STANDARD OPERATING PROCEDURES FOR ANTIRETROVIRAL THERAPY

FAMILY HEALTH INTERNATIONAL

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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, post-exposure prophylaxis (PEP) and standard precautions for the outpatient setting.

Leine Stuart, PhD, ACRN, wrote the SOPs in collaboration with other FHI staff members. Special thanks are extended to Ya Diul Mukadi, MD, MPH, Kisten Nolan, MPH, RN, BSN, 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.

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ACRONYMS

AIDS Acquired immunodeficiency syndrome

ART Antiretroviral therapy

ARV Antiretroviral

CDC U.S. Centers for Disease Control and Prevention

CSF Cerebral spinal fluid

FHI Family Health International

HAART Highly active antiretroviral therapy

HBC Home-based care

HIV Human immunodeficiency virus

IEC Information, education and communication

IV Intravenous

LFT Liver function test MO Medical officer MOH Ministry of Health

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
PEP Post-exposure prophylaxis

PI Protease inhibitor

PLHA Persons living with HIV/AIDS

PMTCT Prevention of mother-to-child transmission

RCO Registered clinical officer

SARS Severe acute respiratory syndrome SOP Standard operating procedure STI Sexually transmitted infection

TB Tuberculosis

TLC Total lymphocyte count

USAID U.S. Agency for International Development

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
- Counselors
- Health facility management
- Receptionists
- Maintenance 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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SOP 1	01:	New Patient Registratio	n
Date a	red by: dopted: wed 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

- 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 1	.04:	Determining Eligibility	
Date a	red by: adopted: wed 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. <u>Occupational exposure</u>: 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. <u>Non-occupational exposure</u>: 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 1	05:	Pre-ART Counseling	
Date a	red by: adopted: wed 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 pretreatment 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 1	106:	The Eligibilit	y and Quality Review Committee	
Date a	ared by: adopted: wed 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.

SOP 1	08:	ARV Drug Regimens	
Date a	red by: dopted: wed by:		
	Name/Grade	Signature	Date
Nation provide		bed in combination therapy in accordance well Drug Therapy. The following medication re	
Α.	Adults and adolescents:	D4T (Stavudine) + 3TC (Lamivudine) + E	Foxironz
	Adults and adolescents.	600 mg/day	navirenz
	Pregnant women or women likely to become pregnant:	D4T (Stavudine) + 3TC (Lamivudine) + N	Vevirapine
	Patients with TB: Eligible to begin ART after the intensive phase of TB treatment has been completed. The preferred regimen is:		Efavirenz
В.	Second line	ooo mg aay	
	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	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 1	12:	Record Ke	eping		
Date a	red by: dopted: wed by:				
	Name/Grade	Sign	nature	1	Date

Procedures

- A. Each patient will have a **medical record on file** at the HCC. For patients with a preexisting 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 1	113:	Health Facility Referral Management		
Date a	red by: adopted: wed 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 1	14:	Community Care and Referral Management		
Date a	red by: adopted: wed 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.

STANDARD OPERATING PROCEDURES: ANTIRETROVIRAL THERAPY FOR ADULTS AND ADOLESCENTS

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:

				PATIE	NT IDE	NTIFI	CATION:					
Patient nam	ıe:						Re	gistration nu	ımber:			
Residential												
P O Box:												
Telephone i	number: I	Home_			Wor	rk		Cell				
Date of birth	າ:					A	ge:	G	ender: 🗆 N	/lale	□ Fem	ale
Marital status: □ Married □ Single □ Divorced □ Separated □ Widow(er)												
Primary lang	guage: _											
Occupation								n leave 🛚	Unemploye	ed		
If child:												
Are parer	nts living?	? Yes_	No	If ye	es, nam	nes:						
With who	m does t	he child	d live?									
Name:					Relatio	nship	·					
In school	: Yes	No_	If y	es, school	name:				(Grad	e:	
Dependent	children/	siblings	s in home	e :								
Name		Age	Gender	Name		Age	Gender	Name	Α	ge	Gende	: r
1.				3.				5.				
2.				4.				6.				
				EMER	RGENC	Y CO	NTACT:					
Name:							Relationsh	nin [.]				
Home addre								"P				
P O Box:												
Telephone												
1 diaprioria							MATION:					
Name of ref	errina en	ter:										
Type of fac □Antenatal □ Walk-in \	cility: [Govei Private		□ Private h	ospital/ □ Per	nursir nal sys	stem 🗆 S	enter □ N Diagnostic ub. abuse s			pital PMTCT -referra	
Funding ty	ne: □ Pa	itient oi	ıt of nock	ret ⊓ Me		DING:	ce: Type:		□ 5	Speci	ial proje	-ct
□ Employee	sponsor	ed: Em	ployer: _		_ Oth			□ Waiver (iai proje)
Change of		4				1		T		ı		7
Date	From	То		Date	From		То	Date	From	То		

