidity medications for clients, including TB preventive therapy, anti-TB drugs, and cotrimoxazole, if the emergency reduces or closes certain service delivery points. Where stocks are limited, consider a priority list of clients who should be offered MMD. Programs should work with the relevant logistics and SCM agencies to ensure adequate stock of all necessary medications.
- Expand DSD through community initiation and refills of ART and other commodities. Clients currently on ART should be followed up for side effects virtually if safety is a concern, using phones, SMS, and other channels.

- Establish alternate ART distribution plans with clear SOPs if clinics, drop-in centers, or other service delivery points are unable to function because of the crisis. Examples include decentralized community distribution, pharmacies, private clinics, online ordering, and home delivery (if acceptable to service recipients and safe). LINKAGES' Sustaining Access to HIV Treatment in Indonesia through the Jak-Anter Antiretroviral Treatment Home Delivery System can be used as a resource.
- Programs may also consider leveraging ART support groups where one member can collect the MMD ARVs for their group and for other groups to minimize the need for multiple people to visit the pharmacy. Processes for referral to new distribution sites should be tested ahead of time. The handling of confidential medical records, ARV stocks, proper recording keeping, and communication with potential confused or distraught clients will require careful planning.
- Help peer navigators/case managers continue supporting HIV-positive individuals while ensuring their safety through phone-based support, virtual case management software, and online platforms (such as the Online Reservation App).
- Determine alternative processes for taking and transporting VL samples if main laboratories are not operating at capacity or are closed. Facility staff could also consider delaying routine VL testing until the capacity of laboratory services normalizes (but continue to provide ongoing support for adherence). If VL testing capacity is reduced, certain groups of PLHIV such as those who with opportunistic infections, suspected treatment failure, and not virally suppressed should be prioritized for VL testing.
- Consider alternative systems for VL sample collection at the community level, such as the use of DBS, plasma separation cards, home collection, and testing at private facilities/laboratories.
- Transport samples to other regions or sites where there are no disruptions or where the capacity still exists. It is essential that a reliable transport system be planned, tested, and ready to implement during an emergency. This should also include innovative ways to transport samples, including the use of bicycles, boats, and motorcycles.

More guidance is available in FHI 360's Practical Considerations for Mitigating the Impact of Polycrises on Key-Population-Focused HIV Programs.

Annexes

Annex 1. Case Management Services by Cadre

	Intervention	Clinic Staff (Public Clinic or Clinic Led by Community-based Organization, Civil Society Organization, or Nongovernmental Organization)*										Implementing Partner†				
1	Case management to initiate and refill antiretroviral therapy (ART)	Peer outreach worker, peer navigator	Psychosocial, mental health officer	ART counselor	Nurse	Clinician	Case manager	M&E officer	SCM officer‡	Pharmacy officer‡	Laboratory technician‡	Program manager	Site coordinator	SCM officer	Laboratory officer	M&E Officer
	Oversight of case management											X	X			X
	Supply chain management								X	X	X			X	X	X
	Clinical and laboratory assessment for ART initiation and follow-up				X	X										
	CD4, VL sample collection, transport, and testing				X§						X§				X	
	Initiation of ART, optimized regimen				X**	X										
	ART refill, multimonth dispensing (MMD)	X			X											
	Differentiated service delivery (DSD)††	X			X											
	ART adherence counseling and monitoring	X	X	X	X		X									
	Missed appointment tracking, interruption in treatment (IIT), VL testing eligibility, non-virally suppressed						X					X	X			
	Client tracing for missed appointments, IIT, VL testing eligibility	X					X									
	Enhanced ART counseling to non-virally suppressed clients	X	X		X	X	X									
	Switch to second-line regimen					X										

* Direct service delivery role
† Technical guidance, monitoring, and supervisory roles
‡ In cases where this cadre is not available, another cadre should take on these roles and responsibilities.
§ In some settings, only laboratory personnel are authorized to collect laboratory samples; however, when task shifting/sharing is possible, it is recommended to engage nurses for this task.
** Only nurses trained on ART should prescribe treatment.
†† Specifically, DDD through community clinics, drop-in centers, public and private health facilities, public and private pharmacies, home delivery, and delivery through community groups

