ICAP Approach to Starting Antiretroviral Therapy in the Era of Treat All

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Columbia University
Mailman School of Public Health

ABOUT ICAP

ICAP was launched in 2003 at Columbia University's Mailman School of Public Health. A leader in global health and health systems strengthening, ICAP provides technical assistance and implementation support to governments, non-governmental and community-based organizations around the world.

Preface

This guide was developed as part of a four-volume series that aims to assist with implementation of effective strategies that support reaching the global 90:90:90 targets.[a] The Test and Treat All compendium includes four documents that describe ICAP's approach to the following:

1) **Targeted HIV Testing.** This document describes innovations that support an increase in yield in HIV testing, especially among subpopulations that have historically been hard to reach.
2) **Antiretroviral Therapy Initiation in the Era of Treat All.** This document describes approaches to ensuring high uptake and coverage of antiretroviral therapy (ART) in the context of the Test and Treat approach, and clinical follow-up during the first six months of treatment.
3) **Differentiated Service Delivery.** This document describes key considerations for the implementation of differentiated service delivery (DSD) models.
4) **Viral Load Scale-Up.** This document describes key considerations for preparing for national implementation and scale-up of routine viral load (VL) monitoring.

These guides can be used to assist in considering successful strategies to increase targeted HIV testing, improve ART coverage and retention in care, and maximize adherence support services to ensure VL suppression (VLS). All four documents highlight areas that need to be prioritized, while maintaining a focus on critical issues not adequately covered in other resources. They are intended to complement the "ICAP Package of Care for People Living with HIV"

The target audience of this guide includes clinical staff and health managers supporting implementation and scale-up of HIV treatment, specifically for Test and Treat programs.

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[a] Targets include: 90 percent of all people living with HIV know their HIV status; 90 percent of all people with diagnosed HIV infection receive sustained ART; and 90 percent of all people receiving ART achieve viral suppression.

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Acronyms

ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Azidothymidine
CrAg	Cryptococcal Antigen
CTX	Cotrimoxazole
DQA	Data Quality Assessment
DSD	Differentiated Service Delivery
EMR	Electronic Medical Record
FSW	Female Sex Workers
GBV	Gender-Based Violence
Hb	Hemoglobin
HCW	Health Care Worker
HF	Health Facility
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IPT	Isoniazid Preventive Therapy
IRIS	Immune Reconstitution Inflammatory Syndrome
KP	Key Populations
LF-LAM	Lateral Flow Urine Lipoarabinomannan Assay
LP	Lumbar Puncture
M&E	Monitoring and Evaluation
MAT	Medically Assisted Therapy
MDT	Multidisciplinary Team
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
NAT	Nucleic Acid Test
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan For AIDS Relief
PLHIV	People Living With HIV
PMTCT	Prevention of Mother-to-Child Transmission of HIV
PWID	People Who Inject Drugs
QA	Quality Assurance
RAG	Red, Amber, Green
SMS	Short Message Service
SOP	Standard Operating Procedure
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
VL	Viral Load
VLS	Viral Load Suppression
WHO	World Health Organization

Executive Summary

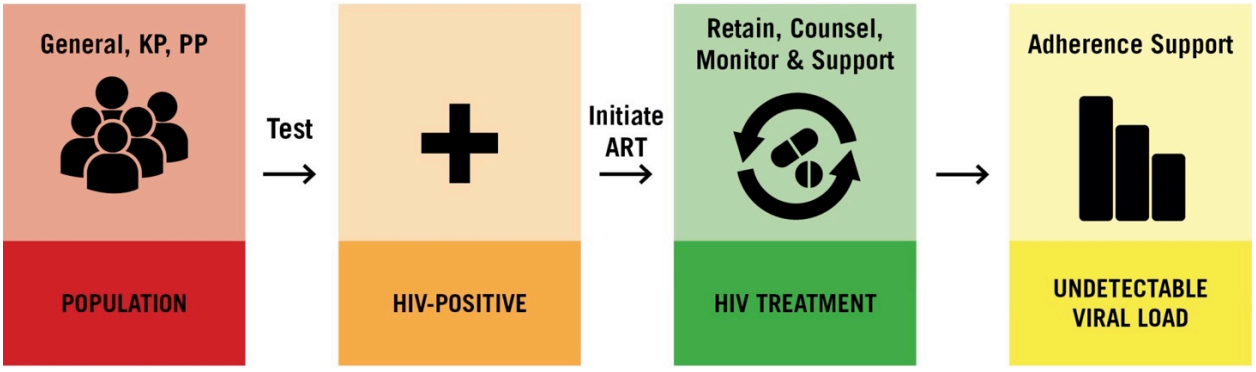
This document focuses on ART initiation in the era of Test and Treat and includes a variety of clinical, monitoring, and evaluation resources from ICAP-supported country programs and international organizations.

The document is divided into seven sections:

- The first section describes the importance of **retesting for verification** of HIV-positive results prior to or at ART initiation.
- The second section describes **key counseling messages** around ART initiation, both at the health facility (HF) level and in the community.
- The third section provides guidance on rapid **ART initiation,** with a particular focus on: individuals newly diagnosed with HIV; those previously diagnosed with HIV and enrolled in care, but not on ART (formerly known as pre-ART); and those presenting with advanced disease. It also includes special considerations for initiating ART in infants, children, and adolescents.
- The fourth section describes **clinical follow-up** and support, including laboratory follow-up, during the first six months of treatment for individuals presenting with early disease; those with advanced disease; infants, children and adolescents; and those in whom ART initiation is deferred.
- The fifth section describes **community ART initiation**, including information on which clinical and support services should be offered in the community and keys to successful linkage to care at health facilities.
- The sixth section focuses on **monitoring and evaluation (M&E)**, including considerations related to data systems, planning, monitoring and use of data, program evaluation, and data security.
- The final section describes **key health systems considerations** for implementing Test and Treat programs, including policy, human resources, infrastructure, commodities, laboratory, quality assurance, and information systems considerations.

It is important to note that ART initiation has implications on other steps along the HIV care continuum (see Figure 1). This guide focuses specifically on the **timing of ART initiation** to optimize patient treatment outcomes and retention in care.

Figure 1: HIV Care Cascade



I. Introduction

In 2015, the World Health Organization (WHO) released a recommendation to provide HIV treatment to all adults, adolescents, and children living with HIV, regardless of CD4 cell count or disease stage.[1] This recommendation was based on evidence that early initiation of ART improves morbidity and mortality outcomes for people living with HIV (PLHIV).[2] Furthermore, early treatment has a significant prevention benefit, as VLS prevents HIV transmission.[3] This makes the 'Test and Treat' approach important for epidemic control and it consequently plays a vital role in the WHO's public health approach to HIV treatment and care.

In 2017, the WHO reinforced the importance of early treatment by recommending rapid initiation of ART for all eligible PLHIV, defined as within seven days of a confirmed HIV diagnosis.[4] The same guidelines recommend that same-day ART initiation be offered to *all* PLHIV who are ready to start, while continuing to emphasize people-centered care. Same day or rapid initiation has also been shown to improve retention in care and clinical outcomes.[5, 6, 7, 8] However, PLHIV should not be coerced to start ART and should be supported to make an informed decision about when to begin treatment.

Box 1. Populations in which same day ART initiation is highly recommended:

- Patients with advanced disease (CD4 count <200 cells/mm^3 or a WHO stage 3 or 4 event at presentation)
- Pregnant and breastfeeding women
- Key populations (KP)
- Infants and children
- HIV-positive partner in discordant couples

The move towards rapid ART initiation, irrespective of CD4 count or disease stage, brings new implementation challenges. More PLHIV will be asked to initiate ART while feeling well, and this approach may conflict with prior messaging they received. Rapid initiation also means that people will be asked to initiate ART soon after receiving a positive HIV test result, which can be overwhelming. Without the routine use of CD4 cell count to assess ART eligibility, there is no laboratory biomarker of immunosuppression, making it easier for people with advanced disease to go undetected at ART initiation. Furthermore, as ART can now be initiated without waiting for laboratory test results, ART initiation in community settings is more feasible, and the need for strong linkage procedures is even more essential.

The purpose of this document is to describe key considerations and suggest approaches to address some of the new programmatic challenges that come with the Test and Treat approach to initiating ART.

II. Retesting for Verification of HIV-Positive Status

Retesting for verification is a quality assurance (QA) activity that refers to the testing of a new specimen from individuals newly diagnosed with HIV and those previously diagnosed, but not yet initiated on ART, and preferably conducted by a different provider using the same national HIV testing algorithm. Previously, CD4 count was used to follow PLHIV over time, and as the CD4 count declined, individuals became eligible for treatment. However, without the routine use of CD4 count to assess ART eligibility, there is no laboratory marker of immunosuppression. This underscores the importance of retesting for verification in the era of Test and Treat to ensure that individuals are confirmed HIV-positive before initiating them on ART.

All newly diagnosed HIV-positive individuals and *all* HIV-positive individuals who are not yet initiated on ART should be retested for verification prior to ART initiation. **Those already on ART should <u>not</u> be retested.**[9] Retesting for verification is applicable in all ART initiation settings and applies to all ages. Those younger than the age of 18 months require verification testing using a nucleic acid test (NAT), whereas children age 18 months or older, adolescents, and adults, including pregnant and breastfeeding women, require verification testing according to the national HIV testing algorithm. Those testing positive in the community also require retesting for verification. If community testing was done with only one rapid HIV test for triage, then two full testing events using the national algorithm are required. If the full national algorithm was used in the community, then a second testing event is needed to verify HIV-positive status. Ideally, retesting for verification should occur at the site of ART initiation. This helps to ensure that the provider initiating ART knows that the individual's positive test result has been verified, and reduces the potential for unnecessary repeat retesting. However, if retesting for verification is not available on the same day, this should not delay ART initiation, especially in infants.

Retesting for verification prevents wasting of resources as it ensures that individuals are not needlessly placed on ART, and it is far less costly than lifetime ART for those with a false HIV-positive status. Programs that have implemented retesting for verification have noted that they were able to do so with minimal costs, which more than paid for themselves.[10]

For more information on retesting for verification, including how to manage discordant test results, see ICAP's *Handbook on Implementing Retesting for Verification Before/At Antiretroviral Therapy Initiation*.

III. Counseling and Support

A. Health Facility Level

As countries transition to adopting the global guidelines for Test and Treat, many PLHIV will be advised to start ART while they feel well. Not all individuals will be ready to start ART on the same day of diagnosis, and it will be important that they fully understand why they are being offered treatment and to address any of their questions or concerns. This message may conflict with what they have heard previously about ART eligibility based on CD4 count. Counseling should be people-focused and centered on supporting an individual's preferences. Education, counselling, and psychosocial support may be provided by health care workers (HCW), peers, treatment partners, or community extension workers (community health workers) and can be done in individual or group settings. All messages should be adapted to ensure that they are appropriate to the local context and population, including the use of appropriate terminology and references to available services. Below are key messages that should be provided at the time of ART initiation.