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 efter clinical decumentation completed.
 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=homebased 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 vi	sit:	Date:
_ _ _	Determine reason for visit Obtain and record socio-economic data Obtain and record vital signs and weight Direct patient to MO	
Second	l visit:	Date:
_ _ _	Collect appointment card and medical reco Record presenting symptoms Obtain and record vital signs and weight Direct patient to MO	ord
Third v	isit:	Date:
0	Collect appointment card and medical reco Record presenting symptoms Obtain vital signs and weight Refer to MO as needed Direct to ART Nurse if MO consult not indic	
Ongoin	g 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

Client Name: Client Registration Number:								
Date of Birth:/ [Date of HIV+		est: (HIV I HIV II Both HIV I & HIV II_					
		MED	CATIONS					
Current Medications:								
OI Prophylaxis: Cotrimoxazole? You	es No)	INH? Yes No					
For other conditions: Medication na	ame:		Medication name:					
Past ARV experience: Yes N	No If Ye	s, list dru	ugs and dates	9.1				
Drug		Dura	tion (taken from what date to what date)				
Drug		Dura	ation (taken from what date to what date	e)				
			ation (taken from what date to what date					
Drug Allergies:					a k c			
Women Only:								
Rahy treated? Vec No	If t							
Baby treated? Yes No			:/(use dd/mm/yy) /SICAL EXAM FINDINGS					
<u>HI</u>	STORY AN	ND PHY		n, progress	sion,			
Presenting Problem (in patient's treatment and response):	STORY AN	ND PHY	(SICAL EXAM FINDINGS ory of chief complaint(s) (onset, duration tom screen					
Presenting Problem (in patient's treatment and response): Condition	STORY AN	ND PHY	ry of chief complaint(s) (onset, duration of chief complaint) tom screen Other Acute/Chronic Conditions	n, progress	No			
Presenting Problem (in patient's treatment and response): Condition Jaundice	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension					
Presenting Problem (in patient's treatment and response): Condition Jaundice Chronic cough	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension Asthma					
Presenting Problem (in patient's treatment and response): Condition Jaundice	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension					
Presenting Problem (in patient's treatment and response): Condition Jaundice Chronic cough Difficulty swallowing	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension Asthma Heart Disease					
Presenting Problem (in patient's treatment and response): Condition Jaundice Chronic cough Difficulty swallowing Skin rash, itching	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension Asthma Heart Disease Hepatitis					
Presenting Problem (in patient's treatment and response): Condition Jaundice Chronic cough Difficulty swallowing Skin rash, itching Chills	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension Asthma Heart Disease Hepatitis Diabetes Malaria					
Presenting Problem (in patient's treatment and response): Condition Jaundice Chronic cough Difficulty swallowing Skin rash, itching Chills Sexually transmitted infections	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension Asthma Heart Disease Hepatitis Diabetes					
Condition Jaundice Chronic cough Difficulty swallowing Skin rash, itching Chills Sexually transmitted infections Persistent headaches	STORY AN	ND PHY	tom screen Other Acute/Chronic Conditions Hypertension Asthma Heart Disease Hepatitis Diabetes Malaria Other:					

