New Horizons Advancing Pediatric HIV Care Collaborative

Management of Treatment Failure for Pediatric and Adolescent Patients

Resource Package

Version 2.0 August 2022
Cover Photo: SBU, Tebatso Moiketsi, and Matseliso Nchori (left - right) are young people who access HIV services at the adolescent corner at the Queen Elizabeth II Health Center in Maseru, Lesotho. The youth-freindly services and their peer support group helps them adhere to treatment.

Photo by Makopano Letsatsi/EGPAF, 2021

While the Elizabeth Glaser Pediatric AIDS Foundation makes effort to use photos which accurately depict the actions, topics, or populations referenced, unless specifically indicated, the photographs in this document do not imply program participation, health status, attitude, behavior, or action on the part of persons who appear therein.
# Table of Contents

Acknowledgements .......................................................................................... 5

Acronyms and Abbreviations ........................................................................... 6

Toolkit Overview ............................................................................................... 7

Management of Treatment Failure Algorithm for Pediatric and Adolescent Patients ........................................................................... 8

Management of Treatment Failure Algorithm .................................................. 11

Example of Pediatric/Adolescent HIV Treatment Clinical Review Form .......................................................................................... 13

Pocket Pediatric and Adolescent Adherence Counseling Assessment and Interventions Checklist .......................................................... 15

Checklist for Adherence Interventions ............................................................... 16

Monitoring Adherence & Psychosocial Support Interventions .......................... 17
Acknowledgements

This document was developed by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), with funding support from Johnson & Johnson, in support of the New Horizons Advancing Pediatric Human Immunodeficiency Virus (HIV) Care Collaborative. The New Horizons Collaborative is a multi-sectoral, coordinated effort aimed at improving and scaling pediatric and adolescent HIV and AIDS care and treatment through increased awareness, research, health systems strengthening, and access to antiretroviral medicines. The main objectives of the collaborative are 1) to address an immediate humanitarian need for advanced HIV antiretroviral therapy (ART) for children and adolescents and 2) to support health systems strengthening for national HIV and AIDS programs.

The development of the Management of Treatment Failure for Pediatric and Adolescent Patients Toolkit is the result of collaboration between the following individuals:

- Natella Rakhmanina, MD, PhD, Senior Technical Advisor, EGPAF
- Mary Spencer, MPH, Technical Officer, EGPAF
- Katie Wallner, MSc, Technical Officer, former EGPAF
- Mayowa M. Tiam, MBChB, MMed, FCP, Consultant
- Kelsey Brosnan, Design & Brand Manager, EGPAF
- Cosima Lenz, Technical Officer, Adolescents and Youth, EGPAF

The Elizabeth Glaser Pediatric AIDS Foundation thanks Johnson & Johnson for their support to develop this resource package.

The authors wish to thank Ts’epang Mohlomi, Dr. Esther Tumbare, Dr. More Mungati, Dr. Mamello Moqhali Sekese, Dr. Tsitsi Vimbayi Chatora, Ishmael Chakafa, Nkalimeng Mokhathi, and past and current staff of EGPAF in Lesotho who helped support the validation of the first version of this toolkit with health care providers at EGPAF-supported facilities in Lesotho. We thank the Kenya Ministry of Health for sharing their clinical review form for treatment failure, which was modified and included in this package.

The authors also wish to thank EGPAF’s Dr. Judith Kose, Lydia Mpango, Mary Namubiru, Rebecca Bailey, Justine Odionyi, and Rachel Samdahl for their assistance with reviewing and packaging this document.

## Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3TC</td>
<td>Lamivudine</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquire immunodeficiency syndrome</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>Antiretroviral</td>
</tr>
<tr>
<td>DOT</td>
<td>Directly observed therapy</td>
</tr>
<tr>
<td>DTG</td>
<td>Dolutegravir</td>
</tr>
<tr>
<td>DWIT</td>
<td>Directly witnessed ingestion therapy</td>
</tr>
<tr>
<td>EAC</td>
<td>Enhanced adherence counseling</td>
</tr>
<tr>
<td>EGPAF</td>
<td>Elizabeth Glaser Pediatric AIDS Foundation</td>
</tr>
<tr>
<td>FTC</td>
<td>Emtricitabine</td>
</tr>
<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>HCW</td>
<td>Health care worker</td>
</tr>
<tr>
<td>INSTI</td>
<td>Integrase inhibitors</td>
</tr>
<tr>
<td>NNRTI</td>
<td>Non-nucleoside reverse transcriptase inhibitors</td>
</tr>
<tr>
<td>PEP</td>
<td>Post-exposure prophylaxis</td>
</tr>
<tr>
<td>PI</td>
<td>Protease inhibitors</td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of mother-to-child transmission of HIV</td>
</tr>
<tr>
<td>PrEP</td>
<td>Pre-exposure prophylaxis</td>
</tr>
<tr>
<td>PSS</td>
<td>Psychosocial support</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TDF</td>
<td>Tenofovir disoproxil fumarate</td>
</tr>
<tr>
<td>VL</td>
<td>Viral load</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
About This Toolkit
This toolkit was developed in response to an identified need by health care providers on the steps needed to identify and address potential treatment failure among children and adolescents living with HIV. It aims to complement existing national and global guidelines on viral load monitoring and treatment-experienced HIV and to serve as an easily accessible reference within health care facilities.

This toolkit was updated in 2022 to reflect the current WHO guidelines for treatment management among people living with HIV.

Purpose of This Toolkit
The objective of this toolkit is to provide general guidance on determining treatment approaches for pediatric and adolescent patients with a high HIV viral load (VL). It contains tools for use in clinical practice by health care workers to support achieving viral load suppression or switching to a new or optimal treatment regimen.

Target Audience: Who Should Use This Toolkit?
This toolkit is primarily for health care providers, lay counselors, and multidisciplinary teams working with children and adolescents living with HIV.

How to Use This Toolkit
The toolkit is divided into three sections:

1. Management of treatment failure algorithm
2. HIV treatment failure clinical review form
3. Adherence counseling assessment and interventions checklist

---

Management of Treatment Failure Algorithm for Pediatric and Adolescent Patients

Introduction
The WHO recommends universal ART and routine VL monitoring for all people living with HIV.

The New Horizons Collaborative developed this management of treatment failure tool to assist health care workers (HCWs) in resource-limited settings to identify and support pediatric and adolescent patients failing ART.

The tool includes a two-page algorithm that guides HCWs on the steps to systematically evaluate patients on ART who are not virally suppressed. It encompasses clinical, laboratory, and psychosocial evaluations and the necessary actions to respond to patients’ needs.

Front Page: Steps to evaluate (blue boxes) and to manage (yellow boxes) patients with non-suppressed VL, (i.e. VL above 1000 copies/mL and/or above 50 or 20 copies/mL, depending on the type of test and lowest VL threshold available), including actions needed. Key components include:

- Completing a thorough clinical history: HIV disease history, ART history and co-morbidities, and developmental history
- Laboratory evaluation: baseline and repeat VL and previous resistance test results if available
- Psychosocial evaluation and adherence support: assessing and addressing barriers to adherence and supporting patient psychosocial well-being

Back Page: Brief summaries of virologic, immunologic, and clinical treatment failures and useful resources.

Audience: Medical doctors, clinical officers, nurses, case managers, professional counselors, and other treatment supporters.

Evaluation for Treatment Failure
Below is a detailed outline explaining the steps in the algorithm to evaluate treatment failure.

Review ART History:
- Knowing past ART regimens is important. In evaluating patients with an unsuppressed VL, the clinician should review all previous ART regimens the patient has taken. This history may provide information on potential past HIV drug resistance, drug intolerance, and drug-associated toxicities.

- For example, HIV within a patient who was prescribed lamivudine (3TC) in the past might have developed M184V or M184I HIV mutations, which are associated with resistance to lamivudine and emtricitabine (FTC) but may be protective for developing resistance to other drugs, such as tenofovir disoproxil fumarate (TDF).

- It is important to know if any treatment interruptions or substitutions have taken place in the past due to stockouts, adverse drug reactions, or any other causes.

Evaluate for Advance HIV Disease, Co-morbidities, and Malnutrition:
- All patients with non-suppressed VL should be evaluated for advanced HIV disease, including significant co-morbidities, malnutrition, and opportunistic infections.

- Untreated infections and other significant diseases and malnutrition can all negatively affect patient adherence, decrease CD4 cell count, and weaken the control of HIV with ART.

- If a patient is at risk for co-morbidities and/or malnutrition, provide prophylactic treatment and/or nutritional support.