Key Messages for Provider Counseling on Test and Treat in Adults and Adolescents

- *Treatment is now recommended for all PLHIV regardless of CD4 count, including people who do not feel sick.*
- *The sooner you start treatment, the healthier you will remain and you will be less likely to develop HIV complications and other illnesses, such as certain cancers and heart disease.*
- *Treatment makes you less likely to pass HIV to your sexual partners, drug-sharing partners, or unborn or breastfeeding baby.*
- *Treatment can be started right away.*
- *When HIV is active in the body, it makes a lot of virus. Antiretrovirals (ARVs) stop HIV from making more virus. Viral load measures how much HIV is in the blood and if ARVs are working well — the goal is a low VL.*
- *It is important that you take your medicine every day so that it will work well and keep HIV from harming you. ARVs do not cure HIV, which is why you must continue taking them. A late dose is better than a missed dose.*
- *We will do a test called VL in 3-6 months to see if the ARVs are working well. If you are taking ARVs every day and they are working well, the VL will usually be low (less than 1000) after six months. It is important to know your VL results. Make sure to come back and ask for your VL results.*
- *It is also important that you come to all of your visits so that we can ensure all is going well for you and address any problems you are having promptly. As time goes on, these visits to the HF will become less frequent and some services may be provided in the community.*
- *Taking ARVs regularly and having a low VL prevents HIV from hurting your brain and keeps your memory, intelligence, and ability to solve problems strong.*
- *Taking ARVs regularly keeps you physically and emotionally strong. Low VL can help you grow well and prevent mood problems such as depression and anxiety.*
- *It is helpful to identify someone you trust to tell about your HIV status. We can help you with this process if you like.*
- *If you have any concerns, we can help you address them.*

On the day of initiation, at a minimum, individuals should establish a short-term adherence plan. This should include a strategy on when they will take their medication, how they will remember to take it, and where they will store it. They should also be made aware of common medication side effects and strategies to address them. It is also important to inform people early about VL measurement in order to prepare them for future testing and to emphasize its importance going forward.

Box 2. Special messages for individuals enrolled in care, but not yet on ART (formerly known as Pre-ART):

- *We know that in the past we monitored your CD4 count to see if you were eligible for ART.*
- *We now know that ART benefits all PLHIV, including those with a high CD4 count. The good news is that now all PLHIV should start ART, based on recent information that shows, without a doubt, the benefits of treatment for all. We can start ART today without having a recent CD4 count.*
- *We now think of HIV as a chronic disease, similar to diabetes and hypertension, so we want to start treatment as soon as possible to ensure that you remain healthy.*

Box 3. Special considerations for individuals who had previously been on ART and are returning to care after loss to follow-up or interruption of treatment:

- It is essential not to be judgmental or to stigmatize people presenting for care, including those who have been absent or irregular in care.
- People should be welcomed back and told how good it is that they have returned to care, with consistent messages focusing on the benefits of returning to care, e.g.:
    - *I am very happy to see you today!*
    - *Now that you are back, let us talk about what other needs you may have that we can address.*
- Ask about what motivated them to return to care, what challenges they faced with staying in care in the past, and what can be done to support them now that they have decided to return. This information will help inform the development of an individualized plan to support adherence and retention in care.

Inevitably, individuals will have questions regarding their treatment, and it is important to provide ongoing counseling and support throughout treatment, including how to recognize side effects. It is also important to elicit questions and concerns from individuals after the provider has provided the above key messages. Suggested responses to common concerns are listed in Table 1.

Table 1: Suggested Responses to Common Concerns at ART Initiation

Common Concerns	Responses
Side effects	*I understand that you are worried about side effects from ART. First, keep in mind that most people tolerate ART well and do not develop side effects. Some people do experience side effects, so it is important to know about the most common ones, and what to do if you experience them. We can help you manage side effects, so it is important to come to the clinic as soon as you experience any.*
Don't feel sick	*I understand that you don't feel sick now, which is great! But keep in mind that ARVs can keep you healthy. They stop HIV from making more virus and help to prevent you from getting sick. They work better if we start them now before you feel sick. ARVs help you live a longer life and prevent serious illnesses from developing over time.*
Need Permission	*I understand that you need to discuss starting ART with (**insert person**); let me know if I can help with that process. You can bring him/her to the clinic and we can talk to him/her together if that would be helpful.*
Travel time/costs	*I know it takes time and money to come to the clinic. Starting ARVs now will prevent you from getting ill in the future, which would mean more trips to the clinic and more days away from work. We will do a test called VL in six months to see if the ARVs are working well. If you are taking ARVs every day and they are working well, the VL will usually be low (less than 1000). Keeping the VL low is very important and if you achieve this, you may come to the clinic less often. There are also programs where you can refill your ARVs outside the clinic, even within your community. But in order to be eligible to participate in these programs, we need to ensure your VL is low.*
Toxicity	*ARVs are safer than they used to be, therefore we don't expect major problems. But if you feel ill in any way come to the clinic right away and we can evaluate you.*
ART associated with death	*Many people do not start ART until their immune systems are very weak (CD4 counts very low). They find out about their HIV infection late or they decide to start treatment late, and there is a high risk of dying at that point. That is why such patients may die soon after starting ART. These deaths are not due to ART, but due to the fact that the immune system is so weak and it cannot be recovered by ART at this point. New guidelines recommend starting ART early, while the immune system is still strong. We know that people who start ART early can live nearly as long as people without HIV. Also the new drugs are very safe, and have very few side effects.*
ART leads to miscarriages	*ARVs do not cause miscarriages. ARVs have been used in pregnant and breastfeeding women for a very long time to prevent mother-to-child transmission of HIV, and most women go on to have healthy babies.*
Have to stop drinking and using drugs	*ARVs still work when people are drinking or using drugs. It is better that you take ARVs while you are drinking or using drugs, rather than waiting to start them. We can help you cut down or stop drinking or using drugs when you are ready. Keep in mind that it is important to take ART every day, and sometimes people who drink heavily or take drugs forget to take their medicines. So adherence remains very important.*
Inadvertent disclosure of HIV status	*Many people take their HIV medication every day without others being aware of it. Things that people do to take medication confidentially include storing medication in a non-prescription container; keeping medications in a private place; and taking ART along with other medications that they already take. Would any of these be helpful for you? We can provide reminders to take your medications through a short message service (SMS) text message, using a code phrase that only you will recognize, as a reminder to take your ART. You can text us with a coded message if you need to talk with us. We will also give you our telephone number to call confidentially if you have questions or concerns about taking medication.*

Food or medications and ART	*Some people feel better when they eat around the time they take their ARVs, but the ARVs we use now work well whether you take them with food or on an empty stomach.* *Medications can sometimes interact with each other, so it is important to tell your healthcare worker if you are taking any other medicines, including traditional medicine.* Note to provider: Refer individual to any nutrition services if available, as availability of nutrition services, especially where food is scarce, can be helpful in improving retention and adherence.
Lifelong ART	*It can be overwhelming to think about having to do something for the rest of your life. Let's take it day by day for now. Many people incorporate taking their medications into their daily routines, like eating and drinking, and it does not feel disruptive or burdensome for them.*
Doubt diagnosis	*I understand it can be difficult to accept being diagnosed with HIV. We have confirmed your diagnosis by going through the national testing algorithm for a second time. Can I answer any questions for you?*
Disruption of work/life	*I know it takes time away from your life and other responsibilities to come to the clinic. Starting ARVs now will prevent you from getting ill in the future. Getting ill means having to miss work for more frequent clinic visits. We will do a test called VL in six months to see if the ARVs are working well. If you are taking ARVs every day and they are working well, the VL will usually be low (less than 1000) at this time. Keeping the VL low may help you come to the clinic less frequently.*

Counseling Messages for Parents of Infants and Children Starting ART

It is important that HCW speak to caregivers and children in a supportive, non-judgmental manner, using non-technical language, and providing hope and support.

Taking ARVs regularly and having a low VL has many benefits:

- *It prevents other serious illnesses. Low VL means your child has more disease-fighting cells, called CD4 cells, which can fight serious illnesses.*
- *It keeps your child from having extra visits to the clinic because of sickness and having to miss school.*
- *It keeps your child physically and emotionally strong. Low VL can help your child grow well and prevent mood problems such as depression and anxiety.*
- *It allows you and your child to focus on everyday life.*

Giving ARVs is an adult responsibility:

- *Adult caregivers should give children their medication. Assign one person whose "job" it is to give the medication. If that adult cannot give the medication that day, it is that adult's job to find another adult to give the medication.*
- *Put medications somewhere easy to remember that you use every day.*
- *Use an incentive chart or calendar to mark/put a sticker when medications are taken for the day.*
- *If required, you can use pill boxes and/or travel packs.*
- *It is important to observe your child take the medication and make sure it is swallowed, not spit out or thrown away.*
- *It is important to give children truthful information once they start having questions so when they grow up they can learn to take care of themselves.*
- *What you say, including when you tell them about HIV, will depend on their age and how well they can understand.*

Post-Start Counseling and Support

After starting people on ART, it is important to follow-up with them in one to two weeks to assess how they are doing, answer any questions they may have, and help them to manage any side effects or symptoms of immune reconstitution inflammatory syndrome (IRIS). This follow-up is usually done at a scheduled clinic visit, but in certain situations this could be done by phone or through a home visit.

Below are some sample questions to ask people when they are seen for short interim follow-up after ART initiation.

- *How has it been to take ARVs?* Probe: *Have you had any difficulties taking your ARVs?*
- *Have you experienced any problems or symptoms since you started taking your ARVs?*
- *Some people find it difficult to take ARVs every day. Please think back to the past WEEK, how many ARV doses (days) do you think you missed? How about the week before that?*
- *Did you use anything to remind you to take your ARVs? Would it be helpful to use something like a calendar or setting an alarm on your phone?*
- *Have you talked with anyone about your HIV status? Is there someone who could help you remember to take ARVs, or support you while taking them?*
- *Many people have problems taking their pills at some point. Please feel comfortable telling me about challenges you are facing; I am asking because I want to try to find ways to make it easier. Can you remember and describe what happened the last time you missed a dose?*

Please see ICAP's Viral Load Monitoring and Enhanced Adherence Counseling Flipcharts for additional adherence assessment and counseling support for adults, adolescents, and children.

B. Community Messaging

Community messaging that is consistent with national policy and health education provided in facilities is essential to the expansion of ART services. Consistent messages that reflect policy and resonate with local values and practices should be developed and disseminated through multi-sectoral partnerships at national, sub-national, and local levels. Working with civil society, including PLHIV, to develop key messages to support treatment literacy is critical. Consistent messages about treatment initiation should be incorporated into procedures, training, and counseling materials used in community-based HIV testing services (HTS), as such services often constitute the front line of mobilization, education, and engagement in the HIV care continuum. Other important stakeholders can be powerful voices in combating stigma and reinforcing messages regarding Test and Treat, and should be engaged in efforts to disseminate messages, including local social and political leaders, religious figures, and community-based providers facilitating access to HIV testing, such as providers of services related to sexual- and gender-based violence and harm reduction.

IV. ART Initiation

A. Package of Services for Individuals Newly Diagnosed with HIV

Patients testing HIV positive, regardless of entry point, should be enrolled in care and receive their first clinical assessment on the day of diagnosis. When ART is initiated at a HF, all patients should receive an initial assessment, consisting of a comprehensive clinical package and counseling on ART initiation (described in Chapter III) during the first clinical visit (see Figure 2). For more information regarding community ART initiation, see Chapter VI.