FHI 1 Revised: 7/14/2004

Women only: Pregnant: \	Yes No F	Possibly Prea	nant?: Yes	No			
Habits:		, 9					
Smoking: Yes No_	If Yes: Type	9	# /day or wee	k Dura	tion: #/vr	s	
Alcohol: Yes No_	If Yes (Che	ck one): Eve	ry day ≥	Once weekly	≥ On	ce month	nly
LINV Discounting and allegat		-man Dinala	and Nat	disalassal			
HIV Diagnosis and client If disclosed: Disclosed to: F					oortive_	Not Sup	portive_)
Sources of emotional su	pport: Family	Friends	Other	If other specify:_			
		1071	010110				
		VIIA	L SIGNS:				
Height (cm): We	eight (kg):	Temp	(C°):	Pulse (bpm):		B/P: _	
		Physi	cal Exam				
General description of par	tiont procentatio	THE RESERVE OF THE PARTY OF THE	Africa and September 1974				
			al Findings		-		
General Appearance	Present	Absent			Preser	nt	Absent
Pallor			Hepatome				
Febrile			Splenome				
Dehydrated			Tendernes			180	
Jaundiced			Distention				
Peripheral edema			Other findi	ngs			
Other findings			Skin	- I - D 1'1' -			
Lymphatic System				olar Dermatitis			_
Lymphadenopathy			Abscesses				-
Oral		/ %	Herpetic le zoster)	sions (e.g.			
Oral hairy leukoplakia			Kaposi's le	eione			1
Oral thrush			Seborrheic				100
Oral lesions	-		Fungal infe				+
Other findings	-		Other finding				
Respiratory			Neurologica		Abnor	mal	Normal
Rate:				to person, time,			
, 1810			place				
Labored breathing			Speech				
Cyanosis	9		Neck stiffne				
Wheezing				one/both eyes	12.00	150,15	
Intercostal recession/				/paresis (R or L		4	12 -
subcostal recession	1/2		or both)				The state of
Auscultation findings:				of extremities			
Other findings			Other Find		-		Lar
Cardiac	Abnormal	Normal	Mental Statu		Prese	nt	Absent
Heart rate and rhythm			Slow men	Name and Address of the Owner o			
Auscultation findings			Memory lo	oss			
(include murmurs)	Droport	Abcont	Monday	200			
Breasts	Present	Absent	Mood swi				-
Lumps, masses			Depression	Л		0	-
Discharge Genitalia			Suicidal id	leation			
Vaginal/urethral discharge	0		Other finding				
Genital ulcer, other lesion			Julei illiumg	3.			
Inquinal node	1						
enlargement							

FHI 2 Revised: 7/14/2004

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 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

Other diagnostic findings:					
□ Malaria	STI Other	Other			

ARV ELI	GIBILITY	CRITER	RIA
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			

FHI 3 Revised: 7/14/2004

	PLAN
1.	Ol Prophylaxis:
	Cotrimoxazole: Start Continue 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(2)
7.	Next scheduled appointment://(dd/mm/yy)
Me	dical Officer/Physician's Name: Signature:

Revised: 7/14/2004

FHI

HIV CARE CENTER: ART PROGRAM **FORM A106:**

ADULT FOLLOW-UP VISIT FORM

Clinical Care/AF	RT	ADULT FOLLOW-UP VISIT FORM					
Health Facility Name:				Date:			
				stration Number:			
Client Name:	1			am Number:			
Scheduled Visit? Yes Unscheduled/Sickness visit?	No If	yes, did patie	nt come on the	date of appt.? Yes	No	2 25	
Client on ART? Yes	No	If Not	, do not comp	lete ART sections			
Client on CTX prophylaxis	? Yes No	Cli	ent on TB prop	hylaxis? Yes	No		
DATIENT	COMPLAINT	C. /Form	ationto on	ART anks) Charles	II that apply		
ratient Chief Complaint (in			allerits on 7	ART only) Check a	п тат арргу:		
Symptoms		Sympton	ns		nptoms		
Cough	Lipody	strophy/lipoa	rophy/lipoatrophy Pain (Site:				
Dyspnea on exertion	Nause	a		Headache			
Haemoptysis	Vomiti	ng		Dizziness			
Difficulty swallowing	Diarrh				Insomnia		
Skin rash	Abdon	Abdominal discomfort Abnormal dre			ams		
Fever/chills		R quadrant pain Anxiety/Depr					
55 455 × 5		ia/Arthralgia			s (cognitive acuity)		
Blood in urine					s (cognitive acuity		
Fatigue	Pares	inesia	VITAL SI	Other:		TO A STATE OF THE PARTY OF THE	
Weight (kg):			Pulse (B/P:/_		
		PHYSICAL	EXAM FINI	DINGS			
General description of pa	atient presentat		ysical Exam:				
System	Abnormal	Normal	System		Abnormal	Normal	
General Appearance	Abilomiai	Herman	Genitalia				
Lymphatic System			Gastrointes	tinal			
Oral		The state of	Skin				
Respiratory			Neurologica	al			
Cardiac			Mental Status				
Breasts							
Note any abnormal findi	ngs:		191				
Women only: Pregnant:	Yes No		gnant?: Yes_	No_			
la matient approally anti				ASSESSMENT:			
Is patient sexually active?				destions below Adherence Counseld	or for prevention	counseli	
Disclosure to sexual partners Regular condom use:				Adherence Counseld			
riogaiur ooriaoiri aoo.							

