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NEW HORIZONS
ADVANCING PEDIATRIC HIV CARE

Johnson & Johnson

Elizabeth Glaser Pediatric AIDS Foundation

Until no child has AIDS.

New Horizons Advancing Pediatric HIV Care Collaborative

Management of Treatment Failure for Pediatric and Adolescent Patients

Resource Package

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

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Acronyms and Abbreviations

3TC	Lamivudine
AIDS	Acquire immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
DOT	Directly observed therapy
EAC	Enhanced adherence counseling
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
FTC	Emtrictiabine
HIV	Human immunodeficiency virus
HCW	Health care worker
HQ	Headquarters
IRIS	Immune reconstitution inflammatory syndrome
NNRTI	Non-nucleoside reverse transcriptase inibitors
PEP	Post-exposure prophylaxis
PI	Protease inhibitors
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
PSS	Psychosocial support
TB	Tuberculosis
VL	Viral load
WHO	World Health Organization

Resource Package Overview

About This Resource Package

This resource package 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.

Purpose of This Resource Package

The objective of this resource package is to provide general guidance on determining treatment approaches for pediatric and adolescent patients with a high HIV viral load. This document contains tools for use in clinical practice by health care workers in providing children and adolescents with the support needed to achieve viral load suppression or to switch to a new treatment regimen.

Target Audience: Who Should Use This Resource?

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 Resource

The resource package 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 2016 World Health Organization (WHO) *Consolidated Guidelines on the Use of Antiretroviral (ARV) Drugs for Treating and Preventing HIV Infection* recommended universal start of antiretroviral treatment (ART) and routine viral load (VL) monitoring for all people living with HIV. As the treatment coverage rises, the number of people experiencing treatment failure will also increase. The *New Horizons Collaborative* developed this management of treatment failure tool to assist health care workers (HCWs) in resource-limited settings with identification and support of pediatric and adolescent patients failing ART.

The tool is a two-page algorithm that guides HCWs on the steps to systematically evaluate patients on ART who are not virally suppressed (i.e., have VL >1000 copies). It encompasses the 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 viral load, including actions needed. Key components include:

- Evaluating a thorough clinical history: HIV disease history, ART use history, co-morbidities, and treatment adherence.
- Laboratory evaluation: baseline and repeat VL and indications for resistance test.
- Psychosocial evaluation and adherence support: assessing and addressing barriers to adherence and supporting patient psychosocial wellbeing.

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 vital. 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 emtrictiabine (FTC).
- It is important to know if any treatment interruptions or substitutions have taken place in the past due to the stock-outs or any other causes.

Evaluate for Co-morbidities and Malnutrition:

- All patients with non-suppressed VL should be evaluated for significant co-morbidities (including 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 virus with ART.
- If a patient is at risk for co-morbidities and/or malnutrition, provide prophylactic treatment.

Evaluate for ART Side Effects:

- The clinician should know all past and recent ART side effects that the patient experienced, as they might affect past, current, and future adherence to treatment.
- For the evaluation and management of 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 non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs). When a patient is prescribed TB treatment, his/her ARV dosing needs to be adjusted 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, 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 taken. For younger children, ask the caregiver. For older children (usually starting at age 10), 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, dosing difficulties by the caregiver, and non-disclosure of HIV status to the patient can all contribute to poor adherence. Simple daily events, like school attendance and job schedules, can also be significant obstacles to taking medications.

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

- Who picks up the medications? (e.g., mother/father/other caregiver, peer supporter, neighbor)
  - ✓ Record time and frequency (morning only, morning and evening, or evening only).
- What medicines is the patient taking?
  - ✓ Ask for a description of the pills.
  - ✓ Ask to see the pills (when available).
  - ✓ Verify the doses of the ARVs taken against the doses prescribed.
  - ✓ Openly talk with the patient and their caregiver 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?
  - ✓ Where does the patient get their medicines? (e.g., health facility, community outreach group, etc.)
  - ✓ 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.

