STANDARD OPERATING PROCEDURES FOR ANTIRETROVIRAL THERAPY

FAMILY HEALTH INTERNATIONAL

NOVEMBER 2004

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ACKNOWLEDGMENTS

Family Health International (FHI) is proud to present *Standard Operating Procedures for Antiretroviral Therapy*. FHI developed the standard operating procedures (SOPs) to guide clinicians in delivering antiretroviral therapy (ART) services at health facilities in low-resource settings. This series of protocols includes procedures for providing ART to adults and adolescents, adherence counseling and post-exposure prophylaxis (PEP).

Leine Stuart, PhD, ACRN, wrote the SOPs in collaboration with other FHI staff members. Special thanks are extended to Dr. Ya Diul Mukadi and Judith Harkins, MSN, MPH, in Arlington, Va., and to Dr. John Adungosi in Mombasa, Kenya. Their technical expertise and practical guidance were instrumental in the developing these documents. We also acknowledge Cesar Granados, FHI/Arlington, for his excellent administrative support.

Our gratitude also goes to Dr. Francis Otieno and the staff of the Comprehensive Care Center at Coast Provincial General Hospital in Mombasa for pre-testing the SOPs at that facility. From this experience, the FHI team developed the generic version of the SOPs presented here.

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ACRONYMS

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
HAART	Highly active antiretroviral therapy
HBC	Home-based care
HIV	Human immunodeficiency virus
IEC	Information, education and communication
LFT	Liver function test
MO	Medical officer
MTCT	Mother-to-child transmission
NGO	Nongovernmental organization
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
OI	Opportunistic infection
OVC	Orphans and vulnerable children
PI	Protease inhibitor
PLHA	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
RCO	Registered clinical officer
SOP	Standard operating procedures
STI	Sexually transmitted infection
TB	Tuberculosis
TLC	Total lymphocyte count
VCT	Voluntary counseling and testing
WHO	World Health Organization

OVERVIEW

What are SOPs for ART?

With significant reduction in the cost of antiretroviral (ARV) drugs, access to antiretroviral therapy (ART) has become increasingly real for people in low-resource settings. In many countries, governments have developed national guidelines on ART management to define care standards and establish protocols for such areas as eligibility criteria, drug regimens and monitoring HIV-infected clients on ART.

Standard operating procedures (SOPs) describe processes and provide instructions to maximize ART service delivery at health facilities in accordance with national guidelines. They guide clinicians in providing ART to HIV-infected clients and in evaluating performance, thereby serving as a quality assurance tool for management.

Treating HIV-infected clients with ART is highly complex, given the lifelong requirement for ART, the need for best practices to support treatment efficacy, and the rapid evolution of scientific evidence. SOPs are "working" documents that must be adapted to incorporate new or revised procedures to ensure quality ART service delivery.

FHI's Institute for HIV/AIDS is collaborating with ministries of health and other implementing partners to introduce and scale up ART at health facilities in several countries, including Ghana, Kenya and Rwanda. From these experiences, FHI and its partners have developed SOPs for ART delivery; these are in generic format for adaptation to specific national contexts. The SOPs should evolve as new information impacting ART becomes available, and should be revised to update standards and procedures.

Who will use the SOPs for ART?

SOPs are intended for health facility staff, including:

- Medical doctors
- Registered clinical officers
- Nurses
- Adherence counselors
- Health facility management
- Quality assurance staff

What are the objectives of the SOPs for ART?

The primary objective of the SOPs for ART is to provide information on procedures for safe and effective ART delivery to clinical and management staff at health facilities. Specific objectives are to:

- Provide clinical staff with operational information to deliver ART in a health facility setting.
- Ensure that ART service delivery procedures are performed consistently to maintain quality.
- Ensure that procedures comply with health facility standards and national guidelines.
- Serve as training documents to prepare new staff in ART service delivery and reinforce standards for existing staff who need additional training.
- Serve as a quality assurance tool for management to evaluate service delivery and reinforce performance in accordance with health facility standards and national guidelines.

ANTIRETROVIRAL THERAPY (ART) PROGRAM

STANDARD OPERATING PROCEDURES

ANTIRETOVIRAL THERAPY FOR ADULTS AND ADOLESCENTS

PREPARED BY FAMILY HEALTH INTERNATIONAL

OCTOBER 2004

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STANDARD OPERATING PROCEDURES: ANTIRETROVIRAL THERAPY FOR ADULTS AND ADOLESCENTS

SOP 101: **New Patient Registration**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Referrals

1. Patients will **enter the HIV clinical service** by referral through the following channels:

   - HIV voluntary counseling and testing (VCT) service
   - PMTCT service (HIV+ mothers)
   - Antenatal service
   - Outpatient adult department, including parent/guardian referred
   - TB services
   - STI services
   - Inpatient hospital following discharge
   - District hospital
   - Primary health clinic
   - Self-referral

2. When a patient is referred by another service, s/he will receive a referral form to present to Registration and Records at the *(INSERT: Name of center or clinic where HIV care is provided; in this document, reference is the HIV Care Center (HCC)*.

3. The patient will be **referred to the VCT site** in the following circumstances:

   - When a patient has no medical record with an HIV-positive test result, presents with symptoms suggesting HIV/AIDS or reports risk factors for HIV transmission.

   - When referral from another service includes no HIV-positive test result.

4. Patients who present as walk-ins and request VCT services with or without symptoms suggestive of HIV/AIDS shall be directed for VCT services and will not be registered at the HCC.

5. HIV-infected patients who subsequently choose to be regularly seen and managed at the HCC will be referred for registration.

B. Registration

1. All referrals (except VCT) will be **interviewed by the Registration Clerk**, who will record such information as the patient's address, biographical data, next of kin and other emergency contacts, source of funding and other details on the **HCC Registration Form.** The form is filed in the patient's medical record.

2. The patient is also entered into the **HCC Attendance and Treatment Follow-Up Register**, which records her/his visits; an **HCC Registration Number** is assigned to each patient. The patient's HCC registration number is entered into her/his medical record.

3. Registration and Records will **establish a medical record** for each patient who has an HIV-positive test result on record or has been referred by a registered VCT center.

4. The patient will be issued an **HCC Patient Appointment Card** for recording dates of patient's scheduled appointments and visits to the HCC.

5. After registration or when the patient reports to Registration and Records for an appointment, the patient and her/his medical record will be **referred to the Triage Nurse**.

SOP 102: **Patient Re-visits**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

On subsequent visits

1. The patient will **report to Registration and Records** for the scheduled appointment, or as a walk-in to address emergent medical or other needs.

2. At each visit, the Registration Clerk will **update information on the patient's HCC Registration Form** in the medical record to maintain current information, such as address, telephone and funding source.

3. At each visit, the patient's HCC registration number will be recorded in the **HCC Patient Appointment and Attendance Register**.

4. The patient will then be **referred to the Triage Nurse** with the medical record.

SOP 103: **Initial Patient Assessment**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. First visit

1. The **Triage Nurse** will:

   - Determine the reason for the visit.
   - Obtain data on presenting systems and vital signs.
   - Discuss informed consent for medical treatment and obtain a **Voluntary Consent Form for Medical Treatment** signed by the patient.
   - Complete the **Triage Nurse Assessment Form**.
   - Direct the patient with, if appropriate, the parent/guardian to the MO/RCO for assessment.

2. The **MO/RCO** will:

   - Complete a baseline assessment using the health facility's **Clinical Care: Initial Adult Assessment Form**, including presenting symptoms, drug allergies, past medical history and systemic examination.
   - Classify the patient according to the World Health Organization staging system.
   - Request a diagnostic HIV test from the laboratory, if the patient presented without an HIV test result or with an HIV test result from a facility outside of the catchment area.

- Briefly discuss ART:
  - what it is
  - existence of eligibility criteria
  - determination of patient's interest in starting ARVs if eligible

- If CD4 testing capacity is available: order the CD4+ test if the patient is in Clinical Stage 3 or 4, as well as additional laboratory tests (See below: **Baseline Laboratory Testing**).

- Initiate treatment for acute symptoms and manage any existing treatable conditions.

- Initiate prophylaxis with Cotrimoxazole (CTX) if patient is in Stage 2, 3 or 4 and has no contraindications (e.g., CTX allergy, pregnancy, acute respiratory symptoms, acute liver symptoms).

- Direct the patient to Registration and Records to schedule a follow-up visit and instruct the patient to return in one week.

- Direct the patient to the treatment room or laboratory for specimen collection.

  Baseline laboratory testing:

  - ❑ HIV serology (if necessary)
  - ❑ Complete Blood Count (includes Total Lymphocyte Count)
  - ❑ CD4+ count (if Clinical Stage 3 or 4)

B. Second visit

1. The **Triage Nurse** will:

   - Collect the patient's medical record at Registration and Records.

   - Record new presenting symptoms reported by the patient/guardian and the patient's vital signs on the **Triage Nurse Assessment Form**.

   - Direct the patient to the MO.

2. The **MO/RCO** will do the following:

   - Inform the patient of the laboratory test results from the last visit.

   - The RCO will refer the patient to the MO if he/she meets the Clinical and Social Criteria for ART, e.g., WHO Stage 4, WHO Stage 3 with a CD4 cell count of 350, or a CD4 of 200 or less.

   - The MO will review the patient's status: if s/he meets the Clinical and Social Criteria for ART (**See SOP 104: Determination of Eligibility**), and if the patient is ready to begin ART, the MO will complete the **"Start ARV Treatment" in the Plan section of the Clinical Care: Initial Adult Assessment Form** (if the

patient is newly enrolled at the HCC) or ***the Clinical Care/ART: Adult Follow-Up Visit Form*** (if the patient is an established client at the HCC).

- The MO will then refer the patient to the Adherence Nurse for the **First Counseling Session (See SOP 105: Pre-ART Counseling)**.

- **If the health facility has established an Eligibility Committee to select patients for ART:** The MO will include the patient on the list of those patients who meet the Clinical and Social Criteria for ART and together with the patient files, submit these to the Eligibility Committee as soon as the patient is assessed to be ready to start ART.

Eligible Patient

a. Discuss reasons for eligibility for ART (see **SOP 104: Eligibility Criteria**).

b. Review information provided during the last visit about ART and the criteria for enrolling in the program.

c. Counsel the patient about ART adherence, stressing that the first regime has the best chance for long-term success.

d. Assess the patient's readiness to start ART.

e. If the patient agrees to start ART, direct the patient to the Adherence Nurse (See **SOP 105: Pre-ART Counseling**). Give the patient a laboratory request form and direct him/her to the Laboratory after meeting the Adherence Nurse.

Ineligible Patient

a. Discuss reasons for ineligibility.

b. Refer to appropriate services (e.g., social services; VCT for prevention counseling; nutritional counseling).

c. Discuss follow-up schedule: return in three months or sooner if signs and symptoms develop.

SOP 104: **Determining Eligibility**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Purpose

If the facility has established an Eligibility Committee (see **SOP 106: Eligibility Committee),** this Committee will determine each patient's eligibility for ART in accordance with the clinical and social criteria defined for the ART program. The Committee will decide on the eligible patients who will be started on ART and inform the pharmacist in-charge accordingly.

B. Process to start ART

A patient must meet the following clinical and social criteria:

1. Clinical criteria

- WHO Clinical Stage 4 disease irrespective of CD4 cell count or Total Lymphocyte Count (TLC)
- WHO Stage 3 disease + CD4 cell count < 350/mm³
- WHO Stage 1 or 2 disease + CD4 count < 200/mm³ or < 1200/mm³
- Tuberculosis patient who meets the clinical criteria and has completed the intensive phase of treatment.

2. Social criteria

- Resident of the District in which the health facility is located.
- Excellent compliance with treatment and/or prophylaxis for opportunistic infections (i.e., no missed dose).

- Willingness to visit the health facility regularly and be contacted anytime at home or elsewhere.

- Disclosure of HIV-positive status to a family member or a close friend who will accompany the patient for adherence counseling sessions and support the patient with medication adherence after starting ART.

- Staff member of health facility and their spouse who meet the clinical criteria and are willing to start treatment.

C. Post-Exposure Prophylaxis *(for specific procedures, refer to the SOPs for Post-Exposure Prophylaxis)*

1. Occupational exposure: A health care worker who is exposed at work will be eligible for post-HIV exposure prophylaxis in accordance with the National Guidelines for Antiretroviral Drug Therapy.

2. Non-occupational exposure: A victim of sexual assault will be eligible for post-HIV exposure prophylaxis in accordance with National Guidelines.

D. Deferral

1. A patient with an **acute opportunistic infection** should be treated for the infection before starting ART.

2. A patient who is **not ready to begin ART or is unwilling to follow the adherence counseling and monitoring visit schedule**.

   - The patient will be encouraged to meet with the Adherence Nurse to discuss the reasons for reluctance to begin ART.

   - Barriers to treatment can be identified and strategies to overcome these barriers can be developed.

   - The patient will be counseled to return for follow-up clinical assessment every month, or sooner if signs and symptoms develop.