Evaluate for ART Adverse Drug Reactions:
- The clinician should know all past and recent ART adverse drug reactions that the patient experienced, as they might affect adherence to treatment.

- For the evaluation and management of antiretroviral (ARV) drug specific side effects, refer to WHO and national guidelines, as well as drug insert leaflets.

Identify Drug-Drug Interactions:
- Drug-drug interactions play an important role in patient tolerance of ART and may affect adherence. If drug-drug interactions are not addressed by adjusting the drugs doses or ART regimen when indicated, this can lead to the development of drug-associated toxicity and/or HIV drug resistance, leading to treatment failure.

- For example, rifampicin — used to treat tuberculosis (TB) — can decrease bodily concentrations of integrase inhibitors (INSTIs) and protease inhibitors (PIs). When a patient is prescribed TB treatment, ARV dosing or the ART regimen may need to be changed.

- Other examples of frequently used drugs that can cause drug-drug interactions include antifungal (Ketoconazole) and antimalarial (artemisinin-based) drugs, selected anticonvulsants, antipsychotic drugs, and statins.

Confirming Patient is Prescribed and Has Continuous Access to ART:
Prescribing ART does not mean the patient is actually taking the ARVs. To confirm that the patient is taking the ARVs, the clinician should:

- Verify date of last refill from pharmacy records, or, for patients who refill in the community, handheld records of picking up the ARVs.
• Ask about the names, color, shape, and number ARVs tablets/pellets/granules taken. For younger children, ask the
caregiver, and ask the caregiver to describe or demonstrate
(when feasible) how they give the ART to the child. For older
children (usually starting at age ten), it is useful to ask the
patient directly and then to confirm with the caregiver.

**Evaluate Adherence**

• Poor adherence is the most common cause of treatment
failure among people living with HIV.

• Causes like unpleasant taste of liquids or large size of the
tablets, difficulty swallowing, lack of food, caregiver barriers
(including multiple and/or changing caregivers), and non-
disclosure of HIV status to the patient can all contribute to
poor adherence. Daily events, like school attendance and
job schedules, can also be significant obstacles to taking
medications.

| Who picks up the medications? (e.g., mother/father/mother/
father/another caregiver, peer supporter, neighbor) |
| What medicines is the patient taking? |
| ✓ Record time and frequency (morning only, morning and
evening, or evening only) |
| ✓ Ask for a description of the pills |
| ✓ Ask to see the pills (when available) |
| ✓ Openly talk with the patient and their caregiver/
treatment supporter about the challenges with taking
the medication (e.g., storing the medications at home
or school, taste, size of tablet, difficulty swallowing,
feeling sick after taking medication, having food to take
medications with, etc.) |

| Where are the medicines kept? |
| ✓ Record whether the medicines are kept in the
refrigerator, in the cupboard, or any other place |

| Where does the patient take his/her medicines? (e.g., at
home, in school, or at the health clinic) |

• Maintain a non-judgmental, open attitude during the
adherence interview. Do not make the patient or caregiver
feel guilty. Give examples of potential adherence problems
like, “some people have hard time swallowing the pills
because of their size.” The interview’s goal is to find
barriers to adherence and ensure that the patient and/or
their caregiver trust the provider to continue dialogues to
address challenges.

The clinician should make time to interview the patient and
their caregiver, when applicable, to evaluate the following:

**Evaluate Psychosocial Support Needs:**

The patient’s support network and home environment
contribute significantly to their adherence. The following
questions are examples of what can be useful to discuss when
evaluating a patient’s psychosocial support needs:

| Does the patient have reliable housing? Home or community
security issues? |
| Does the patient live with both parents? Other caregiver
or treatment supporter (e.g., grandparent, uncle/aunt, etc.)? For
older children and adolescents, do they live at learning
institution or with a partner? |
| Does the patient/caregiver have regular access to food? |
| Are the patients (for adolescents) and/or their caregivers
employed? |
| Is there any substance abuse by the patient or within the
living environment? |
| Does the patient have any behavioral issues at school or
work? Any behavioral issues at home? |
| Was the patient screened for mental health issues? Is there
any family history of mental health conditions? |
| Any history of past or current abuse (physical or sexual) of
the patient or within the family? |
| Does the patient face any structural barriers to care and
treatment adherence? These could include clinic fees,
transport costs, distance from the clinic, clinic wait times,
iclinic hours, attitudes of clinic staff, drug stock-outs, stigma
and discrimination, and religious or cultural beliefs about
HIV and ART. |
| Are there other family members living with HIV? For HIV-
positive family members, are they on ART? Are there any
family members or caregivers who are opposed to HIV
treatment? |
| Has the HIV status been disclosed to the patient or his/her
status has been disclosed to the caregiver/family/peers? |
| Does the patient and/or caregiver participate in support
groups? What kind of group(s)? |

**Provide Adherence Counseling and Psychosocial Support:**

Below are some examples of action steps that can serve as
a general guide and should be adapted in the local context.