2	Screenings and linkage to other services	Peer outreach worker, peer navigator	Psychosocial, mental health officer	ART counselor	Nurse	Clinician	Case manager	M&E officer	SCM officer‡‡	Pharmacy officer‡‡	Laboratory technician‡‡	Program manager	Site coordinator	SCM officer	Lab officer	M&E officer
	Risk assessment for IIT§§	X		X	X	X	X									
	Advanced HIV disease (AHD) clinical services				X	X										
	Psychosocial services/mental health services		X		X	X	X									
	Post-gender-based-violence medical, legal, social services	X	X				X									
	Sexually transmitted infection screening	X			X	X	X									
	Assess vaccination coverage				X	X	X									
3	**Strategic Information**	**Peer outreach worker, peer navigator**	**Psychosocial, mental health officer**	**ART counselor**	**Nurse**	**Clinician**	**Case manager**	**M&E officer**	**SCM officer‡‡**	**Pharmacy officer‡‡**	**Laboratory technician‡‡**	**Program manager**	**Site coordinator**	**SCM officer**	**Lab officer**	**M&E officer**
	Data collection	X	X	X	X	X	X		X	X	X					X
	Data management, reporting							X								X
	Data use for decision-making	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

‡‡ In cases where this cadre is not available, another cadre should take on these roles and responsibilities.
§§ Risk assessment comprises multiple risk factors, some of which are listed in section 2 of this table.

Annex 2. Virtual versus In-person Case Management

Service	Considerations for Virtual vs. In-person Case Management
Risk assessment for interruption in treatment (IIT)	Risk assessment can be offered virtually or in person. Some clients may not feel comfortable disclosing their risks in-person, but there may also be benefits for building relationships with an initial in-person risk assessment. Screening for advanced HIV disease (AHD) is part of the risk assessment. AHD screening and referral for treatment would typically require sign- and symptom-based assessment as a first step, which can be offered virtually; however, since the AHD assessment requires a clinical examination and CD4 test, an in-person service is needed for this assessment. AHD clinical management would likely require in-person follow-up in most cases. Other risk factors such as violence, stigma and discrimination, disclosure, and mobility can be assessed virtually.
Optimized regimen	The provision of dolutegravir (DTG)-based regimens should be in person at treatment initiation or when the regimen is switched. Thereafter, the optimized regimen can continue being provided through differentiated service delivery (DSD).
Antiretroviral therapy (ART) adherence	• ART adherence monitoring can be provided through a seven-day recall system and counting pill balances at every encounter with the client and at every refill. • ART adherence monitoring should always be paired with adherence counseling and can be offered in person or virtually. • During adherence counseling, motivational counseling skills (see EpiC's Motivational Counseling Training Curriculum) are critical to increase the effectiveness of the counseling. • If direct supervision of pill intake is necessary and done virtually, video must be included. • Intensified ART counseling is usually offered to clients reporting poor adherence, in which case in-person counseling is preferred. • Follow-up support in the home or community can be provided in person or virtually depending on client needs, project operational constraints, and considerations for infectious disease prevention and control. In-person follow-up at home or within the community is particularly important for high-risk clients, as this helps with establishing a relationship with the client. If in-person support cannot be offered, other channels can be used, including phone calls, voice recordings, and WhatsApp video calls, among other examples.
Appointment reminders	Appointment reminders (for adherence monitoring, clinical assessment, ART refill, VL testing) can be offered through automated or manual systems. Reminders can be provided through messages sent to clients via SMS, social media, or emails, or via phone calls made by staff. Automated systems use a software that sends a message to the phone number or email of affected ART clients as identified from an electronic database.
Navigation	Navigation to ART services and referral to other services (e.g., post-violence services) can be provided in person or virtually depending