3. A woman in her **first trimester of pregnancy**.

E. Exclusion criteria

1. Severe or end-stage liver failure.

2. Severe or end-stage renal failure.

3. Severe cardiomyopathy or advanced stage cardiac disease.

SOP 105: **Pre-ART Counseling**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Purpose

1. To educate and counsel patients eligible for ART about HIV disease and ART.

2. To assess the patient's readiness to start ART and adhere to the prescribed medication regimen.

3. To identify patient needs for additional medical and support services.

(For detailed procedures, refer to the SOPs for ART Adherence Counseling.)

B. Procedures

After the MO has determined eligibility for ART during the second visit and discussed treatment initiation, the patient is **referred to the Adherence Nurse** for the first pre-treatment counseling.

1. First Counseling Session

The **Adherence Nurse** will:

1. Register the patient, gather additional socio-demographic data.

2. **Assess the patient's knowledge of HIV and discuss the goals of ART**, the reasons for combination therapy, and the importance of medication adherence.

3. With the patient, **identify any difficulties and potential barriers** to keeping medical appointments, taking the medications and adhering to the medications (personal, environmental, social, financial, nutritional).

4. **Identify the patient's needs for other services**, including nutrition, housing, couples counseling and legal aid; with the patient's consent, make appropriate referrals.

5. **Schedule an appointment for the second counseling session**, preferably about three days from the first appointment, to include a family member/friend to whom the patient has disclosed her/his HIV-positive status and who will agree to attend the remaining counseling sessions.

6. **Direct the patient to the laboratory** for additional baseline lab tests as ordered by the MO.

7. **Document the session** on the **Pre-Start Counseling Form**.

2. Second counseling session

The patient will report to Registration and Records with the family member/friend. The patient will be directed to:

✓ The **Triage Nurse**, who will determine if the patient has developed signs and symptoms that require assessment by the MO/RCO.

1. If yes, the patient is directed to the MO/RCO for clinical consultation.

2. If no, the patient is directed to the Adherence Nurse.

✓ The **Adherence Nurse** will:

1. Review the previous counseling session and **answer the patient's questions**.

2. **Discuss the role of the family member/friend** regarding social support and ART adherence

3. **Obtain commitment** from the patient and the family member/friend to ART.

4. **Discuss that ART is not a cure** and does not prevent transmission of the virus; **ongoing prevention is essential**.

5. Discuss the **benefits, risks and side effects of ARVs**.

6. Jointly **develop strategies that will help the patient adhere** to the ARV regimen.

7. **Schedule an appointment for the third counseling session** on the day when the patient will visit the MO to begin ART.

8. **Document the session** in the **Pre-Start Counseling Form**.

SOP 106: **The Eligibility and Quality Review Committee**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Composition of Committee

If the health facility establishes an ART Eligibility Committee, members of the Committee will be drawn from among the following:

- The health facility's Chief Administrator
- The Consultant Physician in-charge
- The Pathologist in-charge
- The ART Medical Officer
- The ART Adherence Nurse
- A Pharmacist
- A Social Worker
- A Nutritionist
- A representative from Home-Based Care
- The Obstetrician/Gynecologist in-charge
- The Pediatrician in-charge

B. Procedures and responsibilities

This Committee will:

- Be chaired by the **Physician in-charge** and will meet on a weekly basis.

- Review all cases presented by the MO after **the second visit** and decide on those to be started on ART based on the eligibility criteria.

- Endorse an **Eligibility List** for all patients to be started on ART, which will be sent to the Pharmacist in-charge.

- Review and provide **guidance on difficult clinical cases**, including treatment failure and patients who default on treatment.

In urgent cases, initiation of treatment will be accelerated. The MO will start ART without prior Eligibility Committee deliberation when the following conditions exist:

1. The patient has been assessed to be in WHO Stage 4, or in WHO Stage 3 with clinical signs and symptoms of severe immunodeficiency.

2. The patient has no acute condition requiring immediate treatment.

3. Delay of treatment is expected to result in further deterioration of the patient's health and ultimately, in increased morbidity or mortality.

The MO will decide on a case-by-case basis if ART should be started before the results of all baseline laboratory investigations (e.g., CD4) are available.

The MO will present the patient's case to the Eligibility Committee at the next scheduled meeting.

SOP 107: **Initiating ART**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Purpose

1. To prepare the patient for ART, including education on each individual drug, dose, schedule, possible side effects, how to manage side effects and drug adherence.

2. To begin treatment by issuing the prescription for the ARV regime.

3. To complete the Third Pre-Start Adherence Counseling session.

B. Procedures

The patient will follow the same procedure and report to registration, then be directed to:

✓ The **Triage Nurse,** who will document new signs and symptoms and take vital signs, then **refer the patient to the MO**.

✓ The **Medical Officer (MO)** will:

1. **Assess symptoms** since the last visit and treat as needed.

2. **Review the laboratory results** from the patient's previous visit.

3. **Counsel the patient** about:

   - The ARV regime
   - ART adherence
   - Possible medication side effects, when and where to report them
   - Follow-up monitoring visits and lab schedule

4. **Provide a written schedule of the prescribed medications.**

5. Complete **"The Initial Treatment Prescribed" section** of the patient's **Clinical Care: Initial Adult Assessment Form** (if the patient is new to the HCC) or the **Clinical Care/ART: Adult Follow-Up Visit Form** (if the patient is an established client at the HCC).

6. Instruct the patient to **schedule an appointment** for clinical consultation in **two weeks.**

7. **Issue the prescription for the ARV regimen.**

8. Refer the patient to the **Adherence Nurse**.

In urgent cases, initiation of treatment will be accelerated. The MO will start ART without prior Eligibility Committee deliberation when the following conditions exist:

1. The patient has been assessed to be in WHO Stage 4, or in WHO Stage 3 with clinical signs and symptoms of severe immunodeficiency .

2. The patient has no acute condition requiring immediate treatment.

3. Delay of treatment is expected to result in further deterioration of the patient's health and ultimately, in increased morbidity or mortality.

The MO will decide on a case-by-case basis if ART should be started before the results of all baseline laboratory investigations (e.g., CD4) are available.

The MO will present the patient's case to the Eligibility Committee at the next scheduled meeting.

✓ The **Adherence Nurse** will:

1. **Review the patient's medication regime**, including:
   - Schedule of each medication
   - Dose of each medication
   - Food requirements of each medication

2. Stress the importance of **100 percent medication adherence**.

3. **Discuss possible side effects:**
   - Which side effects to report to the HCC health staff immediately
   - Which side effects can be managed at home and how to do so
   - To continue taking the medications despite side effects

4. **Explore ways of living positively:** the importance of a positive attitude, social support, healthy food and spiritual aid.

5. **Identify needs** (the patient's and the household's) that have not been addressed before; provide referrals to appropriate services.

6. **Discuss ongoing prevention,** including specific strategies to prevent transmission of the virus to sexual partner(s) and possible re-infection.

7. **Schedule an appointment with the Adherence Nurse in 48-72 hours** to assess possible side effects and medication adherence.

8. **Direct the patient to the pharmacy** to obtain the ARVs.

STANDARD OPERATING PROCEDURES: ANTIRETROVIRAL THERAPY FOR ADULTS AND ADOLESCENTS

SOP 108: **ARV Drug Regimens**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

The ARV medications will be prescribed in combination therapy in accordance with the National Guidelines for Antiretroviral Drug Therapy. The following medication regimens are provided as examples:

A. First line

Adults and adolescents: D4T (Stavudine) + 3TC (Lamivudine) + Efavirenz 600 mg/day

Pregnant women or women likely to become pregnant: D4T (Stavudine) + 3TC (Lamivudine) + Nevirapine

Patients with TB:
Eligible to begin ART after the intensive phase of TB treatment has been completed. The preferred regimen is: D4T (Stavudine) + 3TC (Lamivudine) + Efavirenz 800 mg/day

B. Second line

Adults and adolescents: AZT (Zidovudine) + DDI (Didanosine) + Lopinavir/Ritonavir (Kaletra)

or

AZT (Zidovudine) + DDI (Didanosine) + Nelfinavir

SOP 109: **Monitoring Patients on ART**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Adherence monitoring after starting ART

Forty-eight to 72 hours after starting ART, the patient and family member/friend will report to registration for adherence monitoring. The patient will be directed to the **Adherence Nurse,** who will:

1. **Assess the patient for adverse drug effects**. If necessary, the patient will be referred immediately to the MO/RCO for further assessment and symptom management.

2. **Assess medication adherence**:
   - Discuss the patient's experience with the medications.
   - Identify any difficulties reported by the patient in taking the medications.
   - Develop strategies to manage these difficulties and achieve adherence.
   - Consider observations offered by the patient's family member/friend.
   - Review each medication, dose, schedule, possible side effects and how to manage.

3. **Report any serious difficulties with adherence** or concerns about the patient's commitment to ART to the MO/RCO.

4. **Provide support and encouragement** and instruct the patient to report any serious adverse effects to the HCC; if these occur as an emergency, instruct the patient to immediately see the MO for assessment and management or go to the Emergency Room if the Clinic is closed.

5. **Review prevention** and risks of HIV transmission while on ART.

6. For families where more than one member is HIV infected but only one is eligible for ART, **explain the dangers of sharing the medications** with the other infected members (for example, the spouse or child).

7. **Schedule the next counseling visit** on the same day as the patient's appointment with the MO/RCO if there are no adherence concerns.

   - If the patient is not adhering but wants to continue treatment, schedule a visit within the next 48 hours for intensive follow-up.

   - If the patient is adhering and can be contacted by telephone, the Adherence Nurse will call the patient in 5-7 days to check on the patient's status and reinforce medication adherence.

8. **Document the session** on the **ART Adherence Counseling Form**.

B. Clinical and adherence monitoring

1. Clinical and adherence monitoring visit schedule

- First two months: every two weeks
- Thereafter: every month

After a minimum three months on therapy, the patient will report to the Triage Nurse for the monthly visit. **If the patient is stable on ART**, namely:

- Does not have side effects from the medications or has well-managed side effects; and
- Is strongly adherent to the medications, defined as not missing one ARV dose since the previous visit.

The Triage Nurse will complete a **rapid assessment of the patient's status** and **provide a prescription** for the next month's supply of ARVs. The patient's visit will be documented in the **Rapid Follow-Up Visit Form**.

The patient will be referred to the MO or RCO whenever s/he reports new or intensified symptoms indicative of medication side effects or an adverse clinical event. More frequent visits will be scheduled if the patient develops symptoms or experiences difficulties in adhering to the medications. Assessment notes will be included in the **Form for the Medical Follow-Up of Adult Patients on ART** and the **ART Adherence Counseling Form**, which are retained in the patient's medical record.

2. Laboratory monitoring

First year

- Second patient visit **(before starting ART)**

  - Baseline viral load (if included in the health facility's protocol)
  - LFTs
  - Renal function tests
  - Complete urinalysis
  - Chest X-ray
  - **For women:** cervical PAP smear

- Month One
  - **If the patient is taking Nevirapine:** LFTs
- Month Three
  - Full Blood Count (includes Total Lymphocyte Count — TLC)
  - CD4+ Count
  - LFTs
  - Other tests as needed
- Month Six
  - Full Blood Count (includes TLC)
  - CD4+ Count
  - LFTs
  - Other tests as needed
- Month Nine
  - Full Blood Count (includes TLC)
- Month 12
  - Full Blood Count (includes TLC)
  - CD4+ Count
  - LFTs
  - Other tests as needed

Subsequent years

- Every six months:
  - Full Blood Count (includes TLC)
  - CD4+ Count
  - LFTs
  - Other tests as needed

For a **patient who is not responding to treatment**, the viral load test and resistance testing will be requested if testing is available and cost can be covered.

Women will be referred to OB-GYN for a **cervical PAP smear on an annual basis**, or per MO/RCO assessment.

SOP 110: **Change or Interruption of ART**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Change of therapy

1. Drug reaction criteria

- When a patient experiences **a severe reaction or intolerable side effect** that has a high probability of being associated with one of the antiretroviral drugs.
- When **strategies to manage** the severe reaction or intolerable side effect do not reduce the reaction and the patient experiences increased morbidity, threat of mortality and/or reduced quality of life.

2. Drug reaction protocol

- The **offending medication will be identified and discontinued**.
- **Another drug in the same drug class** and among the approved ARV regimens will be started to replace the discontinued drug.
- **The patient will be counseled about the new drug,** including dose, schedule and possible side effects.
- **The change of therapy will be documented in the patient's medical record**.