FHI

Revised: 7/14/2004

ADHERENO	E for CTX, INH and	ARVs: last 3 day	s before t	his visit	
	0 pill missed	1-2 pills missed	3-4 pills	missed	5 > pills missed
CTX (self-reported)			1000		
INH (self-reported)					
ARVs (self-reported)					
	Patient reason for	or missing doses: (c	heck all tha	t apply)	
Unable to pay	Too many pills	Too busy to take	9	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/a	anxious	None	

WHO Stage 1	WHO Stage 4	
Asymptomatic HIV infection	Candidiasis (Esophageal, Bronchi, Tracea, Lungs)	Sept.
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	
Jnexplained Chronic Diarrhea (> 1 month)	Tuberculosis, Extrapulmonary	
Jnexplained 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 Stag	e II 🔃 WHO Stage III 📋 WHO Stage IV	

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 O	N ART: S	kip if patient is n	ot on AH I				
	ADVERSE CL	INICAL E	VENTS: Check al	Il that apply				
uberculosis (pu	ılmonary)		Herpes zos					
neumonia	annona, y	200		Kaposi's sarcoma				
	L didicate						ryptococcal meningitis	
ral/esophagea				armeningus				
Chronic diarrhe			Malaria					
Veight loss afte	er starting ART		Immune Re	econstitution Syndr	ome			
STI			Other:					
	ADVERSE DRUG SY	MPTOMS	REACTIONS:	Check all that app	oly			
Anemia			ness/tingling in	Lipodystrop				
Rash		Hepatotoxio	city	Depression	1			
Sec. M. Sec. Market	10	Blood in uri						
Diarrhea> 3 day				/Complete	ADD Form			
Pancreatitis	nt Failure: Yes No	Not dete	g reaction:	(Complete	a ADN FOITH)			
f Ves indicate	which type: (Refer to National	al Guideline	s for Antiretrovira	I Drug Therapy for	r definition)			
	noxazole: Start Contin	nue D	Discontinue S	Start at a later date Start at a later date				
Cotrin INH: 2. Hosp	noxazole: Start Contin Start Contin Dital Admission: Yes	No	Discontinue	Start at a later date	_			
Cotrin INH: 2. Hosp 3. Orde	noxazole: Start Contin Start Contin Dital Admission: Yes	No C	Pregnancy Test:	Start at a later date Yes No	_			
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Other drugs prescribed:	1		2		
1. Adherence Counselor 2. Other: 3. Other:	: Yes No	0	-		
Next scheduled appointmen	it:/_	/ (use do	d/ mm/ yy)		
edical Officer/Physician	n's Name:			Signature:	

Revised 7/14/2004 4

FORM A107: HIV CARE CENTER: ART PROGRAM

MO/RCO Checklist

Patient's	name:			
First visit	<u>:</u>	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			Compile and submit patient file to Eligibility Subcommittee
_ 	If eligible for ART: discuss eligibility Complete ARV enrolment form			If not eligible for ART: discuss reasons
	Refer to ART Nurse for counseling			
	Refer to laboratory for additional tests		_	
Third vi	sit:	Date: _		
<u> </u>	Assess and treat symptoms as needed Review investigational results Counsel on ARV regime and adherence		<u> </u>	Complete ARV enrolment form Instruct patient to return in two weeks
_	Provide a written schedule of medications		<u> </u>	Issue prescription for ARVs Direct patient to ART Nurse
Ongoing	g visits:			
	□ Assess for adverse drug effects			 Instruct to return in two weeks (first two months), then
	 Manage adverse drug reactions as needed 			monthly, or as needed
	□ Stress importance of med adherence			 Report adverse drug reactions to pharmacy