• Set up routine time and reminders for medicines to be taken
• Provide patient/caregiver with a pill calendar and a pill box,
when available
• Encourage an award system for good adherence for children
and adolescents
• Adjust ART doses and schedules to best fit patient needs
• Assure dosing is based on most recent weight and age
• Simplify and optimize ART regimen
Monitoring of EAC and Psychosocial Support Response:

- Enhanced adherence counseling (EAC) should be developed, performed, and monitored by a multidisciplinary team of health care providers, including doctors, nurses, case manager, treatment support, staff, mental health, and orphans and vulnerable children support staff.

- The patient enrolled in EAC needs to be evaluated on a frequent basis, between everyone to three months, and feedback on EAC interventions should be discussed at the multidisciplinary team meetings.

- Consider patient centered models of providing EACs such as home based and virtual EAC sessions.

Some potential outcome measures are listed below:

- Number of EAC/assessment sessions in the last three to six months.
- Number of home visits conducted in last three to six months, and findings.
- Support structures (e.g., treatment buddy, support group attendance, and caregivers) in place for this patient.
- Duration of DOT in previous three to six months.
- Completion of referrals made.

VL Monitoring:

Routine VL monitoring helps to detect treatment failure early. Once VL >1000 copies/mL has been identified, the regimen switch needs to be considered for patients on non-nucleoside reverse transcriptase inhibitors (NNRTI)-based regimens. For patients with VL between 50-1000 copies/mL, enhanced adherence counseling and additional support are recommended.

Based on the results of the adherence and psychosocial evaluations, provide additional action steps, as needed:

- Assign a person (or team) to provide enhanced adherence counseling (EAC)
- Assess if patient needs to have directly observed therapy (DOT) arranged at home or within the community or by video with the treatment supporter/medical staff. During DOT the healthcare worker/trained caregiver/treatment supporter directly administers the medications to the patient and/or observe and documents the intake. Determine who will provide DOT in close collaboration with the patient and his/her caregiver or support personnel. The person providing DOT needs to be trained in drugs administration and keeping the log of the doses taken.
- Refer patient for mental health professional or substance abuse rehabilitation as indicated
- Counsel on HIV status disclosure and provide disclosure support.
- Provide additional actions to address structural adherence barriers, as well as counselling and support services to address stigma/discrimination/mental health/treatment literacy and hesitancy.
- Treat comorbidities and provide nutritional support.
- Refer to social and nutritional support services as needed.

Once EAC and additional support have been provided to the patient for the duration of three months, repeat assessment of the patient’s VL to evaluate if re-suppression of VL has been achieved. The repeat VL results will determine the next steps in management of the patient’s treatment.

Key action steps for repeat VL follow up:

- For repeat VL <50 copies/mL, maintain current ART regimen
- For repeat VL results >50 copies/mL and <1,000 copies/mL:
  - Keep patient on current ART
  - Continue with EAC
  - Consider switching ART for those receiving NNRTI-based regimens based on clinical considerations and address any adherence concerns
  - Continue DOT/directly witnessed ingestion therapy (DWIT) when indicated
  - Appreciate success and counsel client and treatment supporter on viral suppression
  - Repeat VL in three months
- For repeat VL results >1,000 copies:
  - Prepare patient for change in ART regimen. Explain treatment failure and regimen switch, the importance of adherence, and the timing of the next VL monitoring exam. Assure treatment literacy around new regimen.
  - Provide adherence support on the new regimen. Undertake additional assessment of adherence barriers and interventions to address these barriers.
  - For patient failing second-line ART regimen, arrange for drug resistance testing if indicated by national guidelines. Make sure the patient is taking medications when performing resistance testing (e.g., do not order resistance testing if patient has been off medications for more than a 2-3 weeks).
  - Once resistance testing is available, consult with specialists on sequencing of ART regimen, as applicable and per national guidelines. Third-line or advanced ART national committees are available in many countries at regional or national levels.
  - Assess VL three months or earlier after initiation of new ART regimen as per national guidelines.
Management of Treatment Failure for Pediatric and Adolescent Patients