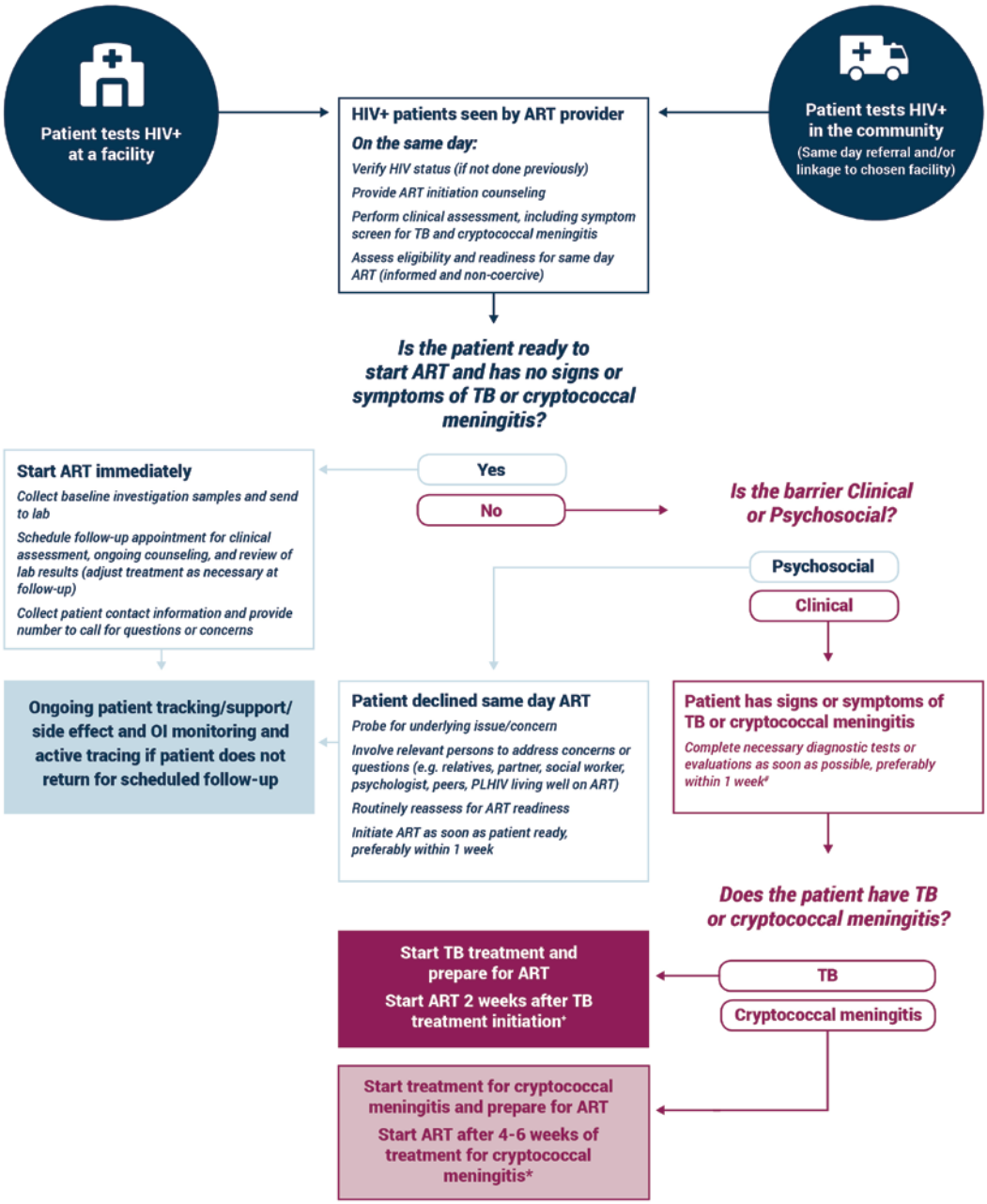
The initial clinical assessment should include clinical staging and screening for opportunistic infections (OI), including screening for tuberculosis (TB) and cryptococcal meningitis (see Box 4). An initial symptom screen for TB can be done by asking about the presence of cough, fever, weight loss or night sweats, followed by TB diagnostic tests (including Xpert MTB/RIF) for those who screen positive (see Figure 3). Cryptococcal antigen (CrAg) should be checked for people with symptoms of meningitis (e.g., headache, confusion) and for all adults and adolescents with a CD4 count <100 cells/mm^3. Although the WHO recommends ART initiation regardless of CD4 count, CD4 measurement at enrollment in HIV care is still important to identify individuals with advanced disease, as clinical staging may miss a substantial number of PLHIV with severe immunosuppression.[11] However, ART initiation should not be delayed while awaiting CD4 results or other routine baseline bloodwork results. This initial assessment serves to identify individuals with advanced disease who will require more intensive evaluation for and management of OI, to mitigate morbidity and mortality (see section C below).

Box 4. Services to be Provided at the Time of Enrollment in HIV Care at Health Facilities:

- ✓ Retesting for verification
- ✓ Clinical staging and OI symptom screen
- ✓ Baseline bloodwork, including CD4 count where available
- ✓ Xpert MTB/RIF if TB symptoms
- ✓ CrAg if CD4 count <100 cells/mm^3 or meningitis symptoms for adults and adolescents
- ✓ Tailored counseling support
- ✓ ART initiation

Patients should receive individualized counseling support to ensure that they are able to make an informed decision regarding ART initiation and are not coerced into starting ART. There will inevitably be people who decline or are unable to initiate ART on the same day. Those who have been assessed and are not ready to start ART should be followed and have ongoing clinical assessment and counseling (see Chapter III). It is also important to document the reasons for any delays in ART initiation, in order to better inform patient follow-up and ongoing counseling (see section on *Patients with Deferred ART Initiation* in Chapter V).

Figure 2: Algorithm for Rapid Initiation of ART



Adapted from Ugandan Ministry of Health and Botswanan Ministry of Health and Wellness algorithms.

See Figure 3 for details on diagnostic evaluation for people with symptoms of TB or cryptococcal meningitis
+ If CD4 <50 cells/mm,^{3} initiate ART within two weeks of TB treatment initiation; if CD4 >50 cells/mm,^{3} initiate ART as soon as possible after TB treatment initiation, and within the first eight weeks of TB treatment. If TB meningitis with low CD4 count, early ART make pose a risk of severe adverse events, so careful monitoring should be provided.
* Defer ART until after four to six weeks of antifungal treatment and evidence of sustained clinical response

B. Starting ART in Patients Previously Enrolled in Care

Previously, there were eligibility criteria for ART initiation (e.g. CD4 <500 cells/mm^3 or WHO Stage III or IV), and people who enrolled in HIV care and were not yet eligible for treatment were referred to as "pre-ART." These individuals should have been receiving routine follow-up to re-assess for ART eligibility. As countries transition to Test and Treat, "pre-ART" individuals who are engaged in care should be initiated on ART at their next clinic visit (see specific counseling messages in Chapter III). However, many individuals previously deemed "pre-ART" may be lost to follow-up, and it is important that they are re-engaged in care using a systematic approach to identify and track them and ensure that they are started on ART as soon as possible.

Box 5. Country Example: Kenya initiated national implementation of Test and Treat in August 2016. Health facilities implemented a systematic approach to identify former pre-ART patients and accelerate ART initiation. The "Check, Flag and Start" strategy consisted of a MDT reviewing patient files of all pre-ART patients and adding stickers to fast-track ART initiation since they were now eligible. Clients were called back to the clinic to initiate ART. Adherence counselors kept track of patients and would follow-up with them until they returned to the clinic and initiated ART.

Once individuals return to care, they should receive the same assessment as those individuals who are newly diagnosed, including retesting for verification, and determining whether or not they have advanced disease.

C. Package of Services for Patients with Advanced Disease

The WHO defines advanced disease as adults, adolescents, and children older than five years with CD4 cell count <200 cells/mm,^{3} or WHO stage 3 or 4 regardless of CD4 count, as well as all children younger than five years of age.[4] Rapid ART initiation is particularly important for individuals presenting with advanced disease, because they have a significantly higher risk of mortality, especially in patients with CD4 cell count <50 cells/mm.^{3} Leading causes of mortality among patients with advanced disease are TB, cryptococcal meningitis, bacterial infections, toxoplasmosis, and *Pneumocistys jirovecii* pneumonia. These individuals may have a less favorable response to ART compared to those initiating treatment earlier in the course of HIV infection, including a less robust CD4 count recovery on treatment.

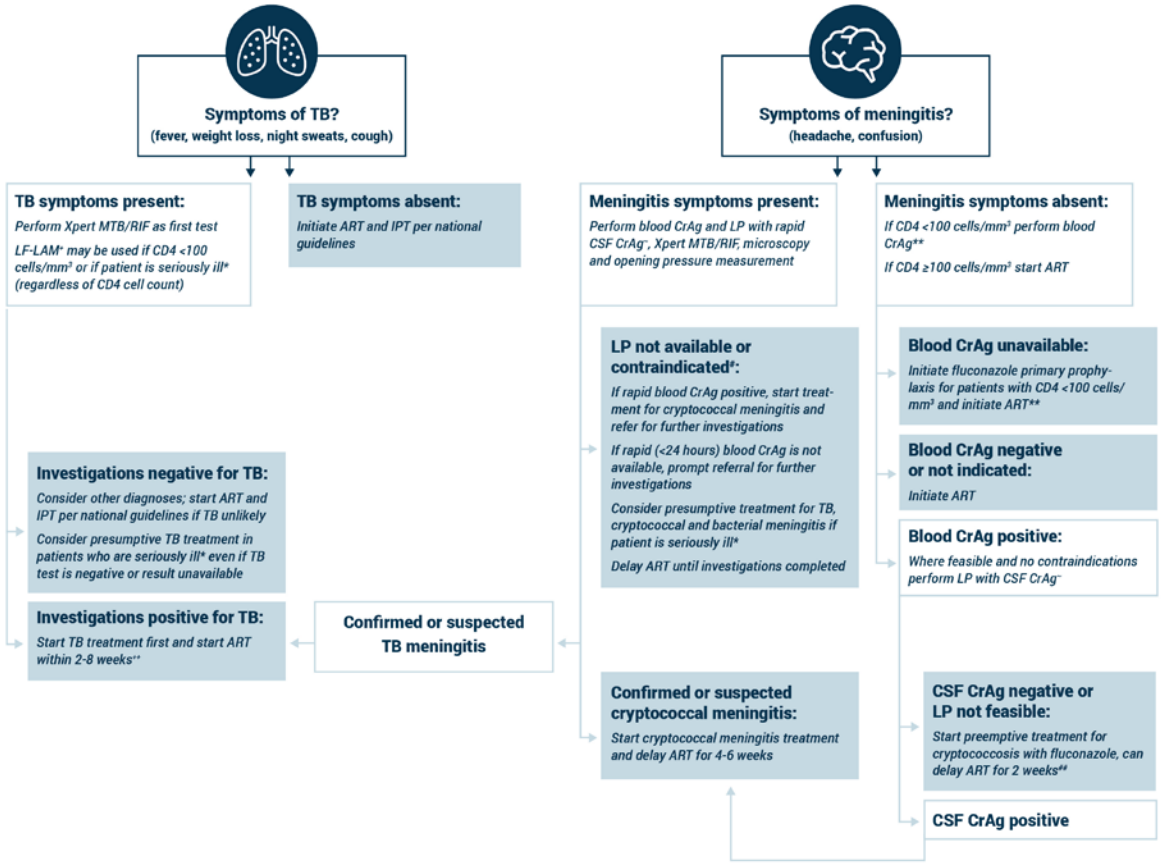
Box 6. WHO Package of Care for Patients with Advanced Disease

- ✓ Rapid initiation of ART
- ✓ Screening for cryptococcal meningitis for asymptomatic adults and adolescents with CD4 count <100 cells/mm^3 with serum CrAg or by symptoms, and fluconazole as indicated (Figure 3)
- ✓ Screening and treatment for TB, or IPT, as indicated (Figure 3)
- ✓ CTX prophylaxis
- ✓ Intensive follow-up

Strategies to reduce early morbidity and mortality among individuals presenting to care with advanced disease include: screening and treatment for common co-morbid conditions, rapid initiation of ART, prompt initiation of OI prophylaxis, and close follow-up and monitoring so that adherence can be supported and complications, such as adverse drug reactions and/or IRIS, can be diagnosed and appropriately managed. The WHO recommends a package of interventions for individuals with advanced disease (Box 6).[4, 12] This package includes: 1) screening for and diagnosis of TB (with Xpert MTB/RIF and lateral flow urine lipoarabinomannan assay (LF-LAM)); 2) CrAg screening (ideally with results available in <24 hours) for asymptomatic adults and adolescents with CD4 cell count <100 cells/mm^3 or for any PLHIV with symptoms of meningitis, and fluconazole as pre-emptive therapy or prophylaxis as indicated (see Figure 3); 3) isoniazid preventive therapy (IPT) for adults and children >one year of age without active TB; 4) cotrimoxazole (CTX) prophylaxis for all infants or children under five years of age, or with CD4 ≤350 cells/mm^3, clinical stage 3 or 4 disease, or any CD4 count/WHO stage in settings with high malaria prevalence.[10, 12, 13]

The interventions listed above should be provided for all individuals presenting with advanced disease. However if there is suspicion for TB or cryptococcal meningitis, ART may be delayed to complete the necessary diagnostic tests (see section C below and Figure 3 for diagnostics approach). It is also important to rule out pregnancy before fluconazole initiation.