B. Treatment failure

1. Treatment failure criteria

Treatment failure will be defined by the **National Guidelines for Antiretroviral Drug Therapy** and may include the following:

a. Clinical failure

- Occurrence or recurrence of opportunistic infection(s), wasting or dementia after at least three months on ART, excluding immune reconstitution syndromes; or
- Failure to resolve pretreatment opportunistic infection(s).

b. Immunologic failure

- Failure to increase 25-50 cells/mm3 above the baseline CD4 cell count over the first year of therapy; or
- A decrease in CD4 cell count to below the baseline CD4 cell count while on therapy.

c. Virologic failure

- Failure to reduce the viral load to an undetectable level after 6-12 weeks of therapy in a treatment-naïve patient; or
- Failure to reduce the viral load by 1 log (10 fold) or more by 4 weeks after starting therapy, or
- Repeated detection of viremia after virologic suppression (Note: isolated episodes of viremia—"blips" (single levels of 50-1,000 copies/mL)—are usually not associated with subsequent virologic failure)

2. Treatment failure protocol

- **All drugs will be discontinued**.
- **A new regimen will be selected**, the patient will be counseled on each drug (including dose, schedule and possible side effects) and the patient will start the regime.
- **The change of regimen will be documented in the patient's medical record**.

C. Interruption of therapy

1. Pregnancy

For a woman in the **first trimester of pregnancy**, all ARV drugs will be stopped. (Note: If Nevirapine is included in her regime, stop Nevirapine two to three days before the other drugs).

The **drugs will be restarted** in the second trimester if her clinical status at that point supports resumption of treatment.

2. Medication non-adherence

- Patients who are not adherent to the ARV regime will be **counseled by the Adherence Counselor** regarding the importance of medication adherence and strategies to overcome barriers to adherence.

- If a patient continues to be **non-adherent to the ARVs during the two weeks following** the previous counseling session, the patient will be asked to meet with the MO/RCO, who will assess the patient's commitment to continuing ART. The MO/RCO will reinforce the importance of medication adherence.

- **If non-adherence to the ARVs continues during the subsequent two weeks**, the MO will refer the patient's case to the Eligibility and Quality Review Committee for consideration and recommendation regarding the patient's continuation on ART.

SOP 111: **Family-centered Care**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Caring for the family unit

Parents and other immediate family members of HIV-infected children may themselves be HIV-infected. **Care, treatment and support should be made available to all members of the family** to optimize positive health outcomes and reduce the detrimental impact of HIV/AIDS on the family unit. Ongoing care and support can help preserve and strengthen the relationships and the economic function of family members.

B. Family-centered strategies

1. If parents or other immediate family members **do not know their HIV serostatus**, the Pediatric HIV Care Center (PHCC) staff will discuss the benefits of testing and accessing care and support services if the test result is positive. If the test result is negative, strategies to prevent infection and maintain this status can be emphasized.

2. The PHCC staff will **refer any family member who wants to be tested for HIV to VCT services** that are accessible by this family member.

3. For a parent, other immediate family member or guardian who is known to be HIV-infected but is not accessing care and support services, the PHCC staff will **refer this person to the facility's unit that provides care and treatment for adults who are HIV-infected**. The referral will be formal. With this individual's consent, the unit to which the family member is referred will confirm that this individual has registered for care services and that an initial clinical assessment has been completed.

4. **Ongoing communication and coordination of services** are needed to achieve an integrated approach to caring for HIV-infected and -affected family members. To develop a family-centered plan of care, staff from the PHCC and the unit treating HIV-infected adults will meet weekly to discuss the health status and needs of family members. Strategies to care for and support the family will be developed during this care meeting. Family members will be informed about the approach to care when they register with the HCC and the adult HIV care unit. Care and support interventions will be documented in the medical records of both the child and the adult.

SOP 112: **Record Keeping**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Procedures

A. Each patient will have a **medical record on file** at the HCC. For patients with a pre-existing record at the health facility, the old file will be integrated into the new one.

B. The following **forms will be maintained in the patient's medical record**:

1. Triage Nurse Assessment Form
2. Clinical Care: Initial Adults Assessment Form
3. Clinical Care/Antiretroviral Therapy: Adult Follow-Up Form
4. Pre-Start Counseling Form
5. ART Adherence Counseling Form
6. Laboratory Investigation Result Forms

C. The **Registration Clerk** in the HCC Registration and Records Department will:

1. **Facilitate the patient's attendance** for treatment and clinical review in the ART program. S/he will ensure that the patient's medical record is available for each patient visit and that the appropriate forms are included in the file.

2. **Review the clinical management form after the patient's visit to assure its completion.** If incomplete or if missing data on the form are identified, the Registration Clerk will return the form to the appropriate clinician (i.e., MO, RCO, Adherence Counselor, Triage Nurse) for completion.

SOP 113: **Health Facility Referral Management**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Policy

To assure that the patient's clinical needs are fully met, the HCC staff will refer the patient to the following **services within the health facility for specialized management**:

1. Inpatient Department
2. Maternal Health Center
3. Antenatal Health Center
4. Specialty Departments (e.g., Gynecology)
5. Laboratory
6. Radiology

B. Procedures

1. The HCC Nurse will **arrange the details of the referral** as ordered by the MO or RCO.

2. Within 24 hours, the HCC Nurse will **contact the Inpatient Department or Specialty Department to which the patient was referred** to assure that the services ordered for the patient are being provided.

3. The HCC Nurse will **document the referral** in the **Clinical Care/ART: Adult Follow-Up Visit Form**. The form will be maintained in the patient's medical record.

4. **Documentation regarding the patient from the referral site** will be included in the patient's medical record.

SOP 114: **Community Care and Referral Management**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Policy

Referral to community services will be provided for HIV-infected patients and their family members who desire assistance with and access to resources to maintain positive health status and effectively manage the multiple dimensions of HIV disease.

B. Procedures

1. Confidentiality

The referral staff will **maintain confidentiality** about each patient and protect the confidentiality of the patient's records.

2. Designated staff

The **HCC nurse** will assist the patient in determining needs and how to best meet those needs.

If **members of PLHA organizations** volunteer at the HCC, they can also assist patients with referral arrangements for needed services, as well as patient education and support.

3. Service areas

The referral staff will **assist the patient in determining needs and how to best meet those needs** in the following areas:

- Health care, including preventing viral transmission
- Nutrition
- Housing

- Home-based care
- Economic support/employment
- Activities of daily living
- Mental health
- PLHA association support
- Social relationships
- Recreation and leisure
- Transportation
- Legal assistance
- Spiritual support

4. Referral process

1. The referral staff and the patient will jointly **develop a service plan** that defines the patient's needs and the steps to meet those needs. The plan will be updated in accordance with the patient's needs.

2. The referral staff will **make referrals** and coordinate delivery of services to meet the patient's needs.

3. The referral staff will **track referral requests** and follow-up to assure that the patient's needs are met.

4. The referral staff will maintain a record of meetings with the patient, the referrals made for the patient, and the outcomes of the referrals. This **documentation will be maintained in the patient's medical record**.

SOP 115: **Monitoring and Evaluation**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Clinical monitoring and mentoring

1. The **Eligibility Committee** will meet weekly to review difficult patient cases.

2. The **HCC Multidisciplinary Care Team** will meet weekly to share insights, discuss issues pertaining to patient care and participate in brief care updates on topics of interest. All care staff will be invited, including physicians, registered clinical officers (RCOs), nurses, adherence counselors, nutritionists, pharmacy staff and laboratory staff.

B. Care indicators

1. **Data on ART management and HIV comprehensive care** will be maintained in the patient's medical record on a continuous basis.

2. **On a monthly basis**, data on defined indicators will be collected and reported by the Data Clerk in accordance with the Ministry of Health's Monitoring and Evaluation (M&E) Plan.

Examples of process indicators

- Number of patients started on ART during the reporting quarter
- Number of patients who stopped taking ARVs during the reporting quarter
- Number of patients whose ARV regime was changed during the reporting quarter
- Number of patients on ART who were lost to follow-up during the reporting quarter
- Number of patients on ART who received adherence counseling during the reporting quarter

C. Patient satisfaction

A **Patient Satisfaction Survey** will be available for completion by patients enrolled for ART. The patient will be encouraged to fill out the form to provide feedback about the care received, including suggestions for improvement and additional concerns.

SOP 116: **Cost Issues**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Facility policy

The policy of the health facility is to apply existing cost-sharing policies to HIV-infected persons. Waivers and exemptions are provided for those patients unable to meet the cost of treatment, including required laboratory tests. **(This will be revised according to facility policy.)**

B. Accessing treatment when cost-sharing applies

Patients registered at the HCC will complete a waiver request form, if they are unable to meet the costs of the treatment.

This waiver request is then processed using the existing mechanism that involves the Hospital Social Worker and Administration. Upon approval of this waiver request, which also indicates duration of validity, the patient receives the services and drugs without charge.

A patient who is able to pay will be charged for the services and drugs according to the existing cost-sharing rates as determined by facility policy and approved by the Ministry of Health. The patient and/or his/her sponsor, in conjunction with the facility's designated financial staff, will determine the schedule and mode of payment.

A cost-sharing fee, as determined by the health facility, will be charged for clinical consultations, treatment, drugs and routine laboratory and other monitoring tests.

FORM A101: HIV CARE CENTER: ART PROGRAM

HIV Comprehensive Care Center Registration Form

Health facility:_____

PATIENT IDENTIFICATION:

Patient name:_____ Registration number:_____

Residential address:_____ _____

P O Box:_____City/town:_____

Telephone number: Home_____Work_____Cell_____

Date of birth:_____ Age:_____ Gender: □ Male □ Female

Marital status: □ Married □ Single □ Divorced □ Separated □ Widow(er)

Primary language: _____

Occupation: _____status: □ Full time □ Part time □ On leave □ Unemployed

If child:

Are parents living? Yes_____ No_____ If yes, names: _____

With whom does the child live?

Name:_____Relationship:_____

In school: Yes_____ No_____ If yes, school name: _____ Grade: _____

Dependent children/ siblings in home:

Name	Age	Gender	Name	Age	Gender	Name	Age	Gender
1.			3.			5.		
2.			4.			6.		

EMERGENCY CONTACT:

Name:_____ Relationship:_____

Home address:_____

P O Box:_____City/town:_____

Telephone number: Home_____Work_____Cell_____

REFERRAL INFORMATION:

Name of referring enter:_____

Type of facility: □ Government hospital □ Government health center □ NGO/mission hospital □Antenatal clinic □ Private clinic □ Private hospital/nursing home □ Diagnostic HIV testing □ PMTCT □ Walk-in VCT □ CBO □ Home-based care □ Penal system □ Sub. abuse services □ Self-referral

FUNDING:

Funding type: □ Patient out of pocket □ Medical insurance: Type: _____ □ Special project □ Employee sponsored: Employer: _____ □ Other: _____ □ Waiver (date requested:_____)

Change of funding status:

Date	From	To	Date	From	To	Date	From	To

FORM A102: HIV CARE CENTER: ART PROGRAM

Records Assistant Checklist

Patient's name: _____

Registration number (care center): _____

Registration number (ART): _____

MAINTAIN CONFIDENTIALITY OF MEDICAL RECORDS AT ALL TIMES

First visit: Date: _____

- ❑ Establish medical record
- ❑ Complete personal data section of enrolment form
- ❑ Add patient to HIV Care Center register
- ❑ Obtain inpatient file (if appropriate)
- ❑ Direct patient to Triage Nurse

  *
- ❑ After MO visit: issue appointment card
- ❑ Schedule next visit in one week and write date in appointment card
  - ➢ MO
  - ➢ ART Nurse
- ❑ File medical record after documentation by Triage Nurse/MO/ART Nurse completed

Subsequent visits:

- ❑ Collect appointment card from patient
- ❑ Pull patient's medical record
- ❑ Verify patient's personal data and record any changes:
  - ➢ Address
  - ➢ Telephone contact
- ❑ Record patient's visit in HIV Care Center register
- ❑ Direct patient to Triage Nurse

  *
- ❑ After visit: schedule next visit and write date in patient's appointment card and in HIV Care Center register
- ❑ File medical record after clinical documentation completed

FORM A103: HIV Clinical Care Nursing Assessment/Triage Form

Patient Name: _____CCC/ART Registration number: _____

Date	Appt. status	Weight	Temp.	Blood pressure	Pulse	Mobility	General condition	Presenting Problem	Mgmt Req: refer to:

Appt. status
1=scheduled,
2=walk-in,
3=Drug refill,
4=receive results of investigations

Mobility
1=not mobile,
2=difficulty walking,
3=difficulty balancing,
4=difficulty sitting,
5=difficulty rising up,
6=normal

General condition
1=weight loss,
2=fatigue,
3=weakness,
4=unkempt,
5=looks ill,
6=well groomed

Mgmt: refer to:
1=clinical officer,
2=medical officer,
3=casualty, 4=home-based care, 5=STI,
6=TB, 7=nutrition,
8=support counseling
9=adherence counseling

FORM A104: HIV CARE CENTER: ART PROGRAM

Triage Nurse Checklist

Patient's name: _____

Triage nurse: _____

First visit: **Date:** _____

- ❑ **Determine reason for visit**
- ❑ **Obtain and record socio-economic data**
- ❑ **Obtain and record vital signs and weight**
- ❑ **Direct patient to MO**

Second visit: **Date:** _____

- ❑ **Collect appointment card and medical record**
- ❑ **Record presenting symptoms**
- ❑ **Obtain and record vital signs and weight**
- ❑ **Direct patient to MO**

Third visit: **Date:** _____

- ❑ **Collect appointment card and medical record**
- ❑ **Record presenting symptoms**
- ❑ **Obtain vital signs and weight**
- ❑ **Refer to MO as needed**
- ❑ **Direct to ART Nurse if MO consult not indicated**

Ongoing visits:

Date	Reason for visit

For each visit:

- ❑ Collect appointment card and medical record
- ❑ Obtain vital signs and weight
- ❑ Record presenting symptoms
- ❑ Refer to MO as needed
- ❑ Direct to ART Nurse if MO consult is not indicated.