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? Food shortages? Home or community security issues?
- Does the patient live with both parents? Other caregiver (e.g., grandparent, uncle/aunt, etc.)? For older children and adolescents, do they live at learning institution or with a partner?
- Are there other family members living with HIV? For HIV-positive family members, are they on ART?
- Has the patient disclosed his/her status or has been disclosed to?
- Is there any substance abuse by the patient or within the living environment?
- Does the patient/caregiver have access to food?
- Are the patients (for adolescents) and/or their caregivers employed?
- Does the patient participate in support groups?
- Does patient have any behavioral issues at school or work? Any behavioral issues at home?
- Was patient/caregiver screened for mental health issues?
- 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 resistance? These could include clinic fees, transport costs, distance from the clinic, clinic wait times, clinic hours, attitudes of clinic staff, drug stock-outs, stigma and discrimination, and religious or cultural beliefs about HIV and ART.

Provide Adherence Counseling and Psychosocial Support:

Below we provide a few examples of action steps that serve as a general guide and should be adapted in the local context.

- Adjust ART doses and schedule, when indicated.
- Simplify ART regimen, when possible.
- Treat comorbidities and provide nutritional support, when indicated.
- Refer to social and nutritional support services, when indicated.

- Assign a person (or team) to provide enhanced adherence counseling (EAC).
- 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 award system for good adherence for children and adolescents.
  - ✓ Assess if patient needs to have directly observed therapy (DOT) arranged at home or within the community. During directly observed therapy the healthcare worker/trained caregiver/treatment supporter directly administers the medications to the patient while observing and documenting the intake of medications. Determine who will provide DOT. Ensure that this is determined in close collaboration with the patient and his/her caregiver or support person. 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, when 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/adverse belief systems.

Monitoring of EAC and Psychosocial Support Response:

- EAC should be developed, performed, and monitored by the 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 every one to three months, and feedback on EAC interventions should be discussed at the multidisciplinary team meetings.

Some potential outcome measure are listed below:

- Number of EAC/assessment sessions done 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 last three to six months.
- Completion of referrals made.

Repeat Viral Load Monitoring:

Once EAC and additional support described have been provided to the patient for the duration of 12-16 weeks, repeat assessment of the patient's VL is warranted to evaluate if re-suppression of VL has been achieved. The repeat VL results will determine next steps in management of the patient's treatment.

Some potential outcome measure are listed below:

- For repeat VL results <1,000 copies/ml:
  - ✓ Keep patient on current ART.
  - ✓ Continue adherence counselling at each visit.
  - ✓ Continue DOT, when indicated.
  - ✓ Appreciate success and counsel client and treatment supporter on viral suppression and next viral monitoring exam (in 6 months to 1 year).

- If significant improvement but viral load is >1000 copies/mL, continue adherence support and consider viral load at 2-3 months.

- For repeat VL results >1,000 copies:
  - ✓ Plan with patient and caregiver for additional clinic visits to continue close monitoring and EAC.
  - ✓ Prepare patient for change in ART regimen. Explain treatment failure and regimen switch, the importance of continued adherence, and the timing of the next viral load monitoring exam. Increase treatment literacy around new regimen, including samples of second- and third-line ARVs, as applicable.
  - ✓ Continue implementation of EAC activities. Undertake additional assessment of adherence barriers and interventions to address these barriers.
  - ✓ For patient failing second-line ART, arrange for drug resistance testing. 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 week).
  - ✓ Once resistance testing is available, consult with specialists on composition of second- or third-line 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 six months after initiation of second- or third-line ART.