Service	Considerations for Virtual vs. In-person Case Management
	on client needs, project operation, and environmental threats, among other factors. In-person navigation is particularly important during the first few weeks after ART initiation to assist the client to become familiar with the service location(s), service flow, service delivery providers, and other relevant processes. If in-person navigation cannot be offered, other channels can be used such as phone calls, voice recordings, or WhatsApp video calls.
DSD, multimonth dispensing (MMD)	DSD tailors support to be more responsive to client preferences and needs. It typically involves individual or group provision of ART in the community by a peer outreach worker/navigator or provider, fast-track channels at the facility, specialized family/adolescent clinics, private clinics or pharmacies, automated dispensing units, or home delivery, among other options. Similarly, MMD can be provided in person or virtually through, for example, home delivery and automated dispensing units.
ART re-engagement	For timely tracking and tracing of ART clients who miss an appointment or interrupt treatment, providers should initiate the process of re-engagement through virtual channels such as calls or messages, or by having peer navigators conduct in-person community visits if the client is not found during initial virtual attempts.
VL monitoring	VL monitoring takes place at (and beyond) the 180-day mark. Timely VL monitoring regularly requires reviewing the monitoring and evaluation (M&E) system data to create line lists of clients eligible for VL testing, which can be done remotely. However, VL sample collection requires meeting the client in person. Virtual VL monitoring should also be done for all ART clients to assess their viral suppression status. Those who are not virally suppressed should be contacted for enhanced ART counseling and to repeat the VL test. Evidence of viral suppression at 180 days can serve as an indication that patients may have established strong foundations for adherence and continuation in the first 180 days and may not need intensified support going forward, unless a follow-up risk assessment indicates otherwise.

Annex 3. Risk Assessment Tool for Interruption in Treatment (IIT)

This tool includes a list of risk factors associated with interruption in treatment (IIT) as identified in the published literature. Each country project should select the most relevant risk factors based on local context and analysis of project data, if possible. It is strongly recommended to prioritize those newly on treatment, returning to treatment after IIT, non-virally suppressed, and with advanced HIV disease (AHD), as well as children under 5 years. The questions should be translated into local languages and the screening conducted by trained staff at antiretroviral therapy (ART) enrollment and throughout the continuum of care—monthly or quarterly as possible. An electronic monitoring and evaluation (M&E) system should longitudinally track the risk factors or at least the risk category of the client (high risk versus low risk). Note that some risk factors require using a standalone tool, e.g., World Health Organization (WHO) staging, mental health, or stigma and discrimination.

	Risk	Questions	Interpretation	Date Response (Yes/No)	Date Response (Yes/No)
A. CLINICAL					
1	New on ART	Are you [the client] new on ART (started within last 6 months)?	If "Yes," categorize as HIGH RISK		
2	Returning to ART after IIT	Have you restarted ART after interrupting treatment after more than 28 days since the date of the last appointment?	If "Yes," categorize as HIGH RISK		
3	Non-virally suppressed	Is your last viral load (VL) test >1,000 copies/mL?	If "Yes," categorize as HIGH RISK		
4	AHD	• Is the client WHO stage 3 or 4?* • Is the CD4 count <200 cells/mm3?† • Is the client under 5 years?	If "Yes" for any question, categorize as HIGH RISK		
5	Comorbidities	Do you have comorbidities such as hypertension, other cardiovascular diseases, kidney disease, liver disease, diabetes, other non-tuberculosis (TB) pulmonary diseases, or other conditions?	If "Yes," categorize as HIGH RISK		
6	Side effects of treatment	Do you fear/experience side effects from medication that make you want to stop treatment?	If "Yes," categorize as HIGH RISK		
7	Pill burden	Do you experience/fear that taking daily medication for life is/will become tiresome?	If "Yes," categorize as HIGH RISK		

* See Annex 4 for the tool "Standardized Questions to Assess HIV-related Diseases" to stage the client.
† Prioritize CD4 count to assess the client and use WHO stage only if the CD4 count cannot be measured.