FORM A108: HIV CARE CENTER: ART PROGRAM

Eligibility Committee Review Form

Patient name: _	F	Registration number	
Date: _			
Eligibility criteria	a:	Yes	No
Clinical and bio	logical criteria:		
1. HIV test pos	itive		
2. WHO clinica a. Stage II	I: Weight loss >10% Chronic diarrhea > 1 month Unexplained fever> 1 month Oral/pharyngeal candidiasis Oral hairy leukoplakia Pulmonary tuberculosis in last year Other pneumonias /: Esophageal candidiasis Mucotaneous herpes > 1 month Toxoplasmosis Cryptococcal meningitis Extrapulmonary tuberculosis		
	Cytomegalovirus (CMV) Cryptosporidosis with diarrhoea Disseminated mycosis Kaposi's Sarcoma Lymphoma		
	ount 200 or less		
	ntensive phase of TB therapy		
Social and other	er criteria:		
1. Residen	t in catchment area		
2. Attende	d pre-start counseling sessions (two se	ssions)	
3. Health v	vorker or partner		
Eligible for AR\	/s:		
Signatures:			1

FORM A109: HIV CARE CENTER: ART PROGRAM

Pre-ART Adherence Counseling Form

Patient	nt name:	Date:
HCC re	registration number: Couns	seling session number:
>	Additional socio-demographic information:	
>	□ Strong (knows modes of tr □ Basic (knows <u>some</u> modes	ransmission, prevention, signs and symptoms) s of transmission, signs and symptoms) odes of transmission, prevention, signs and
	HIV/AIDS information provided today:	
>	□ What is ART?□ What is ART medication adhe□ What are the primary benefits	and risks of ART? ember or friend to provide support eded when on ART?
>	Patient concerns/barriers to ART: Stigma (family and friends will Afraid of medications (side effection) Doubt that medications will wo Will forget to take medications Depressed/anxious Other	ects; "poison") rk
>	Strategies to overcome concerns/barriers to Disclosure to family member of Management of side effects Reminders/aided to take medi Ongoing counseling Other	r friend
>	Notes:	

FORM A110: HIV CARE CENTER: ART PROGRAM

ART Adherence Counseling Form

Patient name: H			HCC r	HCC registration number:		
Counselor nam	ie:		V	isit date:		
1. <u>Patient</u>	: adher	ence report:				
How many AR\	-	do you take ead Three Four Five Six	h day?			
It can be hard t any doses of yo			ls. During the last thr	ee days before this v	isit, did you miss	
	0 pil	l missed	1-2 pills missed	3-4 pills missed	5 > pills missed	
When was the	last do	se you missed? Today Yesterday Two days ago				
Did you miss:	<u> </u>	One of your p Two of your p All of your pill:	ills			
2. What a	re the	reasons for not	taking your pills? (M	fark all that apply)		
		None Unable to pay Felt well Forgot to take Too many pills To avoid side Ran out of pill Too busy to ta Felt sick/ill Felt depresse Didn't want to	s s effects s ake d/anxious			

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	•		a galandar abaşıklist: li	nk to routing	. ootivit	٨
				.g., calendar checklist; li amily member/friend/"bu		activity	y)
		ide support			,		
				follow-up counseling in 7			
	□ Othe	er:					
	□ Othe	r:					
5.	□ Takes t □ Takes f □ Takes f	three pills per d four pills per da five pills per da	day ar ay and ay and	rt to MO; date reported: nd missed one in three da i missed one in three da i missed one in three da missed one in three day	ays = 89 per ys = 92 perc ys = 93 perc	ent ent	
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:	□ 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
Date:	
Date:	

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

Results of Laboratory Investigations	Patie	nt Name:						CCC/AI	RT#:	
Laboratory Test:	Date									
Haematology			1	T T			T	T		T
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⁾										1
LYMPH % (25 - 50 %)										
CD4+ T cells absolute count (518 – 1981 cells/µL)										
CD8 +T Cells absolute count (270 - 1335 cells/ I)										1
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⁾										1
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)										+
y-GT (8 – 46 IU/L)										
ALK PHOS (80 – 316 IU/L)(M) (64 – 306 IU/L) (F)				-						-
Total Bilirubin (< 17 μmol/dL)										
Direct Billrubin (< 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 mmoVL)									2	
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 mmoVL)										
HDL (<4.9 mmol/L)										
Triglycerides (0.11 - 2.15 mmol/L)					J. Takasa				THE STATE OF	
Others										
Glucose (3.0 - 6.1 mmoVL)										
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









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SOP 101:	Introduction to Adherence Counselin	g
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.