FORM A105: HIV CARE CENTER: ART PROGRAM

CLINICAL CARE **INITIAL ADULT ASSESSMENT FORM**

Health Facility Name: _____ Date: _____

Client Name: _____ Client Registration Number: _____

Date of Birth: ____/____/____ Date of HIV+ Test: _____ (HIV I ___ HIV II___ Both HIV I & HIV II___)

MEDICATIONS

Current Medications:

OI Prophylaxis: Cotrimoxazole? Yes_____ No_____ INH? Yes_____ No____

For other conditions: Medication name: _____ Medication name: _____

Past ARV experience: Yes ___ No ___ If Yes, list drugs and dates

Drug_____ Duration (taken from what date to what date) _____

Drug_____ Duration (taken from what date to what date) _____

Drug_____ Duration (taken from what date to what date) _____

Drug Allergies:

Women Only:

Nevirapine for PMTCT: Yes___ No___ *If yes, date of treatment____/_____/____ (use dd/mm/yy)*

Baby treated? Yes ___ No___ *If yes, date: _____/_____/_____ (use dd/mm/yy)*

HISTORY AND PHYSICAL EXAM FINDINGS

Presenting Problem (in patient's words): *Include history of chief complaint(s) (onset, duration, progression, treatment and response):*

Symptom screen

Condition	Current	Past	Other Acute/Chronic Conditions	Yes	No
Jaundice			Hypertension		
Chronic cough			Asthma		
Difficulty swallowing			Heart Disease		
Skin rash, itching			Hepatitis		
Chills			Diabetes		
Sexually transmitted infections			Malaria		
Persistent headaches			Other: _____		
Visual changes			Other: _____		
Pain: _____location					
Abnormal menses					

FHI 1 Revised: 7/14/2004

Women only: Pregnant: Yes ___ No __ Possibly Pregnant?: Yes ___ No ___

Habits:
Smoking: Yes___ No___ *If Yes: Type_____# /day or week_____ Duration: #/yrs _____*
Alcohol: Yes___ No___ *If Yes (Check one): Every day___ ≥ Once weekly ___ ≥ Once monthly___*

HIV Diagnosis and client and family response: Disclosed___ Not disclosed ___
If disclosed: Disclosed to: Family__ (Supportive__ Not Supportive__) Friend__ (Supportive__ Not Supportive__)

Sources of emotional support: Family__ Friends___ Other___ If other specify:_____

VITAL SIGNS:				
Height (cm): _____	**Weight (kg):** _____.__	**Temp (C°):** _____.__	**Pulse (bpm):**_____	**B/P:** _____/_____

Physical Exam

General description of patient presentation:

Physical Findings

General Appearance	**Present**	**Absent**	**Gastrointestinal**	**Present**	**Absent**
Pallor			Hepatomegaly		
Febrile			Splenomegaly		
Dehydrated			Tenderness		
Jaundiced			Distention		
Peripheral edema			Other findings		
Other findings			**Skin**		
Lymphatic System			Pruritic Paplar Dermatitis		
Lymphadenopathy			Abscesses		
Oral			Herpetic lesions (e.g. zoster)		
Oral hairy leukoplakia			Kaposi's lesions		
Oral thrush			Seborrheic dermatitis		
Oral lesions			Fungal infections		
Other findings			Other findings		
Respiratory			**Neurological**	**Abnormal**	**Normal**
Rate: _____			Orientation to person, time, place		
Labored breathing			Speech		
Cyanosis			Neck stiffness		
Wheezing			Blindness one/both eyes		
Intercostal recession/ subcostal recession			Hemiplegia/paresis (R or L or both)		
Auscultation findings:	_____	_____	Numbness of extremities		
Other findings			Other Findings		
Cardiac	**Abnormal**	**Normal**	**Mental Status**	**Present**	**Absent**
Heart rate and rhythm			Slow mentation		
Auscultation findings (include murmurs)			Memory loss		
Breasts	**Present**	**Absent**	Mood swings		
Lumps, masses			Depression		
Discharge			Anxiety		
Genitalia			Suicidal ideation		
Vaginal/urethral discharge			Other findings:		
Genital ulcer, other lesion					
Inguinal node enlargement					

TRANSMISSION RISK FACTOR ASSESSMENT:	
Is patient sexually active? Yes_____ No ____	*If yes continue with questions below*
Disclosure to sexual partner: Yes_____ No ____	***If no, refer to Adherence Counselor for prevention counseling***
Regular condom use: Yes _____ No _____	***If no, refer to Adherence Counselor for prevention counseling***

WHO CLINICAL STAGE			
WHO Stage 1		**WHO Stage 4**	
Asymptomatic HIV infection		Candidiasis (Esophageal, Bronchi, Tracea, Lungs)	
Persistent Generalized Lymphadenopathy (PGL)		Cryptococcosis, Extrapulmonary	
WHO Stage 2		Cryptosporidiosis with Diarrhea (> 1 month)	
Herpes Zoster (within the last 5 years)		Cytomegalovirus Disease	
Minor Mucocutaneous Manifestations		Herpes Simplex (mucocutaneous > 1 month; or visceral any duration)	
Recurrent Upper Respiratory Tract Infections		HIV Encephalopathy	
Weight loss < 10% of Body Weight		HIV Wasting Syndrome	
WHO Stage 3		Kaposi's Sarcoma (KS)	
Severe Bacterial Infections (i.e., pneumonia)		Lymphoma	
Oral Candidiasis (Thrush)		Atypical Mycobacteriosis, Disseminated	
Unexplained Chronic Diarrhea (> 1 month)		Tuberculosis, Extrapulmonary	
Unexplained Prolonged Fever (intermittent or Constant > 1 month)		Progressive Multifocal Leukoencephalopathy (PML)	
Oral Hairy Leukoplakia		Mycosis, Disseminated (i.e., Histoplasmosis, Coccidiodomycosis)	
Tuberculosis, Pulmomary (within previous year)		Pneumocystis Carinii Pneumonia (PCP)	
Weight Loss > 10% of Body Weight		Salmonella Septicemia, Non-typhoid	
		Toxoplasmosis, CNS	
☐ **WHO Stage I** ☐ **WHO Stage II** ☐ **WHO Stage III** ☐ **WHO Stage IV**			

Other diagnostic findings:
☐ Malaria ☐ STI ☐ Other_____ ☐ Other _____

ARV ELIGIBILITY CRITERIA			
Clinical and Biological Criteria:	**Yes**	**No**	**Comments:**
HIV Test Positive			
CD4 below 200			**Baseline CD4/TLC:** _____
WHO Stage III or IV			
Completed intensive phase of TB therapy			
Social Criteria:			
Resident of catchment area			
Disclosure to selected other person			
Demonstrated consistent use of PT therapy			
Completed pre-treatment adherence counseling sessions			
Health worker or family member			

PLAN

1. **OI Prophylaxis:**

   Cotrimoxazole: Start _____ Continue _____ Discontinue _____ Start at a later date _____

   INH: Start _____ Continue _____ Discontinue _____ Start at a later date _____

2. **Hospital Admission:** Yes _____ No _____

3. **Order Baseline Labs (including CD4):** Yes ____ No ____ Pregnancy Test: Yes ___ No ___

4. **Treatment for Other Conditions:** Yes ____ No ____

   If yes: Diagnosis: _____/Treatment: _____

   Diagnosis: _____/Treatment: _____

5. **Recommend ART:** Yes _____ No _____ Deferred _____ *State reason:* _____

6. **Referrals:**

   Adherence counselor Yes _____ No _____
   Others: (1) _____ (2) _____

7. **Next scheduled appointment:** ___/___/___ (dd/mm/yy)

Medical Officer/Physician's Name: _____ Signature: _____

FORM A106: HIV CARE CENTER: ART PROGRAM

Clinical Care/ART **ADULT FOLLOW-UP VISIT FORM**

Health Facility Name: _____ Date: _____

Client Name: _____ Client Registration Number: _____

Date of Birth: ____/____/____ ART Program Number: _____

Scheduled Visit? Yes_____ No_____ *If yes*, did patient come on the date of appt.? Yes _____ No _____

Unscheduled/Sickness visit? Yes_____ No_____

Client on ART? Yes_____ No _____ ***If Not, do not complete ART sections***

Client on CTX prophylaxis? Yes_____ No_____ Client on TB prophylaxis? Yes_____ No____

PATIENT COMPLAINTS: ***(For patients on ART only) Check all that apply:***

Patient Chief Complaint (in patient's own words):

Symptoms		Symptoms		Symptoms	
Cough		Lipodystrophy/lipoatrophy		Pain (Site: _____)	
Dyspnea on exertion		Nausea		Headache	
Haemoptysis		Vomiting		Dizziness	
Difficulty swallowing		Diarrhea		Insomnia	
Skin rash		Abdominal discomfort		Abnormal dreams	
Fever/chills		R quadrant pain		Anxiety/Depression	
Blood in urine		Myalgia/Arthralgia		Mental changes (cognitive acuity)	
Fatigue		Paresthesia		Other: _____	

VITAL SIGNS:

Weight (kg): _____.__	Temp (C°): _____.__	Pulse (bpm):_____	B/P: _____/_____

PHYSICAL EXAM FINDINGS

General description of patient presentation:

Physical Exam:

System	Abnormal	Normal	System	Abnormal	Normal
General Appearance			Genitalia		
Lymphatic System			Gastrointestinal		
Oral			Skin		
Respiratory			Neurological		
Cardiac			Mental Status		
Breasts					

Note any abnormal findings:

Women only: Pregnant: Yes ___ No __ Possibly Pregnant?: Yes ___ No ___

TRANSMISSION RISK FACTOR ASSESSMENT:

Is patient sexually active? Yes_____ No _____ *If yes, continue with questions below*

Disclosure to sexual partner: Yes_____ No _____	***If no, refer to Adherence Counselor for prevention counseling***
Regular condom use: Yes _____ No _____	***If no, refer to Adherence Counselor for prevention counseling***

FHI 1 Revised: 7/14/2004

ADHERENCE for CTX, INH and ARVs: *last 3 days before this visit*				
	0 pill missed	**1-2 pills missed**	**3-4 pills missed**	**5 > pills missed**
CTX (self-reported)				
INH (self-reported)				
ARVs (self-reported)				

Patient reason for missing doses: ***(check all that apply)***

Unable to pay		Too many pills		Too busy to take		Did not want to take it	
Felt well		To avoid side effects		Felt sick/ill		Shared pills with others	
Forgot to take		Ran out of pills		Felt depressed/anxious		None	

WHO CLINICAL STAGE *: For patients NOT on ART--Skip of patient is on ART*			
WHO Stage 1		**WHO Stage 4**	
Asymptomatic HIV infection		Candidiasis (Esophageal, Bronchi, Tracea, Lungs)	
Persistent Generalized Lymphadenopathy (PGL)		Cryptococcosis, Extrapulmonary	
WHO Stage 2		Cryptosporidiosis with Diarrhea (> 1 month)	
Herpes Zoster (within the last 5 years)		Cytomegalovirus Disease	
Minor Mucocutaneous Manifestations		Herpes Simplex (mucocutaneous > 1 month; or visceral any duration)	
Recurrent Upper Respiratory Tract Infections		HIV Encephalopathy	
Weight loss < 10% of Body Weight		HIV Wasting Syndrome	
WHO Stage 3		Kaposi's Sarcoma (KS)	
Severe Bacterial Infections (i.e., pneumonia)		Lymphoma	
Oral Candidiasis (Thrush)		Atypical Mycobacteriosis, Disseminated	
Unexplained Chronic Diarrhea (> 1 month)		Tuberculosis, Extrapulmonary	
Unexplained Prolonged Fever (intermittent or Constant > 1 month)		Progressive Multifocal Leukoencephalopathy (PML)	
Oral Hairy Leukoplakia		Mycosis, Disseminated (i.e., Histoplasmosis, Coccidiodomycosis)	
Tuberculosis, Pulmomary (within previous year)		Pneumocystis Carinii Pneumonia (PCP)	
Weight Loss > 10% of Body Weight		Salmonella Septicemia, Non-typhoid	
		Toxoplasmosis, CNS	

☐ **WHO Stage I** ☐ **WHO Stage II** ☐ **WHO Stage III** ☐ **WHO Stage IV**

Other diagnostic findings:

☐ Malaria ☐ STI ☐ Other_____ ☐ Other _____

ARV ELIGIBILITY CRITERIA: *For patients NOT on ART--Skip of patient is on ART*			
Clinical and Biological Criteria:	**Yes**	**No**	**Comments:**
HIV Test Positive			
CD4 below 200			**Baseline CD4/TLC:** _____
WHO Stage III or IV			
Completed intensive phase of TB therapy			
Social Criteria:			
Resident of catchment area			
Disclosure to selected other person			
Demonstrated consistent use of PT therapy			
Complete pre-treatment adherence counseling sessions			
Health worker or family member			

PATIENTS ON ART: *Skip if patient is not on ART*

ADVERSE CLINICAL EVENTS: *Check all that apply*

Tuberculosis (pulmonary)		Herpes zoster	
Pneumonia		Kaposi's sarcoma	
Oral/esophageal candidiasis		Cryptococcal meningitis	
Chronic diarrhea		Malaria	
Weight loss after starting ART		Immune Reconstitution Syndrome	
STI		Other: _____	

ADVERSE DRUG SYMPTOMS/REACTIONS: *Check all that apply*

Anemia		Pain/numbness/tingling in extremities		Lipodystrophy	
Rash		Hepatotoxicity		Depression	
Diarrhea> 3 days		Blood in urine			
Pancreatitis		Severe drug reaction: _____ (Complete ADR Form)			

ART Treatment Failure: Yes _____ No _____ Not determined _____
If Yes, indicate which type: (Refer to National Guidelines for Antiretroviral Drug Therapy for definition)

Clinical ART Treatment Failure Yes_____ No _____ Not determined_____
Immunologic ART Treatment Failure Yes _____ No _____ Not determined_____

PLAN: *for all patients*

1. **OI Prophylaxis:**
   Cotrimoxazole: Start _____ Continue _____ Discontinue _____ Start at a later date _____
   INH: Start _____ Continue _____ Discontinue _____ Start at a later date _____

2. **Hospital Admission:** Yes _____ No _____

3. **Order labs:** Yes _____ No _____ Pregnancy Test: Yes _____ No _____

4. **Treatment for Other Conditions:** Yes _____ No _____
   If yes: Diagnosis: _____/Treatment: _____

   Diagnosis: _____/Treatment: _____

5. **ARV Status:**
   Start ARV's ____
   Continue ARVs _____
   Change ARVs _____ ***Reason***: Drug toxicity _____ Treatment Failure _____ TB diagnosis___
   Stop ARVs _____ ***Reason***: Death _____Adverse clinical status/event _____ Lost to follow-up ____
   Client stopped ARVs____ ***Reason***: Drug side effects _____ Felt Well _____ Unable to pay _____

6. **Transfer client to other ART site :** yes___ no ___(if yes, site name_____ and pt .no_____)

TREATMENT PRESCRIBED: *check all that apply*

ARV Drug	Check	ARV Drug	Check
D4T (Stavudine) 30 mg		Nevirapine 200 mg	
D4T (Stavudine) 40 mg		Triomune (Stavudine, Lamivudine, Nevirapine)	
3TC (Lamivudine) 150 mg		ddI (Didanosine) 250 mg	
AZT (Zidovudine) 300 mg		ddI (Didanosine) 400 mg	
Combivir (Zidovudine and Lamivudine)		Kaletra (Lopinavir/Ritonavir)	
Efavirenz 600 mg		Other:	
Efavirenz 800 mg			

Other drugs prescribed: 1._____ 2._____

Referred to:

1. Adherence Counselor: Yes _____ No ____
2. Other: _____
3. Other: _____

Next scheduled appointment: ___/___/___ (use *dd/ mm/ yy)*

Medical Officer/Physician's Name: _____**Signature:** _____

FORM A107: HIV CARE CENTER: ART PROGRAM

MO/RCO Checklist

Patient's name: _____

First visit: Date: _____

- ❑ Complete baseline assessment
- ❑ Classify by WHO staging system
- ❑ Request HIV test, if needed
- ❑ Discuss ART
- ❑ Order CD4 if Clinical Stage 3 or 4, and baseline tests
- ❑ Start treatment for acute symptoms
- ❑ Start prophylaxis for Stage 2, 3 or 4
- ❑ Instruct to return in one week
- ❑ Direct to laboratory

Second visit: Date: _____

- ❑ Assess the patient
- ❑ Inform of investigational results
- ❑ RCO refer to MO if Stage 3 or 4
- ❑ If eligible for ART: discuss eligibility
- ❑ Complete ARV enrolment form
- ❑ Refer to ART Nurse for counseling
- ❑ Refer to laboratory for additional tests
- ❑ Compile and submit patient file to Eligibility Subcommittee
- ❑ If not eligible for ART: discuss reasons
- ❑ Refer to appropriate services
- ❑ Discuss follow-up visit in three months or as needed

Third visit: Date: _____

- ❑ Assess and treat symptoms as needed
- ❑ Review investigational results
- ❑ Counsel on ARV regime and adherence
- ❑ Provide a written schedule of medications
- ❑ Complete ARV enrolment form
- ❑ Instruct patient to return in two weeks
- ❑ Issue prescription for ARVs
- ❑ Direct patient to ART Nurse

Ongoing visits:

- ❑ **Assess for adverse drug effects**
- ❑ **Manage adverse drug reactions as needed**
- ❑ **Stress importance of med adherence**

- ❑ Instruct to return in two weeks (first two months), then monthly, or as needed
- ❑ Report adverse drug reactions to pharmacy

FORM A108: HIV CARE CENTER: ART PROGRAM

Eligibility Committee Review Form

Patient name: _____Registration number_____

Date: _____

Eligibility criteria:	Yes	No
Clinical and biological criteria:		
1. HIV test positive		
2. WHO clinical stage: a. Stage III: ❑ Weight loss >10% ❑ Chronic diarrhea > 1 month ❑ Unexplained fever> 1 month ❑ Oral/pharyngeal candidiasis ❑ Oral hairy leukoplakia ❑ Pulmonary tuberculosis in last year ❑ Other pneumonias b. Stage IV: ❑ Esophageal candidiasis ❑ Mucotaneous herpes > 1 month ❑ Toxoplasmosis ❑ Cryptococcal meningitis ❑ Extrapulmonary tuberculosis ❑ Cytomegalovirus (CMV) ❑ Cryptosporidosis with diarrhoea ❑ Disseminated mycosis ❑ Kaposi's Sarcoma ❑ Lymphoma		
3. CD4+ cell count 200 or less		
4. Completed intensive phase of TB therapy		
Social and other criteria:		
1. Resident in catchment area		
2. Attended pre-start counseling sessions (two sessions)		
3. Health worker or partner		
Eligible for ARVs:		
Signatures: _____		

FORM A109: HIV CARE CENTER: ART PROGRAM

Pre-ART Adherence Counseling Form

Patient name: _____ Date: _____

HCC registration number: _____ Counseling session number: _____

- Additional socio-demographic information:
  _____
  _____

- Patient knowledge of HIV/AIDS:
  - ❑ Strong (knows modes of transmission, prevention, signs and symptoms)
  - ❑ Basic (knows some modes of transmission, signs and symptoms)
  - ❑ Weak (no knowledge of modes of transmission, prevention, signs and symptoms)

  HIV/AIDS information provided today:

  _____

- Topics discussed:
  - ❑ What is ART?
  - ❑ What is ART medication adherence?
  - ❑ What are the primary benefits and risks of ART?
  - ❑ What is a "buddy"?: a family member or friend to provide support
  - ❑ Why is ongoing prevention needed when on ART?
  - ❑ Why is "living positively with HIV" important?

- Patient concerns/barriers to ART:
  - ❑ Stigma (family and friends will find out)
  - ❑ Afraid of medications (side effects; "poison")
  - ❑ Doubt that medications will work
  - ❑ Will forget to take medications
  - ❑ Depressed/anxious
  - ❑ Other

- Strategies to overcome concerns/barriers to ART:
  - ❑ Disclosure to family member or friend
  - ❑ Management of side effects
  - ❑ Reminders/aided to take medications
  - ❑ Ongoing counseling
  - ❑ Other

- Notes: _____
  _____
  _____

FORM A110: HIV CARE CENTER: ART PROGRAM

ART Adherence Counseling Form

Patient name:_____ HCC registration number: _____

Counselor name:_____ Visit date: _____

1. Patient adherence report:

How many ARV pills do you take each day?

- ❑ Three
- ❑ Four
- ❑ Five
- ❑ Six

It can be hard to always take your pills. During the last three days before this visit, did you miss any doses of your ARVs?

0 pill missed	1-2 pills missed	3-4 pills missed	5 > pills missed

When was the last dose you missed?

- ❑ Today
- ❑ Yesterday
- ❑ Two days ago

Did you miss:

- ❑ One of your pills
- ❑ Two of your pills
- ❑ All of your pills

2. What are the reasons for not taking your pills? (Mark all that apply)

- ❑ None
- ❑ Unable to pay
- ❑ Felt well
- ❑ Forgot to take
- ❑ Too many pills
- ❑ To avoid side effects
- ❑ Ran out of pills
- ❑ Too busy to take
- ❑ Felt sick/ill
- ❑ Felt depressed/anxious
- ❑ Didn't want to take them

3. Have you had any side effects from the pills? (Mark all that apply)

Symptoms	Yes	No	Symptoms	Yes	No
Cough	Yes	No	Difficulty swallowing	Yes	No
Dyspnoea on exertion	Yes	No	Fat accumulations	Yes	No
Haemoptysis	Yes	No	Headaches	Yes	No
Fever/chills	Yes	No	Fatigue	Yes	No
Blood in urine	Yes	No	Myalgia	Yes	No
Jaundice	Yes	No	Paresthesia	Yes	No
Skin rash	Yes	No	Pain (Site:_____)	Yes	No
Nausea	Yes	No	Dizziness	Yes	No
Vomiting	Yes	No	Insomnia	Yes	No
Diarrhea	Yes	No	Abnormal dreams	Yes	No
Abdominal discomfort	Yes	No	Anxiety/depression	Yes	No
Right-quadrant pain	Yes	No	Mental changes (cognitive acuity)	Yes	No
Other: _____	Yes	No	Other: _____	Yes	No

4. Suggest strategies to help adherence:

- ❑ Identify reminder aide (e.g., calendar checklist; link to routine activity)
- ❑ Recommend help from family member/friend/"buddy"
- ❑ Provide support
- ❑ Schedule return visit for follow-up counseling in 72 hours
- ❑ Other: _____
- ❑ Other: _____

5. If less than 95 percent adherence: report to MO; date reported: _____

- ❑ Takes three pills per day and missed one in three days = 89 percent
- ❑ Takes four pills per day and missed one in three days = 92 percent
- ❑ Takes five pills per day and missed one in three days = 93 percent
- ❑ Takes six pills per day and missed one in three days = 94 percent

6. Notes:

_____

_____

_____

_____

FORM A111: HIV CARE CENTER: ART PROGRAM

Adherence Counseling Checklist

Patient's name: _____

Counselor's name: _____

First counseling session: Date: _____

- ❑ Review HCC Registration Form
- ❑ Assess patient's knowledge of HIV
- ❑ Discuss ART
- ❑ Identify barriers to adherence
- ❑ Discuss strategies to overcome barriers
- ❑ Answer patient's questions
- ❑ Schedule next counseling session
- ❑ Complete appointment card
- ❑ Complete Pre-Start Counseling Form

Second counseling session: Date: _____

- ❑ Review the previous session
- ❑ Discuss role of support person
- ❑ Obtain commitment to ART
- ❑ Stress that ART is not a cure
- ❑ Answer patient's questions
- ❑ Discuss ongoing prevention
- ❑ Discuss ART benefits/risks
- ❑ Develop adherence strategies
- ❑ Schedule next appointment
- ❑ Complete Pre-Start Counseling Form

Third counseling session: Date: _____

- ❑ Review ART regime
- ❑ Stress 100 percent adherence
- ❑ Discuss possible side effects and how to manage them
- ❑ Explore positive living
- ❑ Answer patient's questions
- ❑ Discuss ongoing prevention
- ❑ Schedule next appointment for 48 to 72 hours
- ❑ Direct patient to pharmacy
- ❑ Complete Pre-Start Counseling Form

Ongoing adherence monitoring:

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

- ❑ Assess for side effects
- ❑ Refer to MO as needed
- ❑ Assess med adherence
- ❑ Report adherence issues to MO
- ❑ Provide support
- ❑ Review ongoing prevention
- ❑ Instruct patient on follow-up
- ❑ Schedule next MO/counseling visit
- ❑ Complete ART Adherence Form