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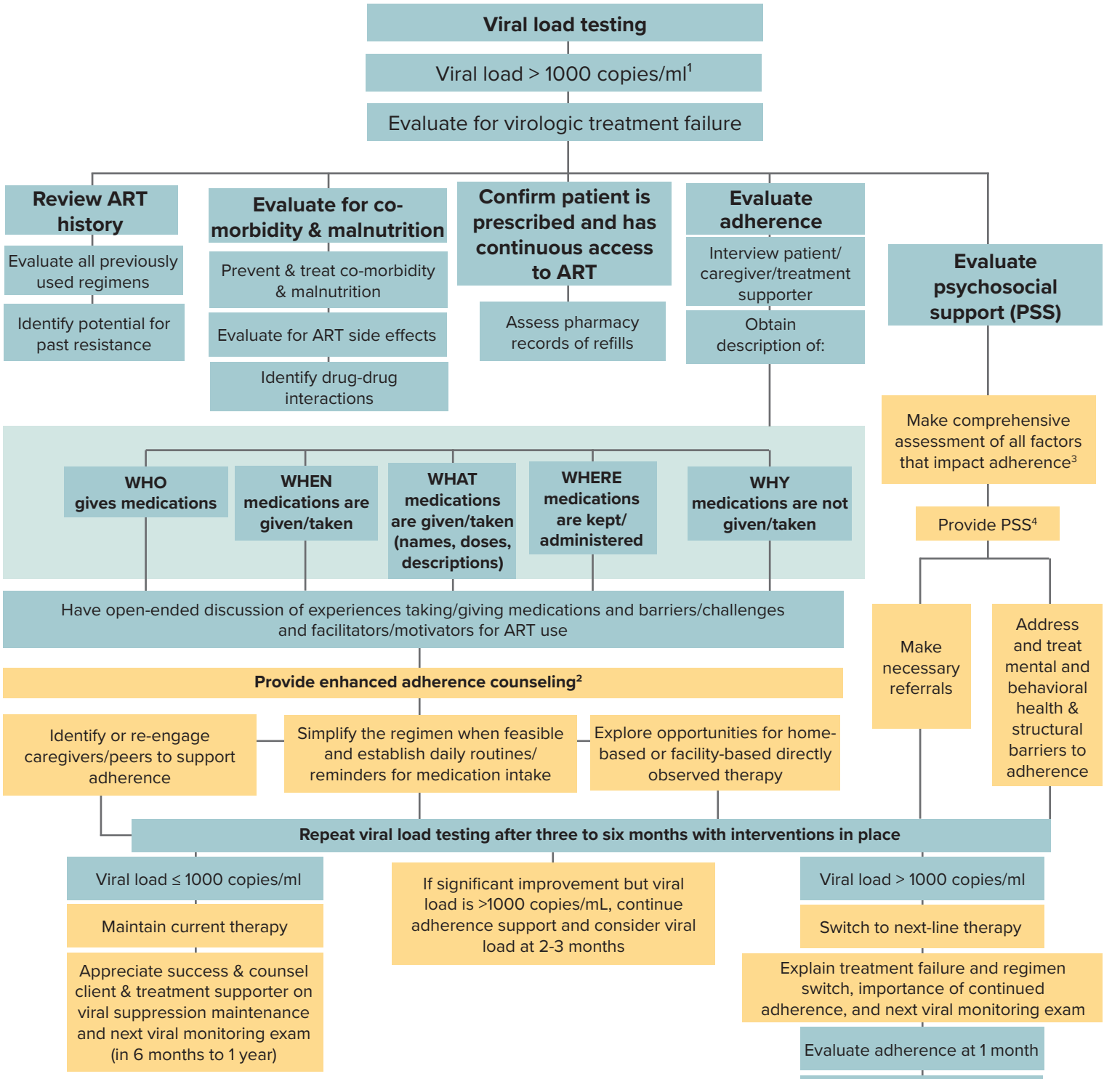
Management of Treatment Failure for Pediatric and Adolescent Patients



[1] Where available, the lower threshold (i.e. 20 copies/mL) can be used instead.

[2] To avoid patient/caregiver confusion with drug names, explain that drug therapies have generic names and trade name, and many agents are co-formulated under a third or fourth name. Ask for description of pills (shape, size, color) if name is unknown.

[3] 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.

[4] 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.

Key

- Investigation/Evaluation
- Actions

The WHO recommends that routine viral load monitoring be carried out at six months, at 12 months, and then every 12 months thereafter if the patient is stable on ART. Viral load testing is the preferred method for determining treatment failure.

Virologic Treatment Failure

Definition	Comments
Viral load above 1000 copies/mL based on two consecutive viral load measurements in three months, with enhanced adherence counseling following the first viral load test	An individual must be taking ART for at least six months before it can be determined that a regimen has failed.