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.

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.

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/Grad	le	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 Monito	oring After Starting ART: 1	The First Session
Prepared by: Date adopted: Reviewed by:			
Name/Gr	ade	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.
- 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:	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 Co	unseling 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

Pa	tien	t name:	Date:
HCC registration number: Counseling session number:		Counseling session number:	
Co	uns	selor's name and signature:	
>	Ac	dditional socio-demographic info	rmation:
>	Pa	Basic (knows some modes of tr	V/AIDS: nission, prevention, signs and symptoms) ansmission, signs and symptoms) of transmission, prevention, signs and
HI	V/A	AIDS information provided today	:
>		what is ART? What is ART medication adhers what are the primary benefits a What is a "buddy"/adherence so A family member, friend or corthe patient to remember to take Why is ongoing prevention nee Why is "living positively with I	and risks of ART? apporter/adherence monitor? ammunity member who provides support and helps the ARVs ded on ART?
>		stient concerns/barriers to ART: Stigma (family and friends will Afraid of medications (side effer Doubt that medications will wo Will forget to take medications Depressed/anxious Other	ects; "poison") ork
>	Str	rategies to overcome concerns/bath Disclosure to family member of Management of side effects Reminders/aides to take medicate Ongoing counseling Other	r friend

FORM B102: HIV CARE CENTER: ART PROGRAM

Adherence Monitoring Record

Patient name:		Registration Number (ART):
Counselor's name:_		Visit date:
1. Patient Adhero	ence Report	
It can be hard to alv		ur last visit, have you missed one or
	Yes	
	No	
If yes, how many d	oses 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 Ass	sessment Methods	
Patie	ent verbal self-report	
- 1	count: number of pills missed_	
	ount. 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 y	your pil	is? (Mark all that apply)
	□ None		To avoid side effect
	□ Forgot to take		Ran out of pills
	□ Too many pills		Felt depressed/anxious
	□ Too busy to take		Didn't want to take them
	□ Felt sick/ill		Felt well
	□ Unable to pay		Shared pills with others
4.	Have you had any side effects from the	he pills?	(Mark all that apply)
	□ None		Abdominal/back pain
	□ Nausea/vomiting		Persistent muscle pain/weakness
	Diarrhea		Chills/fever
	□ Rash		Insomnia
	□ Headache		Anxiety/depression
	Dizziness		Other:
	□ Fatigue/loss of energy		Other:
	 Pain/tingling/numbness in hands or 		
5.	Suggest strategies to help adherence		
	•	e (e.g., c	alendar checklist; link to routine
	activity)	fo:1.	y ma a mah a m/fui ana d/22hay d day22
	•	m rammy	member/friend/"buddy"
	□ Provide support	for follo	vy vy sovenseline in 72 hoves
	□ Schedule return visit	ior iolio	w-up counseling in 72 hours
	□ Other:		
	Other:		
6.	If less than 95 percent adherence: re	eport to	MO; Date reported:
7.	Notes		

FORM B103: HIV Comprehensive Care Center: ART Program

Adherence monitoring record

Patient name:	Registration (ART) number:
1 uten name	Registration (ARI) 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:	□ Assess for side effects
Date:	Refer to MO as neededAssess med adherenceReport adherence issues to MO
Date:	Provide supportReview ongoing preventionInstruct patient on follow-up
Date:	Schedule next MO/counseling visitComplete ART Adherence Form

R101: ANTIRETROVIRAL DRUGS FOR ADULTS AND ADOLESCENTS:

Managing Side Effects

Drug Class/Drug	Dose	Side Effects for Patient	Side Effects for MO/RCO
		Management	Management
Nucleoside Reverse	Transcriptase Inl	hibitors (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 Re	verse Transcriptas	se 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 ideationFat deposit accumulations
Nevirapine	200 mg once	Frequent:	<u>Infrequent:</u>
(Viramune)	daily for 14	Mild rash (in first	Severe rash
	days,	12 weeks; more	associated with
	then 200 mg	frequent in women)	fever, blistering,
	twice daily		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	 Wear loose-fitting shoes or sandals
pain in hands or feet	 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	 Talk about your feelings of confusion or difficulty
concentrating	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









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SOP 101:	Occupational Expos	sure: Treatment of Exposure Site	
Prepared by: Date adopted: Reviewed by:			
Name/Gr	ade	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/Grad	e	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.