FORM A112: HIV CARE CENTER: ART PROGRAM **Laboratory Results Form**

Results of Laboratory Investigations **Patient Name:** _____ **CCC/ART#:**_____

Laboratory Test:	Date													
Haematology														
WBC (4 -11 x10^3 cells/mm^3)														
RBC (4.2 – 6.0 x10^6 cells/mm^3)														
Hb (12-18 g/dL)														
HCT (38.7 –50.4 %)														
PLT (130 -370 x10^3 cells/mm^3)														
LYMPH % (25 – 50 %)														
CD4+ T cells absolute count (518 – 1981 cells/µL)														
CD8 +T Cells absolute count (270 - 1335 cells/ l)														
CD4+/CD8+Ratio (0.46 - 2.7)														
CD4+ T Cells % (24.6 - 47.0 %)														
CD8+T cells % (10.1 - 38.6 %)														
Differential count														
TLC (1102 – 4914 cells/mm^3)														
Neutrophils count (2.00-8.00 10^3/µL)														
Monocyte count (0.10-1.00 10^3/µL)														
Eosinophils count (0.00-0.40 10^3/µL)														
Liver Function Tests														
ALT (SGPT) (<37 IU/L)														
AST (SGOT) (<42 IU/L)														
γ-GT (8 – 46 IU/L)														
ALK PHOS (80 – 316 IU/L)(M) (64 – 306 IU/L) (F)														
Total Bilirubin (< 17 µmol/dL)														
Direct Bilirubin (< 4.3 µmol/dL)														
Total Protein (66 – 87 g/L)														
Albumin (38 – 57 g/L)														
Renal Functions Tests														
Creatinine (65 – 124 µmol/dL)														
Urea (1.7 - 8.3 mmol/L)														
Sodium (135 – 150 mmol/L)														
Chloride (95 – 108 mmol/L)														
Potassium (3.6 - 5.5 mmol/L)														
Lipid Profiles														
Cholesterol (Total) (3.6 - 5.2 mmol/L)														
HDL (<4.9 mmol/L)														
Triglycerides (0.11 - 2.15 mmol/L)														
Others														
Glucose (3.0 - 6.1 mmol/L)														
Amylase (0 -125 IU/L)														
Uric Acid (54 - 424 mmol/L)														
Others:														
Date of next test needed:														

ANTIRETROVIRAL THERAPY (ART) PROGRAM

STANDARD OPERATING PROCEDURES

ART ADHERENCE COUNSELING

PREPARED BY FAMILY HEALTH INTERNATIONAL

OCTOBER 2004

INDEX

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STANDARD OPERATING PROCEDURES: ADHERENCE COUNSELING

SOP 101: **Introduction to Adherence Counseling**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Introduction

A key challenge in HIV clinical management is facilitating ART adherence. According to research studies, a 95 percent adherence rate is associated with controlling HIV replication, which allows an optimal therapeutic response to the medications.

Suboptimal adherence to ART regimens results in:

- Incomplete suppression of HIV replication
- Emergence of resistance to ARVs

ARV resistance may increase the potential for regimen failure, compromise future treatment options and lead to increased risk of mortality.

B. Interventions to enhance adherence

To support ART adherence and help achieve clinical goals (i.e., viral suppression, improved quality of life, and reduced morbidity and mortality), interventions should be tailored to the individual patient as much as possible. Key interventions *before starting ART* include:

- Assessing patient readiness for drug treatment or, if the patient is a child, the readiness of the caregiver(s) to administer the drugs.
- Identifying the types of support that will optimize the patient's adherence to therapy.
- Addressing the patient's individual learning needs, including the importance of ART adherence and the consequences of non-adherence.

Interventions *after starting ART* should also be individualized to the patient and include:

- Ongoing education about the importance of medication adherence and consequences of non-adherence.
- Social support to improve adherence.
- Use of reminders to take medications, such as medication charts or linking doses to daily living patterns (e.g., eating breakfast in the a.m. and dinner in the p.m.).
- Improved communication with healthcare workers.
- Continuous reinforcement of adherence.

C. Factors that affect adherence

Some factors that result in suboptimal adherence to ART relate to the lifelong need for the medications. Adherence to ARVs can decrease over time, particularly when the patient is feeling better and decides that s/he no longer needs to take the medications regularly.

Other obstacles to adherence include:

- Short-term side effects (e.g., nausea, headache, insomnia)
- Long-term toxicities (such as glucose intolerance, pancreatitis, peripheral neuropathy)
- Complexity of the drug regimen (dosing requirements, food requirements)
- Negative attitudes of healthcare workers
- Patient co-morbid health conditions
- Patient attitudes toward the healthcare system
- Patient circumstances (including poverty, lack of social support, lack of transportation for clinical appointments)
- Cost of health care, including medications

Children on ART and their caregivers face particular challenges:

- Disclosing the HIV infection when the child is able to understand and using language and concepts appropriate to the child's age and developmental stage.
- The need to take a liquid drug formulation if an infant or child is unable to swallow a pill.
- Infants or children may resist taking the drugs, whether in liquid or pill form, because of the bad taste or frustration in having to take medicine several times a day, day after day.

At each patient visit, it is important to assess whether any of these factors are impacting adherence to ARVs.

D. Assessing adherence

No best practice or gold standard exists for monitoring adherence. **Patient self-reporting** is basically subjective, but provides the Adherence Counselor and other members of the healthcare team with a measure to assess adherence. Since the accuracy of information recalled beyond three days is questionable, the **ART Adherence Counseling Form** (Form B102) developed for collecting and recording data on patient ARV adherence has a three-day reporting framework.

STANDARD OPERATING PROCEDURES: ADHERENCE COUNSELING

SOP 102: Designated Staff for Adherence Counseling

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Designated staff

The HCC staff member or members selected as ART Adherence Counselors will be responsible for counseling patients on adherence to ARVs. ART Adherence Counselors are members of the HCC's multidisciplinary team of care providers.

Designated staff will complete a two-day training prior to performing the responsibilities of Adherence Counselor. Training will cover:

- The objectives of ART adherence
- What is adherence? What is non-adherence?
- Factors affecting ART adherence
- Challenges to ART adherence
- Assessing the patient for ART adherence
- Counseling techniques
- Monitoring patients on ART:
  - The role of pre-start and ongoing counseling
  - The role of family member/friend
  - Self-reporting
  - Biological markers of treatment effectiveness
- Strategies to enhance ART adherence
- Developing an ART adherence strategy
- Counseling about ARV side effects
- Adherence counseling role plays

The HCC Medical Officer (MO) will provide mentoring and supervision to the Adherence Counselors.

STANDARD OPERATING PROCEDURES: ADHERENCE COUNSELING

SOP 103: **Pre-ART Counseling: The First Counseling Session**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Pre-ART adherence counseling

After the MO has determined probable eligibility for ART and discussed treatment initiation, the patient is referred to the Adherence Counselor for the first pre-ART counseling session.

First counseling session

1. **Introduce yourself** to the patient, giving your name and position.

2. Review information on the patient's **HCC Registration Form**, gathering additional socio-demographic data as needed.

3. Assess the patient's **knowledge of HIV/AIDS**.

4. **Educate on HIV** and correct misconceptions as needed:

   - HIV is a virus that attacks the immune system.
   - There are different routes of HIV transmission.
   - As the immune system weakens over time, opportunistic infections can occur.
   - Healthy living practices can strengthen the immune system (e.g., good nutrition, exercise, rest, social support, positive attitude toward life).

5. **Discuss ART.**

   - The goals of therapy: suppress the virus and improve the immune system; it is not a cure.
   - The reasons for combination therapy.

- The importance of adherence to the medication regime.
- General side effects of ARVs and how to manage them.

6. Identify, with the patient's input, any **difficulties or potential barriers** to keeping medical appointments, taking the medications and adhering to the medications. These difficulties may be:

   - Personal: failure to disclose status; illiteracy
   - Environmental (e.g., transportation)
   - Social (support)
   - Health-related (physical or mental)
   - Related to substance use (alcohol, illicit drugs)
   - Nutritional
   - Financial

7. **Discuss interventions to overcome these difficulties or barriers.** Make referrals to care and support services as necessary.

8. Schedule an appointment for the second counseling session, to include a family member/friend to whom the patient has disclosed his/her HIV-positive status and who will agree to attend the remaining counseling sessions.

9. Complete the appointment card and give to the patient.

10. Complete the **Pre-ART Counseling Form** and file it in the patient's medical record.

STANDARD OPERATING PROCEDURES: ADHERENCE COUNSELING

SOP 104: **Pre-ART Counseling: The Second Counseling Session**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Second counseling session

1. **Review the topics** discussed during the previous counseling session:

   - HIV/AIDS
   - ART and the importance of adherence

2. Discuss the **role of social support in ART adherence**: the role of the family member/friend.

3. Discuss the **ARV treatment program**:

   - ART is not a cure.
   - ART does not prevent transmission of the virus: ongoing prevention is essential to avoid both transmitting the virus to spouse/partner and re-infection.
   - ART has benefits, risks and side effects (how to manage).
   - As part of clinical follow-up, schedule medical visits, adherence monitoring visits and laboratory investigations, including CD4 test.

4. **Review barriers to adherence:** Do they still exist? Are there new ones?

   - Personal: failure to disclose status; illiteracy
   - Environmental (e.g., transportation)
   - Social (support)
   - Health-related (physical or mental)
   - Related to substance use (alcohol, illicit drugs)
   - Nutritional
   - Financial

5. **Define interventions to overcome remaining barriers to adherence.**
6. Ask the patient if s/he has any **questions or concerns**.
7. Schedule the third counseling session and complete the appointment card.
8. Complete the **Pre-ART Counseling Form** and file it in the patient's medical record.

SOP 105: **Pre-ART Counseling: The Third Counseling Session**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Third counseling session

This session occurs after the Eligibility Committee has determined the patient's eligibility for ART, which includes completion of the two adherence counseling sessions. The patient presents to the ART Adherence Counselor after meeting with the MO and receiving the prescription for the ARV regime.

1. Review the **prescribed medication regime** with the patient; show the patient a photo of each medication using an ARV medication chart:

   - The name of each medication
   - The dose of each medication
   - The schedule of each medication: when the patient should take the drug
   - The food requirements of each medication
   - The need to take the medications together/in combination

2. Instruct the patient how to take the medications by swallowing each pill at the correct time with a beverage, preferably a glass of water.

3. Emphasize the importance of **100 percent medication adherence**. Ask the patient how s/he will remember to take each dose of the medications. Together, identify strategies that will work for this patient:

   - Role of support person: friend's reminder
   - Pill diary
   - Pill chart
   - Others: _____

4. Caution the patient not to give the medications to anyone else; **they are prescribed for her/him only**.

5. Discuss **side effects of the drugs** and how to manage them:

   - Identify side effects that usually pass in 2-6 weeks: describe how the patient can manage these side effects at home.
   - Identify side effects that need to be reported to the HCC immediately.
   - Emphasize the importance of taking the medications despite the side effects—most of them do not last and can be managed.

6. Ask the patient if s/he has any **questions or concerns** about the medications, how to take them or the possible side effects.

7. **Schedule an appointment** for the patient to return in **48-72 hours** to meet with the ART Adherence Counselor for monitoring of medication adherence and assessment of medication side effects; give the patient an appointment card.

8. **Direct the patient to the pharmacy** to obtain the medications.

9. Complete the **Pre-ART Counseling Form** and file it in the patient's medical record.

SOP 106: Adherence Monitoring After Starting ART: The First Session

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

ART counseling session 48-72 hours after starting ART

1. Has the patient had any **side effects**?

   Please check which side effects:

Symptoms	Yes	No	Symptoms	Yes	No
Cough	Yes	No	Difficulty swallowing	Yes	No
Dyspnea on exertion	Yes	No	Fat accumulations	Yes	No
Haemoptysis	Yes	No	Headaches	Yes	No
Fever/chills	Yes	No	Fatigue	Yes	No
Blood in urine	Yes	No	Myalgia	Yes	No
Jaundice	Yes	No	Paresthesia	Yes	No
Skin rash	Yes	No	Pain (site:_____)	Yes	No
Nausea	Yes	No	Dizziness	Yes	No
Vomiting	Yes	No	Insomnia	Yes	No
Diarrhea	Yes	No	Abnormal dreams	Yes	No
Abdominal discomfort	Yes	No	Anxiety/depression	Yes	No
Right quadrant pain	Yes	No	Mental changes (cognitive acuity)	Yes	No
Other: _____	Yes	No	Other: _____	Yes	No

2. **Refer to MO/RCO** if the side effect(s) is (are) not being managed at home and is (are) interfering with the patient's quality of life and medication adherence.

3. **Assess medication adherence:**

   - Discuss the patient's experience with the medications.
   - Identify any difficulties reported by the patient in taking the medications.
   - Develop strategies to manage these difficulties and achieve adherence.
   - Consider observations offered by the patient's family member/friend.

4. **Report any serious difficulties with adherence** or concerns about the patient's commitment to ART to the MO/RCO.

5. **Review each medication**: name, dose, schedule, possible side effects and how to manage them.

6. Discuss importance of **100 percent adherence to the medications**.

7. **Provide support and encouragement** and instruct the patient to report any serious adverse effects to the HCC; if these occur as an emergency, instruct the patient to immediately see the MO for assessment and management or go to the emergency room if the clinic is closed.