Figure 3. Diagnostic work-up of patients with signs and symptoms of TB or cryptococcal meningitis.



Adapted from the WHO 'Guidelines on the Management of Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy' (2017) and 'Guidelines for the diagnosis, prevention, and management of cryptococcal disease in HIV-infected adults, adolescents and children' (2018).

#Contraindications for lumbar puncture include significant coagulopathy, suspected space-occupying lesion based on focal nervous system signs, or recurrent seizures and, where possible, confirmed by computed tomography. Raised intracranial pressure does not contraindicate LP in (suspected) cryptococcal meningitis. Other contraindications include major spinal deformity and patient refusal after fully informed consent was sought.
+LF-LAM should not be used as a screening test for TB.
*WHO defines a seriously ill adult as having any of the following danger signs: respiratory rate ≥30 breaths per minute; heart rate ≥120 beats per minute; or unable to walk unaided. Other clinical conditions, such as temperature ≥39ºC combined with other signs such as headache, can also be considered based on local epidemiology and clinical judgement. A seriously ill child is defined as having any of the following danger signs: lethargy or unconsciousness; convulsions; unable to drink or breastfeed; or repeated vomiting. Other clinical conditions such as temperature ≥39ºC and age-defined tachycardia and/or tachypnea can be considered based on clinical judgement.
⁻If access to cerebral spinal fluid (CSF) CrAg is not available and/or rapid results are not available (<24 hours), then India ink test can be used for diagnosis.
**May be considered for CD4 <200 cells/mm³ (WHO conditional recommendation). Not indicated in asymptomatic infants or children due to low prevalence of cryptococcal disease in these populations.
++If CD4 <50 cells/mm³ initiate ART within two weeks of TB treatment initiation, if CD4 >50 cells/mm³ initiate ART as soon as possible after TB treatment initiation, and within first eight weeks of TB treatment. If TB meningitis with low CD4 count, early ART may pose a risk of severe adverse events, so careful monitoring should be provided.
##Limited evidence on timing of ART initiation after starting preemptive antifungal therapy. Southern African HIV Clinicians' Society Guidelines recommend starting ART after two weeks.[14]

Whenever possible, all individuals with advanced disease should be enrolled in supportive systems, which can include SMS messages, supportive phone calls, or home visits. As individuals presenting with advanced disease are at high risk of death during the first weeks of ART, they should be prioritized to receive weekly home visits, whenever possible. A system for identifying individuals with advanced disease who missed an appointment, and activating outreach in a timely manner (ideally within a week), are essential to ensure that these individuals remain engaged in care and to reduce mortality.

D. When to Start ART

Prompt initiation of ART is important to reduce morbidity and mortality in all patients with HIV. Rapid ART initiation should be offered to all people with a confirmed HIV diagnosis in whom it is not contraindicated based on their clinical assessment (Figure 2). The WHO defines rapid initiation as starting ART *within seven days* of confirmed HIV diagnosis. Certain populations should be encouraged to start ART as soon as possible, including on the same day, such as pregnant and breastfeeding women, and children under five years of age.

There are certain clinical conditions that may warrant a delay in ART initiation (see Figure 3). All individuals with signs or symptoms of presumptive TB (including cough, fever, weight loss, and night sweats) should undergo a diagnostic evaluation. If results are not available on the same day, ART initiation should be briefly deferred until exclusion of a TB diagnosis. If a TB diagnosis is confirmed, TB treatment should be initiated first, and ART should be subsequently started within the first eight weeks of TB treatment. PLHIV with TB, who have severe immunosuppression (i.e. CD4 count <50 cells/mm^3), should initiate ART within the first two weeks of TB treatment, due to the high risk of mortality. In PLHIV with TB meningitis and a low CD4 count, early ART initiation may pose a risk of severe adverse events,[15] thus these individuals should be monitored closely. Individuals who screen negative for TB, or in whom a TB diagnosis is excluded, should initiate ART and IPT should be initiated within the first two weeks.

Individuals with signs and symptoms of meningitis should also defer ART initiation until a diagnosis of cryptococcal or TB meningitis can be excluded through performing a lumbar puncture (LP). Early ART initiation is contraindicated in those with cryptococcal meningitis due to the high risk of mortality with IRIS. Where a LP is not feasible, cryptococcal meningitis should be suspected in those with symptoms of meningitis and a positive serum CrAg. Individuals with a confirmed or suspected diagnosis of cryptococcal meningitis should defer ART until after the completion of four to six weeks of antifungal therapy per WHO treatment guidelines.[13] Individuals with a positive serum CrAg and no evidence of meningitis should be initiated on fluconazole pre-emptive therapy for CrAg and ART should be delayed by two weeks (see Figure 3).

E. Initiating ART in Infants, Children and Adolescents

Infants, children and adolescents have unique needs that must be considered when initiating ART. This includes the need for virologic testing for those <18 months old, different formulations of medications that may require special techniques to administer, reliance on caregivers to administer medications, and issues of consent and psychosocial support based on developmental level. The table below includes age specific considerations for initiating ART in infant, children, and adolescents.

	Infants and children ≤ 24 months	Children (2-9 years)	Adolescents (10-19 years)
Retesting for verification/ Confirmatory testing	Send confirmatory polymerase chain reaction test if <18 months, then start ART immediately and do not wait for the results	Retest for verification similar to adults	Retest for verification similar to adults
Consent for treatment	Provide counseling and obtain consent from primary caregiver and legal guardian	Provide counseling and obtain consent from primary caregiver and legal guardian	If an unaccompanied minor, address consent for treatment as per national guidelines
Package of Services	*Similar to adult but consider the following:* • Conduct nutritional assessment and provide support as appropriate • Monitor growth and development • Provide CTX to all infants and young children regardless of CD4 count	*Similar to adult but consider the following:* • Conduct nutritional assessment and provide support as appropriate • Monitor growth and development • Provide CTX to all young children under the age of five years and to older children	*Similar to adult but consider the following:* • Conduct nutritional assessment and provide support as appropriate • Monitor growth and development • Assess sexual reproductive health needs and provide referral as appropriate

	Infants and children ≤ 24 months	Children (2-9 years)	Adolescents (10-19 years)
	• Conduct TB screening adapted for infants and children as per national guidelines • Provide IPT if no active TB and >1 year of age		
Medication	• Provide age-appropriate ARV formulations and counsel caregiver to anticipate changes to ARV regimen or formulation as child grows • Discuss storage and administration of child-friendly formulations with primary caregiver • Demonstrate use of correct measuring tools and proper technique to administer medication	• Ensure ARV formulation is appropriate for developmental level of child (i.e. ability to swallow tablets) • Discuss linking medication to daily activity to support adherence • Demonstrate use of correct measuring tools and proper technique to administer medication • Ensure dose and regimen are adequate based on weight and age	• Provide once daily regimen with fixed dose combination, when eligible, based on age and weight criteria per national guidelines • Discuss linking medication to daily activity to support adherence • Plan for follow up appointments and adherence support for school-going adolescents, including those in boarding schools • Advise use of reminders, such as alarm for adherence
Adherence and disclosure support	• Support disclosure to persons who can be responsible for administering medication when primary caregiver is not present • Counsel caregivers to address challenges related to ARV administration	• Support disclosure to persons who can be responsible for administering medication when primary caregiver is not present	• Support disclosure to persons who can be responsible for supervising medication when primary caregiver is not present • Encourage enrollment in age appropriate adherence support group
Labs	• Baseline hemoglobin (Hb) for infants starting AZT containing regimen; Xpert MTB/RIF if TB screen positive	• Baseline Hb for children starting AZT containing regimen; Xpert MTB/RIF if TB screen positive	• Same as adults
Psychosocial support	• Link mother to support group for postpartum women	• Provide age-appropriate psychosocial support for the child and caregiver	• Baseline psychosocial assessment and linkage to age-appropriate support group • Females screen for gender-based violence (GBV) and provide support • Screen for drug and alcohol use

V. Clinical Follow-up

As described in the previous chapter, all newly-diagnosed individuals should initiate ART within seven days, and preferably on the same day of diagnosis. Those in care and not on ART (formerly known as pre-ART) should initiate ART during their next clinic visit, unless there are contraindications. This is an important paradigm shift for both patients and HCW, and it is important to work with program managers and multidisciplinary teams (MDT) to develop and implement a clinical follow-up package of care adapted to each individual's needs to ensure adherence, retention in care, and VLS.

Clinical improvement and VLS can be expected in individuals receiving ART. However, during the first months of treatment, clinical and laboratory monitoring are necessary to assess treatment response, identify medication side effects and toxicity, address any barriers to adherence, and ensure early identification of IRIS. This section describes the key components of the package of care for the first six months post-ART initiation.

A. Individuals Presenting Well with Early Disease

In the context of Test and Treat, asymptomatic individuals (individuals "presenting well") will be starting ART as soon as possible. Individuals who initiate ART with a high CD4 cell count have a lower risk of morbidity and mortality and are less likely to develop IRIS. Clinical follow-up should include a clinical evaluation, monitoring for treatment response, side effects, and toxicity, and provision of OI prophylaxis as indicated. It is essential that patients receive adherence support to ensure that they remain engaged in care. A system of supportive phone calls and/or SMS text messages related to treatment adherence and appointment reminders are recommended for this group of patients.

Below we describe the key elements of the clinical follow-up package of care during the first six months of ART for individuals presenting well with early disease. Refer to Table 2 and the *ICAP Approach to Differentiated Service Delivery* for more details on the first year on treatment. Elements of the clinical follow-up package for individuals presenting well with early disease include:

- ✓ Clinical assessment
  - WHO staging
  - Symptom screen and clinical exam (Annex 2*: Patient Checklist*)
  - TB symptom screening
  - Screening for IRIS, treatment side effects, and toxicity
  - Sexual and reproductive health screening
  - Mental health screening[b] for depression[16] using the PHQ2 or other national tools (Annex 3: *Patient Health Questionnaire 2*)
- ✓ Lab work as clinically appropriate
  - Baseline CD4 count if feasible
  - Hemoglobin if using azidothymidine (AZT) and creatinine if using tenofovir disoproxil fumarate (TDF).
  - Viral load testing at six months
- ✓ OI prophylaxis
  - IPT if negative TB screen and/or diagnosis of TB has been excluded
  - CTX (as per national guidelines)
- ✓ Adherence assessment, support and counseling (Annex 4: *Enhanced Adherence Counseling Form)*
  - Identify barriers to adherence if indicated (Annex 5*: Questions to assess barriers*)
  - Discuss strategies to overcome barriers (Annex 6*: Tips to improve taking ARVs*)
- ✓ ARV refills until next visit
- ✓ Follow-up appointment

[b] In countries where substance use contributes significantly to the HIV epidemic, consider screening for substance use disorders and treating according to national guidelines.