### Viral Load Testing
Routine viral load monitoring for early detection of treatment failure:
- Obtain and review result by six months after ART initiation, 12 months after ART initiation and yearly thereafter

### Key
- Investigation/Evaluation
- Actions

### Actions
1. Where available, the lower threshold (i.e. 20 copies/mL) can be used instead of 50 copies/mL.
2. To avoid patient/caregiver confusion with drug names, explain that drug therapies have generic names and trade name and that many agents are co-formulated under a third or fourth name. Ask for description of pills (shape, size, color) if name is unknown.
3. Switch after a single elevated viral load should be considered.
4. A second viral load may be considered before regimen switch if DTG-based regimens are unavailable and the results of a viral load test can be returned and acted on rapidly.

### Evaluate Adherence
- Interview patient/caregiver/treatment supporter
- Ask for following information:
  - WHO gives medications
  - WHEN medications are given/taken
  - WHAT medications are given/taken (names, doses, descriptions)
  - WHERE medications are kept/administered
  - WHY medications are not given/taken

### Evaluate Psychosocial Support (PSS)
- Make comprehensive assessment of all factors that impact adherence
- Provide PSS
- Make necessary referrals
- Address and treat mental and behavioral health & structural barriers to adherence

### Review ART History
- Evaluate all previously used regimens
- Identify potential for past resistance

### Evaluate AHD, morbidity & malnutrition ART side effects
- Prevent & treat co-morbidity & malnutrition
- Evaluate for ART side effects
- Identify ongoing and future drug-drug interactions

### Confirm patient is prescribed and has continuous access to ART
- Assess pharmacy records of refills

### Evaluate for virologic treatment failure
- Evaluate adherence

### Evaluate ART side effects
- Identify ongoing and future drug-drug interactions

### Prevent & treat co-morbidity & malnutrition

### Evaluate adherence
- Interview patient/caregiver/treatment supporter
- Ask for following information:
  - WHO gives medications
  - WHEN medications are given/taken
  - WHAT medications are given/taken (names, doses, descriptions)
  - WHERE medications are kept/administered
  - WHY medications are not given/taken

### Make comprehensive assessment of all factors that impact adherence

### Provide enhanced adherence counseling
- Identify or re-engage caregivers/peers to support adherence
- Simplify the regimen when feasible and establish daily routines/reminders for medication intake
- Explore opportunities for home-based or facility-based directly observed therapy

### Have open-ended discussion of experiences taking/giving medications and barriers/challenges and facilitators/motivators for ART use

### Repeat Viral Load Testing after Three Months with Interventions in Place
- Viral load ≤50 copies/mL
  - Maintain current ART regimen
  - Appreciate success & counsel patient & treatment supporter on viral suppression maintenance and next VL in six and then 12 months

- Viral Load > 1000 copies/mL
  - Switch ART regimen
  - Explain treatment failure and regimen switch, importance of continued adherence, and timing of the next VL

- Viral Load > 1000 copies/mL
  - Switch to appropriate regimen

### If viral load is >1000 copies/mL
- If significant improvement but VL is > 50 copies/mL and ≤ 1000 copies/mL, continue adherence support and consider viral load at three months

### If successful but VL is more than 1000
- Switch ART regimen
- Maintain current ART regimen
- Continue EAC
- Repeat VL in three months
- If it is more than 1000, switch ART and follow algorithm on the right

### If failing on the next-line ART regimen
- Consider resistance testing & counseling with HIV expert and/or ART committee to determine next steps in managing patient