8. **Discuss ongoing prevention** and risks of HIV transmission while on ART**.**

9. For families where more than one member is HIV infected but only one is eligible for ART, **explain the dangers of sharing the medications** with the other infected members (for example, the spouse or child) or friends.

10. Ask the patient if s/he has any **questions or concerns**.

11. If the patient has no difficulties with medication adherence: **schedule the next counseling visit** on the same day as the patient's next visit with the MO/RCO (two weeks after starting ART).

12. If the patient is **having difficulties** taking the ARVs and is **not adhering**: discuss strategies to overcome the barriers and schedule a visit for intensive follow-up within the next 48 hours.

13. **Document the session** in the **ART Adherence Counseling Form**.

SOP 107: Adherence Monitoring After Starting ART: Ongoing Monitoring

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Continuous ART adherence counseling/monitoring

The patient will meet with the ART Adherence Counselor after the patient's medical visit according to the following schedule:

- First two months: every two weeks
- After the first two months: once a month

After a minimum of three months on therapy for an adult, and six months on therapy for a child, the patient will report to the Triage Nurse for the monthly visit. If the patient is "stable" on ART, meaning:

- Does not have side effects from the medications or has well-managed side effects; and
- Is strongly adherent with the medications, defined as not missing one ARV dose since the previous visit . . .

The Triage Nurse will complete a **rapid assessment of the patient's status** and **provide a prescription** for the next month's supply of ARVs. The patient's visit will be documented in the **Rapid Follow-Up Visit Form**.

- The patient will be referred to the MO or RCO whenever s/he reports new or intensified symptoms indicative of medication side effects or an adverse clinical event.
- The patient will be referred to the Adherence Counselor whenever medication non-adherence or difficulties taking the ARVs are assessed.
- More frequent visits will be scheduled if the patient develops symptoms or experiences difficulties adhering to the medications. Assessment notes will be included in the **Form for the Medical Follow-Up of Adult Patients on ART** and the

ART Adherence Counseling Form, which are retained in the patient's medical record.

At each visit, the ART Adherence Counselor will:

1. **Assess the patient's adherence** to the medications.

2. Identify **side effects** and refer to the MO or Registered Clinical Officer (RCO) for management, if needed.

3. Discuss with the patient **obstacles or barriers to adherence** and strategies to overcome them.

4. **Encourage the patient** to continue adhering to the medication regime.

5. Emphasize the importance of **ongoing prevention** to reduce the risk of HIV transmission or re-infection with the virus.

6. Explain the **dangers of sharing ARVs** with other HIV-infected family members or friends.

7. Answer the **patient's questions** and respond to her/his concerns.

8. **Refer the patient to care and support services** to meet her/his needs for medical care, psychosocial support, socioeconomic support or human rights/legal support.

9. Complete the **ART Adherence Counseling Form** and file it in the patient's medical record.

STANDARD OPERATING PROCEDURES: ADHERENCE COUNSELING

SOP 108: **Adherence Counseling for Children on ART**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

A. Challenges in delivering ART to children

Several factors **increase the burden of administering ARVs to children**:

1. The **dosage of ARV drugs** is prescribed based on the weight of the child. For some ARVs (e.g., Zidovudine), the dosage is related to body surface area. As the child grows, the dose of each drug must be re-calculated to assure optimal treatment.

2. **Liquid formulations** are required for infants and children who are unable to swallow tablets/capsules.

   - Not all ARVs are provided in liquid formulations.
   - Caregivers must learn how to **accurately measure** liquid formulations (for example, using a syringe).
   - Some liquid formulations have a **bitter taste** and are not palatable to children.

3. Multiple **family stressors** may impact the caregiver's ability to administer ARVs consistently to a child: the caregiver may be HIV-infected; there may be multiple HIV-infected members in the household; the family may be in poverty; substance abuse may be affecting the household.

4. Not disclosing a child's HIV infection to the child can impact medication adherence. Explaining the importance of adherence is difficult if the child does not understand why s/he is taking the medications.

- **Disclosure of HIV infection** must be linked to the developmental level and maturity of the child.
- In general, by age seven, children can understand a relationship between illness and taking medications on a regular basis. However, **each child's level of development and maturity** is the primary factor determining the appropriate time for disclosure and the child's role in taking medications.
- **As the child gets older**, s/he is able to assume a more responsible role in taking medications, and the role of the caregiver changes to more generalized supervision.

5. **Social disclosure** of HIV infection (i.e., disclosing the child's status to other people) is an individualized process related to the caregiver's and family's understanding of HIV disease and level of concern regarding stigma and discrimination. **Counseling** can assist the child, caregiver and, as appropriate, other family members with issues of social disclosure, including key developments in the child's life, such as entrance into school and sexual development.

6. Limitations in **adherence measurement** are more pronounced with children. A pill count, for example, is inappropriate when liquid formulations are used.

B. Strategies to promote adherence with children

1. **Adapting treatment to the family's routine** and, as the child grows, to the child's routine, can help achieve high levels of medication adherence.

   - For example, a twice-a-day medication schedule for a child in school can be associated with one pre-school dose in the morning and one bedtime dose in the evening.

2. When a child's ART regimen is changed, **intensive adherence counseling** helps the caregiver(s) develop confidence in administering the medications correctly. For both liquid and pill formulations, the Adherence Counselor can reinforce the caregiver's knowledge and skills by, during at least three sessions, demonstrating the administration of each medication and observing "return demonstration" by the caregiver. A review of the dose, schedule and techniques for administering each medication to the child should occur **at each follow-up clinical visit.**

3. **Regularity of the child's and caregiver's visits** to the health provider is essential for adjustment of medication dosages as the child grows and increases in weight and body area. **Adherence supporters and home care workers** can assist by reminding caregivers of the importance of regular clinical visits for the child and, when necessary, providing more intensive support (for example, taking the child to a clinical visit when the caregiver is working).

FORM B101: HIV CARE CENTER: ART PROGRAM

Pre-ART Adherence Counseling Form

Patient name: _____ Date: _____

HCC registration number: _____ Counseling session number: _____

Counselor's name and signature:_____

- Additional socio-demographic information:

  _____

  _____

- Patient/Caregiver knowledge of HIV/AIDS:
  - ❑ Strong (knows modes of transmission, prevention, signs and symptoms)
  - ❑ Basic (knows *some* modes of transmission, signs and symptoms)
  - ❑ Weak (no knowledge of modes of transmission, prevention, signs and symptoms)

HIV/AIDS information provided today:

_____

- Topics discussed:
  - ❑ What is ART?
  - ❑ What is ART medication adherence?
  - ❑ What are the primary benefits and risks of ART?
  - ❑ What is a "buddy"/adherence supporter/adherence monitor?
    A family member, friend or community member who provides support and helps the patient to remember to take the ARVs
  - ❑ Why is ongoing prevention needed on ART?
  - ❑ Why is "living positively with HIV" important?

- Patient concerns/barriers to ART:
  - ❑ Stigma (family and friends will find out)
  - ❑ Afraid of medications (side effects; "poison")
  - ❑ Doubt that medications will work
  - ❑ Will forget to take medications
  - ❑ Depressed/anxious
  - ❑ Other

- Strategies to overcome concerns/barriers to ART:
  - ❑ Disclosure to family member or friend
  - ❑ Management of side effects
  - ❑ Reminders/aides to take medications
  - ❑ Ongoing counseling
  - ❑ Other

FORM B102: HIV CARE CENTER: ART PROGRAM

Adherence Monitoring Record

Patient name:_____ Registration Number (ART): _____

Counselor's name:_____ Visit date: _____

1. Patient Adherence Report

It can be hard to always take your pills. Since your last visit, have you missed one or more doses of any of your pills?

- ❑ Yes
- ❑ No

If yes, how many doses did you miss?

- ❑ 1 – 2
- ❑ 3 – 5
- ❑ 5 – 10
- ❑ > 10

When did you last miss a dose?

- ❑ Yesterday
- ❑ Within the last three days
- ❑ Within the last week
- ❑ Within the last month

Did you miss:

- ❑ One of your pills
- ❑ Two of your pills
- ❑ All of your pills

2. Adherence Assessment Methods

	Patient verbal self-report
	Pill count: *number of pills missed*____
	Pharmacy refill records: *Are ARV refills on time?* Yes___ No___
	Patient diary
	DAART/DOTS
	Other

3. What are the reasons for not taking your pills? (Mark all that apply)

- ❑ None
- ❑ Forgot to take
- ❑ Too many pills
- ❑ Too busy to take
- ❑ Felt sick/ill
- ❑ Unable to pay
- ❑ To avoid side effect
- ❑ Ran out of pills
- ❑ Felt depressed/anxious
- ❑ Didn't want to take them
- ❑ Felt well
- ❑ Shared pills with others

4. Have you had any side effects from the pills? (Mark all that apply)

- ❑ None
- ❑ Nausea/vomiting
- ❑ Diarrhea
- ❑ Rash
- ❑ Headache
- ❑ Dizziness
- ❑ Fatigue/loss of energy
- ❑ Pain/tingling/numbness in hands or feet
- ❑ Abdominal/back pain
- ❑ Persistent muscle pain/weakness
- ❑ Chills/fever
- ❑ Insomnia
- ❑ Anxiety/depression
- ❑ Other: _____
- ❑ Other: _____

5. Suggest strategies to help adherence

- ❑ Identify reminder aide (e.g., calendar checklist; link to routine activity)
- ❑ Recommend help from family member/friend/"buddy"
- ❑ Provide support
- ❑ Schedule return visit for follow-up counseling in 72 hours
- ❑ Other: _____
- ❑ Other: _____

6. If less than 95 percent adherence: report to MO; Date reported: _____

7. Notes

_____

_____

_____

_____

_____

_____

FORM B103: HIV Comprehensive Care Center: ART Program

Adherence monitoring record

Patient name: _____ ***Registration (ART) number:*** _____

Visit date	Patient or caregiver report	Missed one or more doses	# of doses missed	When was last missed dose	# of pills missed	Adherence methods	Reasons for missing doses	Side effects experienced	Strategies suggested	Referrals to RCO, MO	Counselor initials
	1=patient report, 2=caregiver (for child) list name and relationship	1=yes, 2=no	1=1-2, 2=3-5, 3=5-10, 4=>10	1=yesterday, 2=in last 3 days, 3=in last week, 4=in last month	1=1, 2=2, 3=all	1=pt verbal report, 2=pill count, 3=diary, 4=DAART/DOTS	1=none, 2=forgot, 3=too many pills, 4=too busy, 5=felt sick, 6=payment, 7=side effects, 8= anxiety or depression, 9=didn't want to take, 10=felt well, 11=shared pills, 12=child refused	1=none, 2=nausea or vomiting, 3=diarrhea, 4=rash, 5=headache, 6=dizzy, 7=fatigue, 8=pain, ting, numb hands or feet, 9=abd/back pain, 10=muscle pain or weakness, 11=chills/fever, 12=insomnia, 13= anxiety or depression	1=reminder aide, 2=buddy, 3=provide support, 4=return visit in 72 hours	Refer if <95% adherence or SE management 1=yes, 2=no	

FORM B104: HIV CARE CENTER: ART PROGRAM

Adherence Counseling Checklist

Patient's name: _____

Counselor's name/signature: _____

First Counseling Session **Date:** _____

- ❑ Review HCC Registration Form
- ❑ Assess patient's knowledge of HIV
- ❑ Discuss ART
- ❑ Identify barriers to adherence
- ❑ Discuss strategies to overcome barriers
- ❑ Answer patient's questions
- ❑ Schedule next counseling session
- ❑ Complete appointment card
- ❑ Complete Pre-Start Counseling Form

Second Counseling Session **Date:** _____

- ❑ Review the previous session
- ❑ Discuss role of support person
- ❑ Obtain commitment to ART
- ❑ Stress that ART is not a cure
- ❑ Answer patient's questions
- ❑ Discuss ongoing prevention
- ❑ Discuss ART benefits/risks
- ❑ Develop adherence strategies
- ❑ Schedule next appointment
- ❑ Complete Pre-Start Counseling Form

Third Counseling Session **Date:** _____

- ❑ Review ART regime
- ❑ Stress 100 percent adherence
- ❑ Discuss possible side effects and how to manage them
- ❑ Explore positive living
- ❑ Answer patient's questions
- ❑ Discuss ongoing prevention
- ❑ Schedule next appointment for 48 to 72 hours
- ❑ Direct patient to pharmacy
- ❑ Complete Pre-Start Counseling Form

Ongoing Adherence Monitoring

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

- ❑ Assess for side effects
- ❑ Refer to MO as needed
- ❑ Assess med adherence
- ❑ Report adherence issues to MO
- ❑ Provide support
- ❑ Review ongoing prevention
- ❑ Instruct patient on follow-up
- ❑ Schedule next MO/counseling visit
- ❑ Complete ART Adherence Form