B. Clinical Follow-up of Individuals Presenting with Advanced Disease

Individuals with advanced disease (WHO stage III/IV or CD4 count <200/mm^3) are at high risk for HIV disease progression, HIV-related complications, and early mortality. They should receive a clinical package of care designed to reduce their risk of morbidity and mortality, including rapid initiation of ART (see *Package of Services for Advanced Disease* in Chapter IV) and require close monitoring for treatment side effects and toxicity, IRIS, and the development of new and severe OIs.

IRIS is a clinical diagnosis and may present as worsening or relapse of a previously diagnosed/treated OI (paradoxical IRIS) or as an inflammatory response to a previously undiagnosed OI (unmasking IRIS). Risk factors for IRIS include: CD4 ≤50 cells/mm^3 and high baseline VL. IRIS usually presents within weeks to months of initiating ART. The severity of IRIS varies from mild and self-limited to life threatening. Management of IRIS includes continuation of ART and treatment of the underlying OI. Rarely, in life threatening circumstances, corticosteroids may be required and ART may be discontinued. Common OIs that may manifest as IRIS include TB, Mycobacterium avium complex, cryptococcal meningitis, or cytomegalovirus.

Whenever possible, weekly supportive home visits, including a clinical assessment (for side effects, signs and symptoms of OIs, and IRIS), as well as an adherence assessment and support, are recommended during the first three to six months of ART. Home visits can be provided by community HCW or a home-based caregiver, and patients should be referred to a HF if any clinical or adherence challenges are detected. If home visits are not available, it is important to ensure weekly check-in calls or text messages to follow-up on individuals with advanced disease during the initial months of ART.

It is essential that there are systems in place to identify individuals who miss an appointment and to activate outreach in a timely manner to ensure that patients remain engaged in care. If resources are limited, individuals with advanced disease should be prioritized for outreach if they miss a visit.

Below we describe the key elements of the clinical follow-up package during the first six months of ART for individuals presenting with advanced disease. Refer to Table 2 and the *ICAP Approach to Differentiated Service Delivery* for more details on the first year on treatment.

Elements of the clinical follow-up package for individuals presenting with advanced disease include:

- ✓ Clinical assessment
  - Symptom screening and clinical exam (Annex 2: *Patient Checklist*)
  - Screening for OIs, especially TB and cryptococcal meningitis (Figure 3)
  - Screening for IRIS, treatment side effects, and toxicity
  - Sexual and reproductive health screening
  - Mental health screening[c] for depression[14] using the PHQ2 or other national tools (Annex 3: *Patient Health Questionnaire 2*)
- ✓ Lab work as clinically appropriate
  - Baseline CD4 count if feasible
  - Serum CrAg testing for adults and adolescents with CD4 <100 cells/mm^3 (if not done previously)
  - Hemoglobin if using AZT and creatinine if using TDF
  - Viral load testing at six months
- ✓ OI treatment or prophylaxis
  - IPT if negative TB screen and/or diagnosis of TB has been excluded
  - CTX (as per national guidelines)
  - Fluconazole as indicated; if serum CrAg positive, CD4 <100 cells/mm^3, LP negative (or not feasible), and no signs or symptoms of meningitis, give pre-emptive therapy with fluconazole

[c] In countries where substance use is a significant contributor to the HIV epidemic, consider screening for substance use disorders and treating according to national guidelines.

for 10 weeks, then fluconazole prophylaxis; if serum CrAg unavailable and CD4 <100 cells/mm^3, give fluconazole as primary prophylaxis.

- ✓ Adherence assessment, support, and counseling (Annex 4: *Enhanced Adherence Counseling Form)*
  - o Identify barriers to adherence if indicated (Annex 5: *Questions to assess barriers*)
  - o Discuss strategies to overcome barriers (Annex 6:*Tips to improve taking ARVs*)
  - o Counseling message should include the importance of seeking medical care early for any symptoms
- ✓ Appointment reminders to support retention in care (e.g. SMS messages or phone calls)
- ✓ ARV refills until next visit
- ✓ Follow-up clinic appointment and scheduled home visit, if available

Table 2: Clinical Follow-up Services after ART Initiation.

	Early Disease *Defined as: clinically well, CD4>200 cells/mm^3*		Advanced Disease *Defined as: clinically unwell, CD4<200 cells/mm^3*	
	Clinical review + ART refill	Psychosocial support	Clinical review + ART refill	Psychosocial support
Visit frequency	wk2, m1, m2, m3*, m4, m5, m6* **milestone visit, patients should be assessed for referral to less-intensive follow-up (DSD models)*	wk2, m1, m2, m3*, m4, m5, m6* **milestone visit, may consider referral to less-intensive follow-up (DSD models)*	wk2, m1, m2, m3, m4, m5, m6	wk2, m1, m2, m3, m4, m5, m6
Visit location	Health facility or mobile clinic with equivalent services	Health facility or in community	Health facility	Health facility or in community
Service provider	• Clinician • Lay HCW (m4, m5)	• Lay counselor • Community HCW	• Clinician	• Lay counselor • Community HCW
Service package	• Clinical assessment (each visit) • OI prophylaxis: o CTX (each visit) o IPT (from wk2) • Lab work if clinically indicated • VL sample collection (m6) • ART refill (each visit) • Follow-up appointment (each visit) Note: If any clinical concerns, move to advanced disease group	• Adherence assessment, support and counseling	Include all 'early disease' package plus: • Screening and management of OIs, especially TB and cryptococcal meningitis For CD4 <100 cells/mm^3 and no signs and symptoms of meningitis: • Check serum CrAg if not done previously (wk2). • If CrAg positive, and LP negative (or not feasible), give pre-emptive therapy with fluconazole for 10 weeks then fluconazole prophylaxis. • If CrAg unavailable give fluconazole primary prophylaxis.	• Adherence assessment, support and counseling • SMS reminder or any model of appointment reminder • Home visits where feasible

C. Clinical Follow-up in Infants, Children and Adolescents

Clinical follow up for infants, children, and adolescents is similar to that for adults, but must also include pediatric specific issues including adjustment of regimens; ARV formulation and/or dosage to account for growth and development; support for age-appropriate disclosure; account for multiple caregivers; and considerations for school-going children and adolescents.

	Infants and children ≤ 24 months	Children (2-9 years)	Adolescents (10-19 years)
Package of Services	*Similar to adult but consider the following for every clinical visit:* • Conduct nutritional assessment (z-score) and provide support as appropriate • Monitor growth and development • Conduct TB screening adapted for infants and children as per national guidelines • Refill CTX for all HIV-infected infants and children < 5 years regardless of CD4 count (*adjust dose based on weight)* • Initiate or refill IPT if TB screen negative, no active TB and > 1 year (*adjust dose based on weight)*	*Similar to adult but consider the following for every clinical visit:* • Conduct nutritional assessment (z-score or mid upper arm circumference) and provide support as appropriate • Monitor growth and development • Conduct TB screening adapted for children as per national guidelines • Initiate or refill of IPT if no active TB (*adjust dose based on weight)* • Refill CTX for all HIV-infected children <5 years regardless of CD4 count and for older children with CD4 <350 cells/mm^3 (*adjust dose based on weight)*	*Similar to adult but consider the following for every clinical visit:* • Conduct nutritional assessment (z-score or body mass index) and provide support as appropriate • Monitor growth and development • Assess sexual and reproductive health needs and provide services or referral as appropriate
Clinic visits schedule	• Monthly visits to the HF including clinical visits during the first year on ART*	• Children <5 years: monthly visits to the HF, including clinical visits during the first year on ART* • Children >5 years: as per national guidelines	• As per national guidelines • Link to existing DSD models specific for adolescents
Medication	• Transition to age appropriate regimes and/or formulations based on age, growth, and developmental stage. • Adjust dosing of ARVs based on weight gain	• Practice pill swallowing • Discuss linking medication to daily activity to support adherence • Develop adherence plan in accordance with school schedule as appropriate • Adjust dosing of ARVs based on weight gain	• Discuss linking medication to daily activity to support adherence • Develop adherence plan for school-aged adolescents, including those in boarding schools • Use of reminders such as alarm for adherence
Adherence and disclosure support	• Counsel caregiver on addressing challenges with medication administration • Provide support to disclose to all caregivers responsible for administering ARVs when primary caregiver is not present	• Provide support to disclose to all caregivers responsible for administering ARVs when primary caregiver is not present	• Support disclosure to any one responsible for supervising medication when caregiver is not present • Support full disclosure of HIV status to the adolescent • Encourage enrollment in age appropriate adherence support group
Labs	• VL as per national guidelines (or CD4 if VL not available)	• VL as per national guidelines(or CD4 if VL not available)	• VL as per national guidelines(or CD4 if VL not available)

	Infants and children ≤ 24 months	Children (2-9 years)	Adolescents (10-19 years)
Psychosocial support	• Counsel caregiver on importance of adherence to treatment and provision of adequate dose of medication • Link mother to support group for postpartum women	• Support age appropriate disclosure to child • Encourage enrollment in age appropriate support group for child and/or caregiver	• Baseline psychosocial assessment and linkage to age appropriate support group • Screen for GBV and provide support or referrals as appropriate • Screen for drug and alcohol use

* For children WHO Guidelines for managing advanced HIV disease and rapid ART initiation of antiretroviral therapy has an expanded definition, including all children under five years of age with advanced disease at presentation, as they have higher risk of disease progression and mortality regardless of their clinical and immunological stage

D. Patients with Deferred ART Initiation

Not all individuals will start ART on the day of diagnosis. There will be some individuals who will not be ready to start ART on the day of diagnosis, and others who have been diagnosed with an OI for which same-day ART initiation is contraindicated, such as TB or cryptococcal meningitis (see algorithm in Figure 2). Individuals who are not ready to start ART on the day of diagnosis should be initiated on ART as soon as feasible, ideally within one week of HIV diagnosis. Even if individuals are not ready to start ART, they should be clinically evaluated to determine if they have advanced disease (for details see Chapter IV), which will inform the delivery of follow-up services.

See the *When to Start ART* section in Chapter IV for recommended timing of ART initiation for patients diagnosed with TB or cryptococcal meningitis.