---

1. Where available, the lower threshold (i.e. 20 copies/mL) can be used instead of 50 copies/mL.
2. To avoid patient/caregiver confusion with drug names, explain that drug therapies have generic names and trade name and that many agents are co-formulated under a third or fourth name. Ask for description of pills (shape, size, color) if name is unknown.
3. Switch after a single elevated viral load should be considered.
4. A second viral load may be considered before regimen switch if DTG-based regimens are unavailable and the results of a viral load test can be returned and acted on rapidly.
5. Status of caregiver, housing, nutrition, financial stability of household, patient/caregiver relationships, school experience, and patient’s achievement level; Substance abuse (drugs and alcohol) by patient/caregiver/family member; mental health; patient/caregiver beliefs about ART. PSS assessment must also address other critical adherence barriers, such as clinic fees, transport costs, distance from clinic, relationship with health care providers, clinic wait times, medication side effects and palatability, religious or cultural beliefs, stigma and discrimination, and lack of self-efficacy.
6. Conduct same-day testing using point-of-care VL testing for a repeat VL test, where available, to expedite the return of results.
7. A PSS package for children and adolescents living with HIV can include health education, support from peers, experience sharing, play therapy, adherence counseling, disclosure support, and nutritional support.
8. Consider switching ART for those receiving NNRTI-based regimens based on clinical considerations and address any adherence concerns.
## Definitions

### Immunologic Treatment Failure

<table>
<thead>
<tr>
<th>Definition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children younger than five years</td>
<td>Persistent CD4 levels &lt; 200 cells/mm³</td>
</tr>
<tr>
<td>Children older than five years</td>
<td>Persistent CD4 levels &lt; 100 cells/mm³</td>
</tr>
<tr>
<td>Adolescents and Adults</td>
<td>CD4 count &lt; 250 cells/mm³ following clinical failure or Persistent CD4 levels &lt; 100 cells/mm³</td>
</tr>
</tbody>
</table>

**Comments**

Without concomitant or recent infection to cause a transient decline in the CD4 cell count.

### Advanced HIV Disease

<table>
<thead>
<tr>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children &gt;5 years: CD4 cell count &lt; 200 cells/mm³ or WHO stage 3 or 4</td>
</tr>
<tr>
<td>All children &lt;5 years old who have been receiving ART for more than one year and are clinically stable.</td>
</tr>
</tbody>
</table>

### Clinical Treatment Failure

<table>
<thead>
<tr>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage three and four clinical condition with exception of TB) after six months of effective treatment</td>
</tr>
<tr>
<td>Adolescents and Adults New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage four condition) after six months of effective treatment</td>
</tr>
</tbody>
</table>

### Virologic Treatment Failure

<table>
<thead>
<tr>
<th>Definition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load &gt; 1000 copies/mL based on two consecutive viral load measurements three months apart, with adherence support following the first viral load test.</td>
<td>An individual must be taking ART for at least six months before it can be determined that a regimen has failed.</td>
</tr>
</tbody>
</table>

**Comments**

Without concomitant or recent infection to cause a transient decline in the CD4 cell count.

### Low Level Viremia

<table>
<thead>
<tr>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load above lowest level of detection (most commonly referenced as 50 copies/mL) and &lt; 1000 copies/mL</td>
</tr>
</tbody>
</table>

**Comments**

Without concomitant or recent infection to cause a transient decline in the CD4 cell count.

---

**References**


Psychosocial Support for Youth Living With HIV
Jaime Martinez, Rana Chakraborty, the COMMITTEE ON PEDIATRIC AIDS. HYPERLINK \l "Pediatrics. 2014 Mar;133(3):558-62. PMID: 24567016

**Patient Name**

**Provider Name**

**Name of Facility**

<table>
<thead>
<tr>
<th>Health Facility Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHC</td>
</tr>
<tr>
<td>Level 2 Hospital</td>
</tr>
<tr>
<td>Level 3 Hospital</td>
</tr>
</tbody>
</table>

**Facility Level & Contact Information**

<table>
<thead>
<tr>
<th>Tel:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHC Level 2 Hospital Level 3 Hospital</td>
</tr>
</tbody>
</table>

**Patient ART ID Number**

<table>
<thead>
<tr>
<th>(do not write name)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Date of Review**

**Patient Details**

<table>
<thead>
<tr>
<th>Date of Birth:</th>
<th>Gender: M/F</th>
<th>Recent Weight:__<strong><strong>kg/Date</strong></strong></th>
<th>Enrolment Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Recent Height (cm)<strong><strong>/Date</strong></strong></td>
<td></td>
</tr>
</tbody>
</table>

**CLINICAL REVIEW**

- Viral Load > 1000 copies/mL: ☐ YES ☐ NO
- Viral Load > 50 copies/mL and ≤ 1000 copies/mL: ☐ YES ☐ NO
- Latest VL: ____________ copies/mL  Date test obtained: _________________  Date received_______________

**Clinical Evaluation and ART History:** Briefly document any significant history, excluding the information in the table below (significant physical findings, history of TB diagnosis, or opportunistic infections [OIs]). Include date, diagnosis and treatment.