R101: ANTIRETROVIRAL DRUGS FOR ADULTS AND ADOLESCENTS:

Managing Side Effects

Drug Class/Drug	Dose	Side Effects for Patient Management	Side Effects for MO/RCO Management
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)			
Lamivudine (3TC, Epivir)	150 mg twice daily	*Infrequent:* ➢ Headache ➢ Nausea ➢ Insomnia	*Infrequent:* ➢ Abdominal pain
Stavudine (D4T, Zerit)	<60 kg: 30 mg twice daily >60 kg: 40 mg twice daily	*Frequent:* ➢ Mild tingling, burning or pain in hands or feet (peripheral neuropathy) *Infrequent:* ➢ Headache. ➢ Nausea/vomiting ➢ Diarrhoea ➢ Insomnia	*Infrequent:* ➢ Moderate to severe tingling, burning or pain in hands or feet (peripheral neuropathy). ➢ Moderate to severe abdominal pain (possible pancreatitis) *Long-term:* Usually multiple symptoms (possible lactic acidosis): ➢ Fatigue/weakness ➢ Nausea ➢ Vomiting ➢ Wasting ➢ Abdominal pain ➢ Dyspnea ➢ Diarrhoea ➢ Myalgias
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)			
Efavirenz (Stocrin) Do not take if pregnant	600 mg once daily at bedtime	*Frequent:* ➢ Dizziness ➢ Headache ➢ Insomnia ➢ Bad dreams ➢ Confusion ➢ Difficulty concentrating ➢ Mild rash ➢ Nausea ➢ Vomiting ➢ Anorexia ➢ Diarrhoea	*Frequent:* ➢ Prolonged CNS symptoms: dizziness, insomnia, bad dreams, confusion *Infrequent:* ➢ Severe rash associated with fever, blistering, desquamation, mucous membrane involvement

			➢ Suicidal ideation ➢ Fat deposit accumulations
Nevirapine (Viramune)	200 mg once daily for 14 days, then 200 mg twice daily	*Frequent:* ➢ Mild rash (in first 12 weeks; more frequent in women)	*Infrequent:* ➢ Severe rash associated with fever, blistering, desquamation, mucous membrane involvement ➢ Hepatotoxicity (jaundice; patient complaining of right/middle upper-quadrant abdominal pain; more frequent in first 4-12 weeks)

Suggestions for managing side effects/symptoms at home

Symptom	***Strategies to Manage***
Headache	▪ Decrease activity; rest in a quiet, dark room with eyes closed ▪ Place cold moist cloth over eyes ▪ Stay out of the sun: decrease exposure to light ▪ Stay hydrated: drink boiled water; avoid caffeine (coffee, tea, carbonated soft drinks) and alcohol ▪ Avoid foods and other stimuli that trigger headaches
Nausea/Vomiting/Anorexia	▪ Stay hydrated: drink boiled water; peppermint or ginger tea ▪ Eat small, bland snacks throughout the day (bananas, white rice, toast, applesauce, porridge, potatoes) ▪ Avoid foods and smells that trigger nausea/vomiting or decrease appetite: spicy, greasy, acidic foods (e.g., oranges, tomatoes) ▪ For nausea/vomiting: drape a comfortably warm moist towel around the neck until the nausea/vomiting subsides
Diarrhoea	▪ Stay hydrated: drink boiled water, weak tea ▪ Don't stop eating, but avoid foods and fluids that can increase diarrhoea (fruits, vegetables, milk products, high fat foods, very sweet foods) ▪ Eat bland foods: white rice, porridge ▪ Maintain good hygiene: wash hands after going to the bathroom, before and after eating, before and after handling any food ▪ *Gently* clean skin around rectal area after each episode of loose stool

Mild tingling, burning, or pain in hands or feet	▪ Wear loose-fitting shoes or sandals ▪ Walk around to help blood circulation to the feet, but not too much ▪ Soak hands/feet in coldest water tolerated ▪ Gently massage hands/feet ▪ Keep hands and feet uncovered in bed
Insomnia	▪ Reduce noise and light: sleep in a quiet, dark room ▪ Avoid exercise and other energetic activity several hours before bedtime ▪ Avoid eating a large meal 3-4 hours before bedtime ▪ Avoid drinking fluids with caffeine at least four hours before going to bed (coffee, tea, carbonated soft drinks) ▪ Avoid drinking alcohol ▪ Consciously relax muscles, especially in shoulders, arms and legs ▪ Perform quiet activities that usually make you sleepy (for example, listening to soft music)
Dizziness	▪ Change positions very slowly (for example, from lying down to sitting) ▪ Use nearby furniture and walls for support if dizziness occurs when walking ▪ Ask family members and friends for support if intense dizziness occurs when walking ▪ Stay hydrated: drink boiled water and fluids without caffeine ▪ Avoid alcohol
Bad dreams	▪ Talk about your dreams with a family member or friend ▪ Recognize that dreams are imagination and not real
Confusion/difficulty concentrating	▪ Talk about your feelings of confusion or difficulty concentrating with a family member or friend ▪ Ask a family member or friend to clarify what confuses you ▪ Focus on one activity or thought at a time
Mild rash	▪ Bathe with unscented mild soap (for example, oatmeal) ▪ Avoid bathing in extra hot water ▪ Protect the skin from sun exposure ▪ Don’t scratch your skin

ANTIRETROVIRAL THERAPY (ART) PROGRAM

STANDARD OPERATING PROCEDURES

POST-EXPOSURE PROPHYLAXIS (PEP)

PREPARED BY FAMILY HEALTH INTERNATIONAL

OCTOBER 2004

INDEX

STANDARD OPERATING PROCEDURES: POST-EXPOSURE PROPHYLAXIS

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STANDARD OPERATING PROCEDURES: POST-EXPOSURE PROPHYLAXIS

SOP 101: **Occupational Exposure: Treatment of Exposure Site**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. Objective

To describe the process for health care workers to manage contact with potentially infectious materials.

B. Procedure

Immediately following exposure:

1. **Wash the areas exposed** to potentially infectious fluids with soap and water.

2. **Flush exposed mucous membranes** with water. If saline is available, flush eyes with saline.

3. **Do not apply caustic agents**, including antiseptics or disinfectants, to the exposed areas.

SOP 102: **Occupational Exposure: Completion of Exposure Report**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. **Inform the Medical Officer (MO)** of the exposure as soon as possible.

B. **Complete the Health Facility Occupational Exposure Incident Report Form**.

1. Date and time of exposure
2. Exposure site(s)
3. Where and how the exposure occurred
4. If a sharp object was involved, type and brand of device
5. Type and amount of fluid
6. Severity of exposure (e.g., depth of sharp puncture)
7. Exposure source:
   - Infectious status
   - If HIV infected, stage of disease, viral load, history of ART
8. Counseling and post-exposure management
9. Details on exposed health care worker:
   - Existing medical status
   - Hepatitis B vaccine status

SOP 103: **Occupational Exposure: Evaluation of Exposure**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. An MO will evaluate the exposure for potential HIV transmission based on:

1. Type and amount of body fluid/tissue

- Blood
- Fluids containing blood
- Semen
- Vaginal secretions
- Cerebrospinal fluid
- Synovial fluid
- Pleural fluid
- Peritoneal fluid
- Pericardial fluid
- Amniotic fluid

2. Type of exposure

- Percutaneous injury
- Mucous membrane exposure
- Non-intact skin exposure
- Bites resulting in blood exposure

3. Infectious status of source

- Presence of HIV antibody
- Presence of HbsAG
- Presence of HCV antibody

4. **Susceptibility of exposed person**

- Hepatitis B vaccine and response status
- HIV, HBV and HCV immune status

B. The exposed health care worker will be offered **pre-HIV test counseling** based on informed consent, as well as ongoing counseling as desired.

C. The **confidentiality of the exposed health care worker** will be maintained.

SOP 104: **Occupational Exposure: Evaluation of Exposure Source**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. If the **HIV status of the source person is not known**, the source person will be informed of the incident and consent obtained to perform HIV diagnostic testing.

- Testing to determine HIV infection should be **performed as soon as possible**; a rapid HIV-antibody test is recommended.
- **Confidentiality of the source person** will be maintained at all times.
- **If the source person is HIV negative**, baseline testing or further follow-up of the exposed health care worker is not necessary.

B. **If the source person refuses to be tested for HIV**, the attending MO will contact the Senior Administrator for authorization to perform the test. (Reference: ***National Guidelines for Antiretroviral Drug Therapy***).

C. Authorization of the Senior Administrator will also be sought when **the source person is confused or in a coma**, or in the case of **a minor where a parent or guardian is not available**.

D. If the **source person is not known,** the exposure will be evaluated on the likelihood of high risk for infection: where and under what circumstances the exposure occurred.

STANDARD OPERATING PROCEDURES: POST-EXPOSURE PROPHYLAXIS

SOP 105: **Non-occupational Exposure to HIV**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. General information after sexual exposure

1. It is biologically possible for PEP medications to prevent HIV infection if taken soon after exposure.

2. There is limited evidence to suggest that prophylactic use of ARV medications is efficacious.

B. To determine whether PEP should be initiated, evaluate the act of assault.

1. Acts with a measurable risk of HIV transmission, including anal penetration, vaginal penetration and injection with a contaminated needle.

2. Acts with a possible risk of HIV trasnmission, including oral penetration with ejaculation, unknown act, contact with other mucous membrane, victim biting assailant, and assailtant with bloody mouth biting victim.

3. Acts with no risk of HIV transmission, including kissing, digital or object penetration of vagina, mouth or anus, and ejaculation on intact skin.

Additional factors to consider include the presence of blood; survivor or assailant with a sexually transmitted disease; significant trauma to the survivor; ejaculation by assailant; multiple assailants or multiple penetrations by assailant(s).

C. When PEP is appropriate, offer it to the survivor as soon as possible.

Beginning PEP more than 72 hours after exposure is not recommended.

SOP 106: **Occupational and Non-occupational Exposure: Management of Exposure to HIV**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. **Perform baseline HIV test** on the person who has the exposure using a rapid antibody test. Also recommended: full blood count, liver and renal function tests.

B. Determine if the exposure if **low risk** or **high risk** for HIV infection (see **SOP 105: Non-occupational Exposure to HIV** and **SOP 107: Selection of Drugs for PEP**).

C. **Start ARV medications within 1-2 hours of exposure** if possible. If a delay occurs, initiate PEP as soon as possible. For non-occupational exposure, starting PEP is recommended within 72 hours of exposure. For occupational exposure, there is currently no defined interval after which PEP is not effective.

D. **Administer PEP for 28 days.**

E. **Perform recommended serology** after exposure:

Two weeks	Full blood count Liver and renal function tests
Six weeks	HIV serology
Three months	HIV serology
Six months	HIV serology

F. Offer counseling to the person who has been exposed to HIV:

- Assure maintenance of **confidentiality**.

- For health care workers, instruct on **probability of infection from accidental exposure** (CDC statistics):

  - 0.3% from percutaneous injury from HIV-infected source
  - 0.03% from mucocutaneous exposure from HIV-infected source

- Instruct on **benefits and possible adverse effects of ARV prophylaxis**.

- **Counsel on prevention** with sexual partners until HIV infection has been ruled out.

SOP 107: **Occupational and Non-occupational exposure: Selecting Drugs for HIV Exposure**

Prepared by:
Date adopted:
Reviewed by:

Name/Grade	Signature	Date

A. Risk definition

1. Low risk

- Exposure to a small volume of blood or fluid contaminated with blood from asymptomatic HIV-infected patients with low viral load.
- Percutaneous exposure with a solid needle.
- Any superficial injury or mucocutaneous exposure.

2. High risk

- Exposure to a large volume of blood or potentially infectious fluids.
- Exposure to blood or blood-contaminated fluids from an HIV-infected patient with a high viral load.
- Injury with a hollow needle.
- Deep and extensive injuries.
- Confirmed ARV drug resistance in the source patient.

B. Regimen for risk category:

Risk category	ARV Prophylaxis
Low	Zidovudine (AZT) 300 mg twice a day X 28 days Lamivudine (3TC) 150 mg twice a day X 28 days *(NOTE: Regimen may be dispensed as Combivir 1 tab twice a day)* **Option to Zidovudine or Lamivudine: Stavudine 30mg/40mg BID**
High	Zidovudine (AZT) 300 mg twice a day X 28 days Lamivudine (3TC) 150 mg twice a day X 28 days Efavirenz (EFV) 600 mg QD **Option to Efavirenz: Nelfinavir 1250 mg BID** *(NOTE: Combivir 1 tab twice a day may replace Zidovudine + Lamivudine)*

Nevirapine is NOT recommended for PEP.

C. Toxicity of ARVs

1. Adverse symptoms with ARVs, such as headache, nausea and diarrhea, are common.

2. Management without changing the PEP regimen is recommended (e.g., prescribing analgesic, antimotility or antiemetic agents).

3. Please refer to the health facility's SOPs on adverse drug reactions for reporting toxicities.

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