Clinical and Psychosocial Support for Patients Not Ready to Initiate ART

Historically, retention among individuals who have not initiated ART (formerly called 'pre-ART' patients) has been lower than among those on ART. In order to keep these individuals engaged in care until they are ready to initiate ART, a package of care, including clinical follow-up and psychosocial support, should be provided (see Table 3). Provision of this package allows providers to address treatment preparedness, while supporting informed decision-making about ART initiation, as well as retention in care. At each visit to the HF or contact with the patient, psychosocial support and counseling should be provided. When counseling the patient, it is important to ensure the following:

- ✓ Do not be punitive or judgmental if the patient is not ready to initiate ART
- ✓ Assess possible barriers to ART initiation (Annex 5: *Questions to assess barriers*)
- ✓ Work with the patient and existing support systems to identify strategies to overcome any barriers to ART initiation and involve relevant persons to address concerns or questions (e.g. relatives, partner, social worker, psychologist)
- ✓ Link patients with community networks of peers or other PLHIV, to provide ongoing counseling and support to encourage ART initiation

Table 3: Package of Care for Patients who Defer ART Initiation

Package Of Care For Patients who Defer ART Initiation	
Individuals presenting well	Individuals presenting with advanced disease
• Short interval appointments to facilitate rapid ART initiation, ideally every two to four weeks • Basic clinical screening including TB screening, and assessment of readiness to initiate ART at all visits • Provision of OI prophylaxis as indicated • Ongoing treatment literacy education and counseling on the importance of ART initiation and adherence to treatment • System to track patients who miss appointments and ensure their engaging in care (e.g. SMS or phone call reminders)	• Frequent facility and/or home visits to monitor clinical status and assess patient readiness to initiate ART, ideally every one to two weeks • Regular screening for OIs, especially TB and cryptococcal meningitis • Provision of OI prophylaxis • Ongoing treatment literacy education and counseling on the importance of ART initiation and adherence to treatment • System to track patients who miss appointments and ensure their engagement in care (e.g. SMS or phone call reminders)

VI. Community ART Initiation

A. Benefits of Community ART Initiation

Community-based HIV testing can reach individuals who do not access testing services at health facilities. Community testing may be conducted in the home, as part of public campaigns and health promotion events, in mobile units located in venues accessible and convenient for intended beneficiaries, or at the workplace. However, there are challenges associated with linkage to facility-based HIV care and treatment services following a positive HIV test in a community–based setting. One way to strengthen engagement in care following diagnosis in community-based settings for adults and adolescents is to initiate HIV care and treatment at the testing location.[17] This includes verification testing, education, and counseling about the benefits of immediate ART initiation, and dispensing an initial supply of ART if the individual is willing to start treatment.

B. Clinical Considerations for Community-based ART Initiation

Ideally, all individuals initiated on ART in the community should be seen at a HF (or mobile clinic offering equivalent services) within two to four weeks of ART initiation to establish ongoing care. Some elements of the clinical package of services offered to those initiating ART (see Chapter IV) may be provided in the community, while other elements may be more appropriate to include during the first visit at a HF. At a minimum, individuals initiated on ART in the community should receive:

- ART initiation counseling and an assessment of readiness to start ART
- Symptomatic screening for signs and symptoms of TB (cough, fever, weight loss, night sweats) and cryptococcal meningitis (headache, confusion)
- Blood draw for required baseline laboratory assays as available (see Box 7)
- A "starter-pack" supply of medication for up to 30 days, or the same supply provided for patients initiated at the HF
- Referral to and scheduling of a follow-up appointment at a HF within two to four weeks
- Individuals who initiate ART should be contacted one to two weeks later to assess how they are doing, answer any questions they may have, help manage any side effects they are experiencing, and if necessary, refer them to the HF earlier for a clinical assessment.

Box 7. Baseline bloodwork considerations in the community.

It is no longer necessary to have the results of baseline bloodwork prior to starting ART. Decisions about which baseline blood tests to obtain in the community (e.g. CD4 cell count, creatinine for those started on TDF-containing regimens, CrAg) will vary depending on local resources and national guidelines. While data are limited, a study in Haiti found that only 4% of people initiated on ART prior to lab results being available required adjustments to their ART regimen due to their baseline renal function.[6] Decisions should be informed by local epidemiological data, including the prevalence of underlying renal disease and the proportion of PLHIV in the population who have advanced disease (CD4 <200 cells/mm^3) at the time of diagnosis.

Options for community ART initiation baseline bloodwork include:

1) No baseline bloodwork at the time of ART initiation, and a short period before follow-up at a HF for regular laboratory blood tests
2) The use of point of care technology for required blood tests[5, 17]
3) Blood drawn in the community, with specimens sent to the HF laboratory and results linked to the patient's chart; systems should be in place to be able to contact patients with abnormal results prior to their routine follow-up appointment

People starting ART in the community are ambulatory, and therefore are more likely to be clinically well. However, protocols should be in place to refer individuals for immediate management at a HF if they appear clinically ill. The WHO defines adults as being seriously ill if they have any of the following danger signs: respiratory rate ≥30 breaths per minute, heart rate ≥120 beats per minute, or unable to walk unaided. Mobile units should be outfitted and located to ensure that services are confidential and in compliance with local requirements for clinical care.

C. Linkage to Facility-Based Services Following ART Initiation in the Community.

To avoid treatment interruption, special attention must be paid to ensure successful linkage to health facilities from the community. Proactive follow-up with patients and two-way sharing of information between health facilities and community providers are essential to ensure that individuals initiated on ART in the community are appropriately monitored and retained on treatment.

Keys to successful linkage:

- Community-based providers should schedule a follow-up appointment at the HF before the patient's medication supply runs out; ensure that the facility staff are alerted to expect the client on the scheduled date; and actively follow up with the individual to ensure that he/she is linked following ART initiation.
- Community-based providers should coordinate with health facilities to assign the patient a unique identifier (ID) number during community ART initiation.
- To ensure continuity of care and to avoid repeat blood tests, all information collected by the community-based provider that is relevant to the HIV care and treatment medical record should be filed at or transmitted to the HF prior to the initial appointment.
- Community-based outreach workers can serve as trusted navigators for follow-up of individuals who initiate ART in the community, providing reminders of upcoming appointments, additional counseling, and referrals for issues such as GBV and intimate partner violence.
- Providers from health facilities should work closely with outreach workers to ensure continuity of care and consistency in messages about ART and living well with HIV.
- Protocols and standard operating procedures (SOP) for community-based ART initiation should include measures to improve and track successful linkage to health facilities. Where possible, a formal two-way referral system to ensure seamless communication with linking facilities is ideal. However, other mechanisms can be used to ensure linkage, including sending a card to the receiving facility requesting confirmation that the new patient was seen; providing a telephone number to reach the community-based provider in case of questions about linkage; providing the patient with a pamphlet or list of facilities and supportive services, or using an interoperable electronic system that is integrated with the HF system.
- Whenever possible, individuals should be referred to the HF of their choice. However, community-based ART providers should also ensure that they are familiar with any local rules and regulations regarding HF catchment areas and be prepared to refer individuals to health facilities outside of the immediate area if required or requested by individuals. This scenario is especially important to prepare for if programs are serving mobile or transient populations.

Box 8. Special considerations for Key Populations

- Key Populations including female sex workers (FSW), people who inject drugs (PWID), men who have sex with men (MSM), and transgender individuals, face additional stigma and discrimination, and may benefit from community-based ART initiation, often at "KP hotspots".
- Effective outreach workers for KPs are often peers, who are members of the KP community and may be HIV-positive themselves.
- If possible, KPs should be linked to clinics that are sensitive to their needs and are considered "KP friendly". This may require programs to identify, map or sensitize appropriate health facilities.
- If available, PWID should be linked to clinics that can provide integrated care with medication-assisted therapy (MAT).

- Community ART initiation programs must be included in forecasts of medication stock needs at the HF in order to avoid shortages and disruptions in treatment, for both the community ART starter packs as well as ongoing medications dispensed at the HF.

Box 9. ICAP in Tanzania Example

ICAP's community-based testing initiative in Tanzania pioneered the community ART initiation approach in 2016. Historical comparisons with linkage to care following a positive diagnosis at ICAP mobile testing units show that linkage to care increased from 39% to 84% in the first six months of community-based ART initiation.

- ICAP community outreach volunteers work in collaboration with providers from affiliated health facilities to provide HIV testing services and ART initiation in mobile units (tents or vehicles) for key and vulnerable populations.
- Upon arriving at a mobile unit, clients are provided with a unique identifier number written on an ICAP card, and detailed client demographic and contact information are collected for future follow-up.
- Individuals who test positive for HIV are offered immediate ART initiation, with linkage to HIV care and treatment at affiliated health facilities.
- Individuals who agree to start ART are enrolled as a new ART patient in the mobile unit and are given a clinic card with an assigned facility ART ID number by the affiliated HF provider. After a symptom screen and additional counseling and education, they are provided with a two-week supply of medication as per national guidelines. Follow-up visits at the HF are scheduled no later than one week after initiating ART so that the patient does not run out of medication if he/she should miss the appointment.
- Individuals who are <u>not</u> willing to start ART immediately are counseled on the benefits of immediate initiation of ART, given a referral to the affiliated HF within two weeks, and linked with a community outreach volunteer for navigation to care.

Follow-up to ensure linkage:

- Upon returning to the facility after the mobile outreach event, the facility provider ensures that the records of patients who initiated ART in the community are filed appropriately, and that follow-up appointments are registered so that the staff expect the new ART patient at the scheduled time.
- Community outreach volunteers are responsible for reminding clients of upcoming appointments and following-up with them if they miss their appointment.
- National MOH referral forms are given to all who test positive, with their ICAP unique identifier number documented. Upon the patient's arrival at the HF, the feedback portion of the referral form is completed by the receiving HF staff and returned to ICAP to demonstrate successful linkage.
- During monthly meetings with the HF staff, ICAP confirms receipt of referral forms to verify that referred clients are successfully enrolled and retained in care. A list of referred clients who have missed appointments and/or are lost to follow-up is shared with ICAP to enable active follow-up by community outreach volunteers.

VII. Monitoring and Evaluation Considerations

While many countries have established successful HIV care and treatment M&E systems, in order to monitor ART initiation in the context of Test and Treat, M&E systems must be adapted to effectively monitor and track clients from HTS to ART initiation. Identifying ART initiation successes and challenges helps inform any changes necessary to achieve desired program outcomes. Key adaptations and considerations for M&E of ART programs include ensuring that data systems are updated, implementing data-driven program planning, ensuring appropriate program evaluations are conducted, and ensuring data confidentiality and security.

A. Data Systems

To ensure timely initiation of all HIV-positive individuals on ART, data systems must be designed to meet the changing programmatic needs and priorities of Ministries of Health (MOH), funders, and implementing partners. This involves linking HTS and ART M&E systems, as well as including relevant documentation of retesting for verification, determining the timing of ART initiation, tracking individuals who defer ART, and implementing community testing and ART initiation. These data systems may include a combination of paper-based and electronic tools. While electronic tools are preferable, paper tools can be used to document and track all of these services.

i. Paper-based tools

Linkage of HTS and ART M&E systems: In most contexts, HTS and ART M&E systems are separate. Linkage to HIV care and treatment can be documented in the HTS register through recording of the individual's unique ART ID. This unique ID is usually assigned by the HIV care and treatment clinic. Often, the HTS register may have incomplete information regarding linkage to the HIV care and treatment clinic, and there is usually limited documentation in the ART register regarding HTS. To enable routine monitoring and improvement of the timing of ART initiation, a number of key variables are critical and should be recorded in the HIV care and treatment patient file and ART register, including: (1) date and location of first HIV-positive test, and (2) date, location, and result of retesting for verification.

Retesting for verification: It is important that tests conducted for retesting for verification are recorded in patient files as well as in registers to document which individuals have received which tests and when. However, for reporting purposes, tests done for verification should not be reported as unique or new HIV tests. Some countries have established a "retesting" log book to enter only clients undergoing retesting for verification. This log book is used to ensure provision of quality of services and to track stock of HIV test kits. It is not used to report on routine HTS indicators.