**Clinical findings:**

________________________________________________________________________________________________
________________________________________________________________________________________________
________________________________________________________________________________________________
________________________________________________________________________________________________

**TB history:** ☐ CURRENT  ☐ PAST  ☐ NEGATIVE

**Hepatitis B:** ☐ YES ☐ NO

**TB and OIs history:** ☐ YES ☐ NO

If yes, detail dates, diagnosis, and treatment.

________________________________________________________________________________________________
______________________________________________________________________________________

**Any side effects to ART (current or past)? If yes, specify below.** ☐ YES ☐ NO

**ARV regimen:**

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Any exposure to prophylactic prevention of mother to child transmission (PMTCT)/post-exposure prophylaxis (PEP)/Pre-exposure prophylaxis (PrEP) (current or past)?** If yes, specify below. ☐ YES ☐ NO

**Date:**

**Prophylactic regimen:**

**Regimen**

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Stop Date</th>
<th>ARV Regimen (List all ARVs)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st line:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd line:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotrimoxazole prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd line:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other Medications**

**Comment on any previous treatment interruptions, if any.**

________________________________________________________________________________________________
________________________________________________________________________________________________

**Current ART:**

**Does patient take his or her ART?** ☐ Yes ☐ No ☐ Not Sure

**Have you verified refill information with the pharmacy?** ☐ Yes ☐ No

**Have you/your staff performed the pill count?** ☐ Yes ☐ No

**Who gives patient medications:** ☐ Patient self-administers medicine ☐ Directly Observed Therapy

**If directly observed therapy, which caregiver administers?** ☐ Mother ☐ Father ☐ Grandmother ☐ Grandfather

**Other (specify)__________________________**
Where does patient/caregiver refill medicines?
- Clinic
- Community Pharmacy
- Community Support Group
- Other (specify) ____________________________

Where are medications stored at home?
______________________________________________________________________________________

Where does the patient take his/her medicines?
- Home
- School
- Orphanage
- Mid-way Clinic
- Other (specify) ____________________________

When are medicines taken?
- Morning
- Evening
- Morning and Evening
- Other (specify) ____________________________

Are medicines taken with food?
- Yes (specify) ____________________________
- No (specify) ____________________________

Does patient use pill calendar?
- Yes
- No

Does patient use pill box?
- Yes (describe type) ____________________________
- No

Does patient/caregiver use reminders to take medications?
- Yes (describe type) ____________________________
- No

Ask the patient and/or caregiver about adherence concerns. Any barriers identified (e.g., forgetfulness, taste, etc.)?

<table>
<thead>
<tr>
<th>Adherence Barriers Reported by Patient</th>
<th>Adherence Barriers Reported by Caregiver</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Is patient and/or caregiver enrolled in any support groups?
- Patient (describe type) ____________________________
- Caregiver (describe type) ____________________________
- No

Brief Psychosocial Assessment:
Main caregivers: (specify names and relation) ____________________________
Parents alive? (specify names and relation) ____________________________
Lives at home? (If no, specify) ____________________________
Attends school/college? (If yes, specify grade) ____________________________
Has friends? Partner? (If yes, specify either or both) ____________________________
Sexually active (in past 12 months)? (If yes, specify) ____________________________
For females, past/current pregnancy? Any children? (If yes, specify) ____________________________
Uses drugs/smokes/alcohol? (If yes, specify) ____________________________

Is patient and/or caregiver disclosed about HIV status?
- Patient (describe type) ____________________________
- Caregiver (especially important for adolescents) ____________________________
- No (specify plans for disclosure) ____________________________

Laboratory Results

<table>
<thead>
<tr>
<th>Date test obtained</th>
<th>CD4</th>
<th>Viral load</th>
<th>Other test</th>
<th>Date test received</th>
<th>Any other significant findings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Has drug resistance testing ever been done for this patient?
- YES
- NO

If yes, state date done and attach the detailed results. Describe key findings from results below.
______________________________________________________________________________________
______________________________________________________________________________________

Assessment of Nutritional Status¹

Patient's weight kg:

Is the patient malnourished?
- YES
- NO

¹These are adult BMI cutoffs. For adolescents, use BMI/age and for children <age 5 use weight/height z-score or mid upper arm circumference (MUAC).
Poor adherence is an important potential cause of treatment failure. Patient adherence needs to be addressed regularly, preferably at every encounter. From the beginning of care and treatment for HIV, it is vital to support patient adherence to antiretroviral (ARV) medications. The adherence assessment and checklist below are designed to support health care providers in the systematic evaluation of adherence and development of adherence support interventions.