	Risk	Questions	Interpretation	Date Response (Yes/No)	Date Response (Yes/No)
B. STRUCTURAL					
1	Violence	In the past 24 months, have you experienced economical, emotional, physical, or sexual violence?	If "Yes" to any aspect of the question, categorize as HIGH RISK		
2	Mental health	Select from evidence-based validated tools‡	If "above cutoff" for any question, categorize as HIGH RISK		
3	Stigma and discrimination	Select from stigma index tools§	If "Yes," categorize as HIGH RISK		
4	Economic issues	Is it/will it be difficult to keep HIV clinic appointments due to lack of money for transport?	If "Yes," categorize as HIGH RISK		
5	Distance from health facility	Is it/will it be difficult to reach the clinic because of the distance or lack of transport?	If "Yes," categorize as HIGH RISK		
6	Mobility	Are you anticipating traveling outside this region, for longer than two months? Migrant? Displaced? Moving across borders?	If "Yes," categorize as HIGH RISK		
7	Food insecurity	Do you sometimes go to bed hungry/lack food?	If "Yes," categorize as HIGH RISK		
8	Family/peer support	Do you have someone who can remind you about or make sure you are taking your medications?	If "No," categorize as HIGH RISK		
9	HIV disclosure	Have you told someone you trust about your HIV status?	If "No," categorize as HIGH RISK		

‡ Mental health screening should only be offered in the context of a broader mental health package of services and in alignment with The 8Cs Model of Collaborative Consultation for Mental Health and Psychosocial Support Programs. Examples of screening tools include Kessler 6–12, PHQ9, and AUDIT.
§ See About the Stigma Index.

Annex 4. Tool to Assess HIV-Related Diseases

When a person living with HIV has or is suspected to have any of the signs or symptoms below, they should be transferred to an HIV treatment facility immediately for further clinical assessment and treatment/prophylaxis. The following tool can provide guidance for conducting the client's clinical staging, but it does not replace the comprehensive World Health Organization (WHO) clinical staging guidance or national staging guidelines.

Common Symptoms among Individuals with HIV-Related Disease	
1	Prolonged fever with unknown causes
2	Coughing, rapid breathing, difficult breathing, rapid heartbeat
3	Loss of >10% of body weight, unknown causes
4	Skin, genital, or anal issues
5	Diarrhea, severe thirst, stomachache
6	Swollen lymph nodes in neck or armpits
7	Severe headache
8	Need for assistance while walking
9	Dizziness or fainting
10	Abnormal behaviors, changes in behavior
11	Unable to recognize places, time, relatives
12	Lying in bed for prolonged periods
Common Infections and Signs in Individuals with HIV-Related Disease	
1	Tuberculosis (TB)/lymph node TB: Cough, fever, weight loss, night sweats, swollen lymph nodes in neck, armpits
2	Oral thrush: White patches that can easily be wiped off in the mouth and tongue
3	Esophageal thrush: Pain when swallowing, often accompanies oral thrush
4	Herpes: Small blisters, breaking and forming scabs and ulcers around nose, mouth, genitals, anus
5	Fungal infection: Damage to the skin on the face, body, arms, legs
6	Encephalitis: Headache, confusion, paralysis or weakness in limbs
7	Meningitis: Headache, vomiting, sensitivity to light, stiff neck

Annex 5. Guide for Services to Mitigate Risk Factors

This job aid is intended to guide providers on what services to offer clients based on specific risk factors. Although the risk assessment tool used in a given context may not include all risk factors listed in the table below, providers should facilitate discussions with clients on barriers to treatment, including client needs, concerns, beliefs, and challenges, and provide support as applicable. In addition, cadres offering risk mitigation support should refer to EpiC's HIV Treatment Adherence Counseling and Retention Guide: A Job Aid for Counselors and Providers Working with People Living with HIV and use motivational counseling techniques (see EpiC's Motivational Counseling Training Curriculum) when having discussions with the client.

	Risk	Service
A. Client-specific Risks		
1	Advanced HIV disease (AHD)	• Management of symptoms • Counseling for patients and their families • CrAg, LF tuberculosis lipoarabinomannan (TB-LAM) testing • Treatment of infections • Preventive therapy including tuberculosis (TB) prophylaxis (latent TB treatment), cotrimoxazole prophylaxis, and cryptococcosis prophylaxis • Provision of ART and counseling and support to stay on prophylaxis/treatment
2	Comorbidities	• Link to comorbidities clinic • Assess drug interactions • Support adherence to comorbidity medications
3	Mobility	• Link to another ART clinic for refill and care when on travel • Offer multimonth dispensing (MMD)
4	Substance use	• Offer harm reduction education • Refer to harm-reduction services • Refer to Alcoholics Anonymous groups
5	Lack family/peer support	• Offer enrollment in peer support groups • Offer counseling to the family
6	Multiple family members living with HIV	• Offer family-centered clinics • Offer clinic friendly to children living with HIV • Link to OVC programs
7	Lack disclosure	• Discuss barriers to disclosure, pros and cons of disclosure, and how and when to disclose • Assist with identification of individual(s) to whom the client might disclose • Offer disclosure support
8	Sex work	• Condom and lubricant promotion and provision • Educate on condom-negotiation skills • Offer/refer to economic empowerment services