Timing of ART initiation: While the aim of Test and Treat in many countries will be same day initiation, not all people will be eligible or ready for rapid or same-day initiation as described earlier. It is recommended that information on deferral of treatment is documented in registers as well as the patient file. In addition, a follow-up plan/appointment date should be recorded to ensure follow-up. For standardized documentation, registers and patient files should include spaces to document (1) the timing of ART as same day or deferred and (2) if deferred, date of follow-up and reasons for deferral. To standardize the documentation of reasons for deferral, the reasons should ideally be categorized and coded (such as 1=patient not ready, 2=TB, 3=cryptococcal meningitis, 4=other, specify).

Deferred ART: Tracking is required for individuals who defer treatment initiation, as well as those previously not eligible for treatment (previously called "pre-ART"), who have not yet initiated ART. While they will enroll in HIV services and receive a patient file and unique ART ID, they will not be entered in the ART register. Establishing a separate filing system could be an alternate approach for differentiating files of clients who have not initiated ART. In other clinics, it may be best to use a deferred ART register, which would replace the prior pre-ART register. This will enable providers to continue to actively assess such individuals for ART initiation.

ii. Electronic systems

In countries with existing electronic medical records (EMR) in the HIV care and treatment clinic, the ART module requires adapting to capture (1) date and location of first HIV-positive test, (2) date and location of retesting for verification, and (3) information on the timing of ART initiation and reasons for deferral, as described for paper systems above.

It is important to note that EMR systems that are only used in the HIV care and treatment clinic may be limited, as they often lack information on HIV testing. It is recommended to establish an integrated EMR system that is inclusive of other services, in addition to routine HIV care and treatment. In a single integrated EMR system, an individual record will have relevant information recorded in an HTS module as well as the ART module, which will contain information on deferral noted above. While separate EMR systems for HTS and ART are not ideal, this is acceptable as long as the EMR systems use a common unique ID or can link the two system IDs.

Use of a common unique ID is critically important and enables information to be shared between different EMR systems within a HF (for instance between the HTS and ART EMRs) and between EMR systems at different health facilities and/or care provided at other levels of the health system, such as the community. For instance, case-based surveillance is only possible with a common unique ID where important milestones during the HIV care provided to each PLHIV are reported to a central data warehouse from any HF or community site providing care. Through case-based surveillance, continuity of care can be tracked and monitored at a national level.

Any EMR systems in use should be programmed to generate automated reports of all people who miss their appointments, PLHIV who are lost to follow up, as well as people who have deferred ART and require consistent re-engagement and follow-up.

iii. ART initiation at community level

All services provided at the community level, such as HIV testing and ART initiation, need to be fully documented and coordinated with nearby health facilities. Guidelines and SOPs should be developed to oversee coordination of assignment of unique IDs, systems for the flow of data between the community and HF, and two-way referral systems to link people who initiate in the community back to the HF that will oversee ongoing care. Community data systems can include copies of HIV care and treatment registers and forms and transfer the information into the HF-based registers at regular intervals. Community modules can be developed that sync relevant information with HF EMR systems, and in reverse, HF EMR systems can automatically send updates to the community module to notify community providers of individuals who missed appointments or who deferred ART.

It is important in the context of any community ART initiation program to follow the correct guidelines for reporting of ART initiation: per the President's Emergency Plan For AIDS Relief (PEPFAR) reporting requirements, people who receive ART starter packs in the community are not counted as newly initiating on ART until they arrive for follow up care at the HF.[18] Information on the number of starter packs used and overall patient volume are key variables to inform ongoing supply chain decisions.

iv. Ensuring data quality

To ensure good data quality, the revised M&E systems, data flow, tools, and roles and responsibilities discussed above need to be documented in updated SOPs and data quality assessments (DQA). When the changes to the M&E system are relatively small, the SOPs and DQA tools previously in use will likely require only minor updates. When the proposed changes to the M&E system are significant, such as introducing entirely new M&E tools to track community ART initiation or development of a new comprehensive EMR, this requires the development of new SOPs and DQA tools accordingly.

Box 10. Country Example

In Ethiopia, catchment area meetings are held regularly to review two-way referral data. The HF staff and community organizations meet to review overall numbers and lists of individuals' names referred in both directions and compare with those who arrived.

B. Planning, Monitoring and Use Of Data

Initiating all individuals who test HIV-positive on ART actually simplifies both the patient flow and the data flow of the program. It also simplifies documentation as patients are directly entered into an ART register rather than having to complete a pre-ART register and ART register. As a result, no new systems for reporting are needed to implement this program. However, a few considerations are listed below.

i. Targets for the transition to Test and Treat

As a country moves from having eligibility criteria for initiating ART (such as CD4 or WHO stage thresholds) to Test and Treat, all individuals who are enrolled in care and not on ART (formerly pre-ART) at the time of transition will immediately be eligible for ART, as well individuals newly tested HIV-positive. There will likely be a surge period with an increase in the monthly initiation numbers for a short time as the previously ineligible individuals are initiated, which will then taper off once the pre-ART individuals are initiated. Planning for this increase is imperative to ensure laboratory and drug supplies are available as well as planning for higher volumes of patients in the health facilities (and/or prioritize implementing models of differentiated care). Once the initial group of previously ineligible individuals are initiated, the rate of people initiating will likely return to previous levels as the rate is dependent on HIV incidence.

ii. Monitoring progress

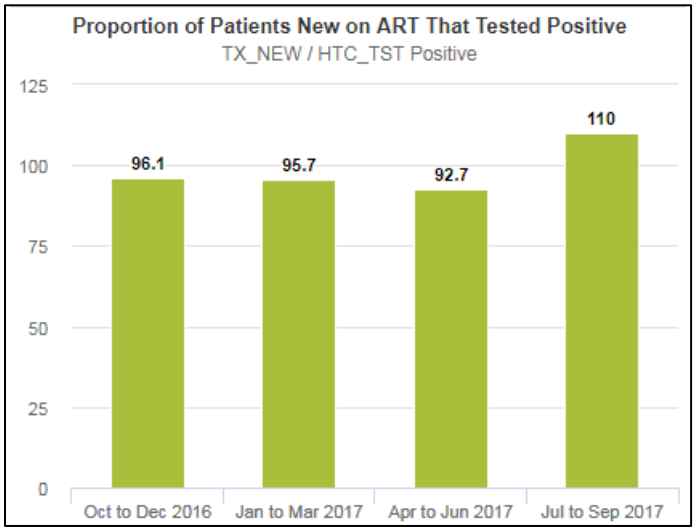
As data are collected, programs must routinely review results, including number testing HIV-positive, number linked to treatment, and number initiating ART. Results must be compared to targets to determine if efforts have achieved desired progress and where it is necessary to refine efforts and redirect resources. ART initiation indicators should be aligned with country and funder reporting requirements. Illustrative ART initiation performance indicators are shown in Table 4.

Table 4: Illustrative Recommended Indicators for Monitoring and Evaluation of Test and Treat[1]

1. Number of adults and children newly enrolled on ART (also known as PEPFAR indicator TX_NEW)
2.Number and percentage of newly diagnosed HIV-positive starting ART[2]
3.Number and percentage of newly diagnosed HIV-positive starting ART within one day/one week[3]
[1]All indicators may be disaggregated by sex, age, pregnancy and breastfeeding status, TB/HIV status, advanced disease, and Key population group. Clear definitions should be published for all indicators, such as the PEPFAR MER indicator reference guide, available at https://www.pepfar.gov/documents/organization/274919.pdf. [2]Use of person-level data to assess this is best, where possible, to include the same people in the numerator and the denominator. However, if only aggregate data are available, in the context of Test and Treat, the total number of people testing HIV-positive becomes a very good proxy denominator for this indicator, since they are all eligible for initiation on treatment. This aggregate proxy calculation is done routinely by PEPFAR using aggregate data (TX_NEW/HTC_TST_POS), see example in Figure 4 below. [3]Assessed via quality assurance activities, as data may not be readily available from routine paper-based M&E systems. May be available routinely if comprehensive EMR systems are in use that capture linked HTS and ART data.

To utilize ART initiation data effectively, it is possible to design simple dashboards or interactive tools, as part of the electronic health information systems, to summarize trends in linkage to initiation and stratify by age, sex, or other disaggregations, such as location of testing and geographic region. These graphics can also be prepared manually if no electronic system is available. It is recommended that health facilities review their own data regularly. Results can also be presented in a geographic context, incorporating available regional background surveillance data, such as HIV prevalence and data on population sizes.

Figure 4. Example Dashboard on ICAP INSIGHT for Linkage to Initiation. The aggregate proxy calculation for indicator 2 above, percentage of newly diagnosed HIV-positive starting ART, is shown here. Note that from July to September 2017 the performance went above 100% as the program in this country implemented catch up activities to ensure ART initiation of those missed in previous quarters.



C. Program Evaluation

Process and outcome evaluations should be conducted throughout the life of a program to determine progress toward the achievement of program objectives, evaluate the relationship between initiation strategies and key outcomes, and inform mid-course modifications. Evaluation questions and design should be developed in consultation with the funder and other key stakeholders. Table 5 presents illustrative process and outcome evaluation questions.

Table 5: Illustrative Evaluation Questions

Process Evaluation/Monitoring Questions
1. Does the country have a Test and Treat policy developed?
2. What sites are over- or under-performing for Test and Treat? What are the reasons for varying performance?
3. What are the barriers and facilitators for same day ART initiation?
Outcome Evaluation Questions
1. What proportion of people initiated on ART did so on the same day or within one week of their diagnosis? a. Alternative format: What is the mean or median time and the range of timing for starting ART?
2. Is the mean CD4 at baseline changing over time?
3. What are the most common reasons to defer ART?
4. Do PLHIV who initiated ART in the community versus those who started at a HF start ART earlier?
5. Is there a different rate of retention/rate of VLS at six months after ART initiation for PLHIV who initiated ART: a. On the same day versus deferred ART? b. With advanced disease versus early presenters? c. In the community versus at a HF?

Table 6. Example of Red, Amber, Green table. A red, amber, green (RAG) table is a way to visually show performance of health facilities for a single indicator, highlighting levels of performance through color-coding for easy identification of under- or over-performance. RAG tables facilitate discussion to dig deeper into the reasons for under- or over-performance and focus activities on low performers. This table is an example of performance of ICAP-supported health facilities in a country for the linkage proxy, TX_NEW / HTC_TST_POS. Achieving over 100% on this indicator could have many reasons beyond simple data quality errors. In some cases, it is possible that the facility serves as a referral center from other nearby facilities. The local context needs to be taken into account when assessing this performance.

			Results		
REGION	DISTRICT	SITE	HTC_TST_POS (N)	TX_NEW (N)	Linkage Rate (%)
R1	J	J2	36	54	150%
R1	I	I1	84	94	112%
R1	E	E1	323	339	105%
R1	K	K3	107	112	105%
R2	Y	Y1	82	83	101%
R1	B	B2	1	1	100%
R1	F	F2	66	66	100%
R1	G	G2	253	244	96%
R1	C	C1	36	32	89%
R1	D	D1	157	125	80%
R1	L	L2	146	116	79%
R1	H	H2	114	90	79%
R1	H	H1	18	14	78%
R1	B	B3	312	236	76%
R2	X	X1	338	235	70%
R1	K	K2	3	2	67%
R1	G	G1	32	21	66%
R1	A	A2	417	244	59%
R2	Z	Z1	35	19	54%
R1	L	L1	26	14	54%
R1	K	K1	49	26	53%
R1	J	J1	371	188	51%
R1	A	A1	32	16	50%
R1	B	B1	6	3	50%
R1	F	F1	12	6	50%

D. Data Security and Confidentiality

Maintaining the confidentiality and security of health data is critical for all health programs, and especially for health conditions that are stigmatized, such as HIV, and for populations facing stigma and discrimination, including KP, such as MSM, PWID, and FSW.