Current WHO clinical and immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure. There is currently no proposed alternative definition of treatment failure and no validated alternative definition of immunological failure.

Immunologic Treatment Failure

Definition	
Children *Younger than five years* Persistent CD4 levels below 200 cells/mm^3 *Older than five years* Persistent CD4 levels below 100 cells/mm^3	**Adolescents and Adults** CD4 count at or below 250 cells/mm^3 following clinical failure **or** Persistent CD4 levels below 100 cells/mm^3
Comments	
Without concomitant or recent infection to cause a transient decline in the CD4 cell count.	

Clinical Treatment Failure

Definition	
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	**Adolescents and Adults** New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage four condition) after six months of effective treatment
Comments	
The condition must be differentiated from immune reconstitution inflammatory syndrome (IRIS) occurring after initiating ART. For adults, certain WHO clinical stage three conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure. IRIS is a worsening of pre-existing infectious conditions after ART initiation in HIV-positive patients due to inflammatory disorders.	

PSS for children living with HIV addresses their ongoing emotional, spiritual, cognitive, social, and physical needs. It aims to improve the social well-being of patients. PSS can be provided at clinic or community level. At the clinic, PSS can be provided one-on-one by a trained counselor, social worker, psychologist, or nurse. 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.

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Example of Pediatric/Adolescent HIV Treatment Clinical Review Form

Patient Name			
Provider Name			
Name of Facility		**Health Facility Code**	
Facility Level & Contact Information	Tel:	PHC Level 2 Hospital Level 3 Hospital	
Patient ART ID Number *(do not write name)*		**Date of Review**	
Patient Details	Date of Birth : Enrollment Date: Gender: M/F Recent Weight:_____kg/Date_____ Recent Height (cm)_____/Date_____		

CLINICAL REVIEW

Viral Load > 1000copies/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: Side Effect: Action:
ARV regimen: Side Effect: Action:
ARV regimen: Side Effect: Action:

Any exposure to prophylactic PMTCT/PEP/PrEP (current or past)? If yes, specify below. YES NO
Date: Prophylactic regimen:
Date: Prophylactic regimen:

List below history of all ART regimens patient has ever been on.

Regimen	Start Date	Stop Date	ARV Regimen (List all ARVs)	Comment
1st line:				
2nd line				
Other Medications Cotrimoxazole prophylaxis				
3rd line:				

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

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.)?

Adherence Barriers Reported by Patient	Adherence Barriers Reported by Caregiver

Is patient and/or caregiver enrolled in any support groups?

Patient ☐ Yes (describe type) _____ ☐ No

Caregiver ☐ Yes (describe type) _____ ☐ No

Does patient miss clinic appointments? ☐ Yes (specify) _____ ☐ No

Brief Psychosocial Assessment:

Main caregivers: (specify names and relation) _____

Parents alive?(specify names and relation) _____

Lives at home? (If no, specify) _____

Attends school? (If yes, specify grade) _____

Has friends? Partner? (If yes, specify) _____

Sexually active? (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 ☐ Yes (specify disclosure level and timing) _____

☐ No (specify plans for disclosure) _____

Caregiver ☐ Yes (especially important for adolescents) _____

☐ No (specify plans for disclosure) _____

Laboratory Results

Date test obtained	CD4	Viral load	Date test received	Any other significant findings

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 Status[1]

Patient's Body Mass Index (BMI) (kg/m2): ☐ Underweight (<18.5) ☐ Normal (18.5-24.9) ☐ Overweight (25-29.9) ☐ Obese (≥30)

Is the patient malnourished? ☐ Severe Malnutrition (≤-3SD) ☐ Moderate malnutrition (<-2SD) ☐ Normal

[1] These 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).

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PEDIATRIC AND ADOLESCENT ADHERENCE COUNSELING ASSESSMENT AND INTERVENTIONS CHECKLIST

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.

Score	1	2	3
Color Code			
Self-reported adherence	Patient misses >50% of doses	Patient misses 20-50% of doses	Patient misses <20% of doses

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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.**

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MONITORING ADHERENCE 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 and between months four to six following a viral load >1000 copies/mL.

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

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

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