**POCKET ADHERENCE ASSESSMENT**

Based on your evaluation, score patient adherence using the color-coded or score card below. Consider assigning the color code to patient chart at each visit. In case of a discrepancy between scores, pill count needs to be considered to allocate the color-coded score. The checklist for adherence counseling interventions should be completed for all patients, regardless of their score below for self-reported adherence and pill count.

Adherence support structures that should already be in place for patient:

- ✓ Caregiver support
- ✓ Clinic adherence counseling
- ✓ Support group
- ✓ Other treatment supporter

When patient has medication containers, a pill count can be performed.

- ✓ Pill count 0%-20% missing may not require enhanced adherence counseling.
- ✓ Pill count >20% likely requires enhanced adherence counseling.

Scores 1 and 2 require implementation of enhanced adherence interventions.

<table>
<thead>
<tr>
<th>Score</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-reported adherence</td>
<td>Patient misses &gt;50% of doses</td>
<td>Patient misses 20-50% of doses</td>
<td>Patient misses &lt;20% of doses</td>
</tr>
<tr>
<td>Color Code</td>
<td>#</td>
<td>#</td>
<td>#</td>
</tr>
</tbody>
</table>
**CHECKLIST FOR ADHERENCE INTERVENTIONS**

✓ Conduct case review with multidisciplinary team at the facility.

✓ Discuss goals of adherence interventions with the patient and caregiver.

✓ When possible and feasible, perform home visit by social worker and other support staff to determine home factors contributing to poor adherence. Assess storage of ARVs and home food security during home visit.

✓ Review findings from home visit with multidisciplinary team to determine appropriate intervention(s).

✓ Review regimen to reduce pill burden and frequency (once daily regimen preferable, especially for older children and adolescents). In case patient is taking other medicines, consider timing of each drug administration.

✓ Support disclosure (to children based on their age and disclosure to peers/partners for adolescents and adults).

✓ Refer to psychosocial support services and peer support, when applicable.

✓ Refer to mental health services, when applicable.

✓ Refer to substance abuse care, when applicable.

✓ Provide nutritional support including food package, when applicable. Facility multidisciplinary team must review the findings from home visits and should enroll qualifying patients in nutritional program.

✓ Discuss option of directly observed therapy (DOT).
  - If going forward with DOT, decide who will assist and monitor.
  - Patient and/or caregiver, when applicable, must agree to DOT before it is initiated.
  - A clear plan and timelines need to be in place to determine who, when, where, and how DOT will be carried out.
  - Duration of DOT needs to be determined upfront, with clear transition period for when patient can stop DOT.
  - Support and make necessary arrangements for DOT, if performed outside of home (e.g., at school).

✓ Provide and review the usage of pill calendar, check dates of last refills, and carry out pill count at each appointment, when feasible.

✓ Follow up closely on missed refills and appointments, assign case manager/community worker to the case, when feasible.

✓ Plan with patient and/or caregiver how best to motivate the child/adolescent and consider supporting a reward system.

✓ Counsel on the drug names, side effects, and provide tips for intake.
MONITORING ADHHERENCE AND PSYCHOSOCIAL SUPPORT INTERVENTIONS

The information should be monitored during when undertaking three enhanced adherence counseling sessions and other psychosocial support interventions between months one to three following a VL >50 copies/mL.

- ✓ Baseline and repeat viral load test dates and results
- ✓ Number of monthly refills missed
- ✓ ‘Number of adherence counseling/assessment session since last VL
- ✓ Individuals who attended enhanced adherence counseling/assessment sessions (patient, parent, caregiver, treatment supporter, etc.)
- ✓ Number of home visits conducted since last VL
- ✓ Major findings of home visits since last VL
- ✓ Ongoing support structures in place (e.g., treatment buddy, parent/peer support group attendance, caregivers, etc.)
- ✓ If DOT was performed, duration of DOT (one month, one to three months, or three to six months) and format – in-person or virtual

Based on this information, develop a further plan for evaluation and ART based on VL results.