	Risk	Service
9	Mental health condition	• Educate about mental health • Promote healthy lifestyles (regular physical activity, nutritious diet, good-quality sleep, social connection, stress reduction) • Offer life-skills education (decision-making, creative/critical thinking, communication, self-awareness, resilience, problem solving) • Strengthen caregiving skills • Suicide prevention • Link to psychosocial support officer, mental health services officer, specialized services depending on needs • Assist with setting and assessing goals over time
10	Use of traditional medicine	• Educate on the role of traditional and conventional medicine • Educate on the interaction of traditional medicine with antiretrovirals (ARVs)
11	Fear of side effects	• Educate about side effects and their management • Provide contact information for rapid communication • Navigate to clinical services
12	Beliefs about antiretroviral therapy (ART)	• Discuss ART benefits, U=U concept
B. Structural Risks		
1	Violence	• Link to medical, legal, and social services • Offer HIV testing services/post-exposure prophylaxis, sexually transmitted infection screening and treatment, emergency contraception • Offer/refer to safe space
2	Homeless	• Refer to social welfare office
3	Lack regular income, unemployment	• Offer/refer to economic empowerment services • Link to orphans and vulnerable children (OVC) income-generating program
4	Stigma and discrimination	• Offer stigma and discrimination counseling • Offer peer support groups • Facilitate identification of trusted person
5	Financial barriers to accessing services, distance to services too far	• Offer transport allowance • Offer decentralized drug distribution (DDD) • Offer differentiated service delivery (DSD), e.g., facility fast tracking • Offer MMD
6	Work-related barriers to accessing services	• Offer MMD, DDD • Offer flexible ART clinics before/after working hours, on weekends

Annex 6. Longitudinal Tracking Tool for ART Peer Navigators

This tool is intended for use by antiretroviral therapy (ART) peer navigators or case managers, according to their assigned responsibilities, to longitudinally document the outcomes of the risk assessment, ART adherence assessment, CD4 test, dolutegravir (DTG) regimen, multimonth dispensing (MMD), viral load (VL) test, and ART status.

UIC*		Date 1/1/2024							Date 1/2/2024						
	Date started ART	Risk category	ART adherence	CD4	DTG	MMD	VL	ART status	Risk category	ART adherence	CD4	DTG	MMD	VL	ART status
Example: ABC	1/1/24	H	G	no	yes	no	no	A	H	G	>200	yes	no	no	MA

Coding	
Date	DD/MM/YYYY
Risk category	H: High; L: Low
ART adherence	G: Good; P: Poor
CD4	No: Not done; otherwise, document result
DTG	Yes: On DTG; No: Not on DTG
MMD	Yes: On MMD; No: Not on MMD
VL	No: Not done; otherwise, document result
ART status	A: Active MA: Missed appointment (if <28 days from last appointment) IIT: Interruption in treatment (if ≥28 days from last appointment) D: Dead SR: Stopped/refused TO: Transferred out RTT: Returned to ART (if previously IIT)

* UIC=Unique identification code

If the client has missed an appointment or has interrupted treatment, the case manager and/or peer navigator should use the following tool to document the tracing activities.

UIC*					1st call		2nd call		3rd call		1st visit		2nd visit		3rd visit		Final	
	Date of last appointment	Missed appointment or IIT	Phone number	Address	Date	Outcome	Date	Outcome	Date	Outcome	Date	Outcome	Date	Outcome	Date	Outcome	Date	Outcome
Example: ABC	1/1/24	MA	1234	XYZ	1/1/24	Not found	3/1/24	Not found	5/1/24	Not found	8/1/24	Transfer-red out						

Coding	
Date	DD/MM/YYYY
Outcome	New appointment, active Stopped/refused Dead Transferred out Not found

* UIC=Unique identification code

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