Therefore, it is important for programs to establish standardized data security and confidentiality procedures in the collection, transport, storage, and use of data. Effective general standards for securing and protecting paper-based and electronic data have been described previously,[19,20,21] and may be applied or adapted for use in a wide range of settings and populations.

Regarding ART initiation, services provided in community settings have special considerations regarding data security and confidentiality. In these situations, HCW and other data collectors will be in the community, with

paper or electronic records that potentially contain personally identifiable health information, and transporting or transmitting that information to and from health facilities. It is essential that data security measures are in place both in the community and facility.

Paper records should be stored in a locked bag/container in the field when not in use, should not be left unattended, and ideally returned to the HF or office on a daily basis and stored in a locked and secured place. Health care workers and data collectors should not carry more health records/data than they need while in the field. Programs should not collect any personally identifying information on paper records that is not essential for program operations.

Use of electronic records via devices such as smartphones and tablet computers—in place of paper-based records—for facility- and community-based ART initiation can help to ensure confidentiality and security of client information. However, instituting certain basic measures are required to ensure the security of these devices. For example, devices must be encrypted and password-protected. Data must be stored on a secure system (network or cloud), and data must be stored in accordance with the legal requirements of the country. If possible, data should be uploaded to a server on a daily basis so that it is not stored locally on the electronic device for long periods of time. Mobile device management platforms for ongoing management of data collection devices should be implemented as well, allowing for remote data protection on lost/stolen devices, including device lock, wipe, encryption, and password recovery. Lastly, protocol and procedures specifying user roles and notifying users not to share their passwords with anyone intentionally or inadvertently (e.g., in case of loss or theft) should be developed and implemented.

VIII. Key Health Systems Considerations for Test and Treat

Table 7. Key Considerations for Supporting Test and Treat

	National/Health Facility Level	Community Level
Policy/ Political Commitment	• Functional technical working group that includes members of the HIV program, prevention of mother-to-child transmission of HIV (PMTCT) program, implementing partners, HCW, and civil society members (PLHIV) • National guidelines updated to support Test and Treat for all • Clinical fora such as technical working groups or MDT at HF level • Approved policy and guidelines/protocols for Test and Treat, including timing of ART initiation, patient literacy, adherence support, job aids, etc. • Facility-level public health messaging around Test and Treat	• Functional community health group that meets regularly and includes key community leaders, community activists, and health champions (peer educators, health staff, etc.) • Community awareness around updated treatment guidelines • HIV public health campaigns • Established coordination meetings between community leaders and representatives and HF management team
Human Resources	• Endorsement of task-shifting, including nurse initiated and managed ART and lay counselors to support adherence and patient monitoring • Defining of core competencies of each health cadre	• Endorsement of task-shifting to adherence and lay counselors to support community adherence and patient monitoring • Recognition of peer educators/lay counselors as a key health cadre • Strategy for retaining community health workers • Strategy for ongoing training and support of community health workers
Infrastructure	• Facility storage space for additional commodities (ART supplies) at the regional level • Upgrading of pharmacies and dispensaries to provide private space for patient counseling/adherence support interactions	• Community storage space for ART supplies (HIV test kits, monitoring tools and ART starter kits) • Community venues to host community group meetings
Commodities	• Adequate medication supply • Reliable supply chain management, including distribution of inventory, management, and procurement • Simplification and harmonization of treatment regimens	• Support for self-care, including treatment literacy pamphlets • Supply chain assessment and stock management • M&E system to monitor distribution and stock • Audit system for monitoring stock usage
Lab	• HIV retesting strategy for verification • Algorithm for VL monitoring • Transport system for VL specimens • Xpert MTB/RIF testing and urine LF-LAM • Serum CrAg screening	• Algorithm for VL monitoring • Point of care VL • Transport system for VL specimens from community to HF lab

Quality Assurance & Supervision	• Lab staff conduct QA to ensure following of verification testing algorithms • Pharmacist ensures oversight and supervision of pharmacy staff • Quarterly patient review board meetings to ensure adequate support to patients failing to initiate treatment or patients with advanced disease • Defining key counseling messages • Patient readiness assessments to ensure patients are not coerced into starting ART	• Reporting adverse events • Adherence assessmnt tools • Supervision tools for monitoring community testing ART initiation, if applicable • Community
M&E/ Information Systems	• M&E tools that capture date/timing of HIV diagnosis, retesting for verification and ART initiation, as well as potential contraindications for same day start/reasons for deferral • Clear SOPs for data flow between HIV testing points of service and HIV care and treatment patient registers and the patient ART medical record, through comprehensive electronic systems, hybrid electronic-paper systems, or entirely paper-based systems • Defining performance indicators to monitor timing of ART initiation and retention in care • Tools and systems to generate aggregate reports and visualize data for program review • DQA • Identifying patients lost to follow-up • Linkage and referral systems and forms • Data confidentiality and security • Program evaluation	• Tools documenting community testing and linkage to HF for ART initiation/continuation • Tools to capture "starter packs," if available • Clear SOPs for data flow between community tools and facility • Linkage and referral systems and forms • Data confidentiality and security
Acronyms: DQA = data quality assessment; HF = health facility; MDT= multidisciplinary team; VL = viral load		

IX. Tools

To access these tools, copy and paste the URL below into your web browser. Not all hyperlinks will work directly from Word.

Annex 1: ICAP Approach to Differentiated Service Delivery
http://files.icap.columbia.edu/files/uploads/ICAP_Approach_to_DSD_20July17.pdf

Annex 2: Patient Checklist (Kenya)

B. Patient Review Checklist			
(If yes to any of the questions below, confirm they have enough ART until they can reach the clinic and refer back to the clinic for further evaluation; book appointment and notify the clinic)			
Any missed doses of ARVs since last clinic visit: ☐Yes ☐No If yes, how many missed doses: _____			
Any current/worsening symptoms:			
Fatigue: ☐Yes ☐No Cough : ☐Yes ☐No	Fever: ☐Yes ☐No Rash: ☐Yes ☐No	Nausea/vomiting: ☐Yes ☐No Genital sore/discharge: ☐Yes ☐No	Diarrhea: ☐Yes ☐No Other:
Any new medications prescribed from outside of the HIV clinic: ☐Yes ☐No If yes, specify:			
Family planning: ☐Yes ☐No Method used:		Pregnancy status: ☐Pregnant ☐Not Pregnant ☐Not Sure	
Referred to clinic: ☐Yes ☐No If yes, appointment date: DD___MM_____YYYY _____			
Signature of patient upon receipt of the ART:			

Annex 3: Patient Health Questionnaire 2
http://www.cqaimh.org/pdf/tool_phq2.pdf

Annex 4: Enhanced Adherence Counseling form - Adherence assessment
http://files.icap.columbia.edu/files/uploads/Enhanced_Adherence_Plan_Tool.pdf

Annex 5: Questions to assess barriers to adherence

http://icap.columbia.edu/resources/detail/viral-load-toolkit-flipcharts

Annex 6: Tips to improve taking ARVs
http://icap.columbia.edu/resources/detail/viral-load-toolkit-flipcharts

X. References

[1] WHO. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization; 2015. Available at http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/

[2] Insight Start Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. *N Engl J Med.* 2015;373(9):795-807.

[3] Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med.*. 2011; 365(6):493-505.

[4] WHO. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. Geneva: World Health Organization; 2017. Available at http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/

[5] Rosen S, Maskew M, Fox MP, Nyoni C, Mongwenyana C, Malete G, et al. Initiating antiretroviral therapy for HIV at a patient's first clinic visit: the RapIT randomized controlled trial. *PLoS Med.* 2016;13: e1002015.

[6] Koenig SP, Dorvil N, De JG, Riviere C, Faustin M, Lavoile K, et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. *PLoS Med* 2017;14: e1002357

[7] Ford N, Migone C, Calmy A, et al. Benefits and risks of rapid initiation of antiretroviral therapy. *AIDS*. 2018;32(1):17.

[8] Labhardt ND, Ringera I, Lejone TI, et al. Effect of offering same-day ART vs usual health facility referral during home-based HIV testing on linkage to care and viral suppression among adults with HIV in Lesotho: the CASCADE randomized clinical trial. *JAMA*. 2018;319(11):1103-1112.

[9] WHO. Consolidated Guidelines on HIV Testing Services. Geneva: World Health Organization; 2015. Available at http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/

[10] Adler M, Behel S, Duncan D, Houston J, Kalou M, Lasry A, Shaffer N, Sands A, and Young PR. Consolidated Guidelines on HIV Testing Services: 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection 2015. ANNEX 9: Technical guidance update on quality assurance for HIV rapid diagnostic tests. Available at https://www.ncbi.nlm.nih.gov/books/NBK316036/

[11] Hakim J, Musiime V, Szubert AJ, Siika A, Mallewa J, Agutu C et al. Enhanced prophylaxis plus antiretroviral therapy for advanced HIV infection in Africa. *N Engl J Med.* 2017; 377; 233-45

[12] WHO. Guidelines for the diagnosis, prevention, and management of cryptococcal disease in HIV-infected adults, adolescents and children, March 2018. Geneva: World Health Organization. Available at http://www.who.int/hiv/pub/guidelines/cryptococcal-disease/en/

[13] Mfinanga S, Chanda D, Kivuyo SL, Guinness L, Bottomley C, Simms V et al. Cryptococcal meningitis screening and community-based early adherence support in people with advanced HIV infection starting

antiretroviral therapy in Tanzania and Zambia: an open-label, randomised controlled trial. *Lancet*. 2015;385:2173–82

[14] The Southern African HIV Clinicians Society. Guideline for the prevention, diagnosis and management of cryptococcal meningitis among HIV-infected persons: 2013 update. *South Afr J HIV Med*. 2013;14(2).

[15] Török ME, Yen NTB, Chau TTH, et al. Timing of initiation of antiretroviral therapy in human immunodeficiency virus (HIV)–associated tuberculous meningitis. *Clin Infect Dis*. 2011;52(11):1374-1383.

[16] WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection Recommendations for a public health approach - Second edition. Geneva: World Health Organization; 2016. Available at http://www.who.int/hiv/pub/arv/arv-2016/en/

[17] Labhardt ND, Ringera I, Lejone TI, et al. Effect of offering same-day ART vs usual health facility referral during home-based HIV testing on linkage to care and viral suppression among adults with HIV in Lesotho: the CASCADE randomized clinical trial. *JAMA*. doi:10.1001/jama.2018.1818

[18] PEPFAR MER indicator reference guide v2.2 Oct 2017, Page 89. Available at https://www.pepfar.gov/documents/organization/274919.pdf

[19] Centers for Disease Control and Prevention. Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2011. https://www.cdc.gov/nchhstp/ProgramIntegration/docs/PCSIDataSecurityGuidelines.pdf

[20] UNAIDS. Guidelines on protecting the confidentiality and security of HIV information: Proceedings from a workshop. 2006. http://data.unaids.org/pub/Manual/2007/confidentiality_security_interim_guidelines_15may2007_en.pdf

[21] UNAIDS. The privacy, confidentiality and security assessment tool: Protecting personal health information. 2016. http://www.unaids.org/en/resources/documents/2016/confidentiality_security_assessment_tool