SOP 105:	Non-occupational E	Non-occupational Exposure to HIV		
Prepared by: Date adopted: Reviewed by:				
Name/Grad	de	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 assailant 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.

ANTIRETROVIRAL THERAPY (ART) PROGRAM

STANDARD OPERATING PROCEDURES

STANDARD PRECAUTIONS FOR THE OUTPATIENT SETTING

PREPARED BY FAMILY HEALTH INTERNATIONAL

AUGUST 2005









INDEX

STANDARD OPERATING PROCEDURES: STANDARD PRECAUTIONS FOR THE OUTPATIENT SETTING

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STANDARD OPERATING PROCEDURES: STANDARD PRECAUTIONS FOR OUTPATIENT SETTINGS

A. Overall objective

• To describe the process for health care workers to reduce the risk of transmitting bloodborne and other pathogens through minimizing exposure to blood and body fluids.

B. Specific objectives

- To provide clinical staff with operational information to perform the elements of standard precautions in the health facility setting.
- To serve as a training guide to prepare new staff on standard precautions and reinforce standards for existing staff needing additional training.
- To serve as a quality assurance tool for health facility management to monitor and evaluate that clinical performance of standard precautions is consistent and in accordance with health facility standards, national guidelines and other stakeholders requirements.
- To ensure that standard precaution procedures comply with health facility standards, national guidelines and other stakeholders requirements.

C. Occupational exposure

These SOPs were written to help prevent disease transmission. If during the course of clinical care or health facility maintenance, a health worker is occupationally exposed to blood and/or body fluid/s (containing blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid or amniotic fluid) through a percutaneous, mucous membrane, non-intact skin or bite, refer to *FHI Standard Operating Procedures for Post-Exposure Prophylaxis (PEP)* to determine next steps.

STANDARD OPERATING PROCEDURES: STANDARD PRECAUTIONS FOR OUTPATIENT SETTINGS

SOP 101:	Hand Hygiene	
Prepared by: Date adopted: Reviewed by:		
Name/Grade	Signature	Date

Procedures: hand hygiene

A. Wash hands to reduce contamination with microorganisms, regardless of exposure to blood, body fluids, secretions and/or excretions.¹

1. When to wash hands

- Wash hands before any patient contact.
- Wash hands after handling any blood, body fluids, liquid or solid waste with soap.²
- Use an antimicrobial agent (waterless antiseptic or alcohol, 70 percent, hand rub) for hygienic hand cleansing.
- Wash hands immediately after each patient encounter.

Figure 1

- If the same patient needs more than one task requiring gloves, such as phlebotomy and a rectal exam, wash hands and change gloves between tasks.
- Wash hands immediately after removing gloves and before touching anything else.³

¹ Body fluids, excretions and/or secretions include cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, breast milk, amniotic fluid, vaginal fluids, saliva, drainage from wounds, urine, feces, vomitus, semen and nasal secretions.

² See SOP 101.A.2. for procedure.

³ See SOP 101.A.2. for procedure.

2. How to wash hands

- Roll up sleeves, removing jewelry and watches.
- Keep nails short and clean.
- Wet hands with continuous and free-flowing water.
- Rub hands together vigorously with soap and lather well, including web spaces between fingers, for a minimum of 15 seconds.
- Do not splash clothing or the floor.
- Rinse both hands carefully under free-flowing water, with hands held down to rinse.
- Pat hands dry with a clean paper towel (preferred) or clean cloth towel (only if clean paper towel is unavailable).
- If the water is from a faucet, turn the faucet off with the paper or cloth towel.
- Dispose paper towel in general medical waste and cloth towel in laundry.

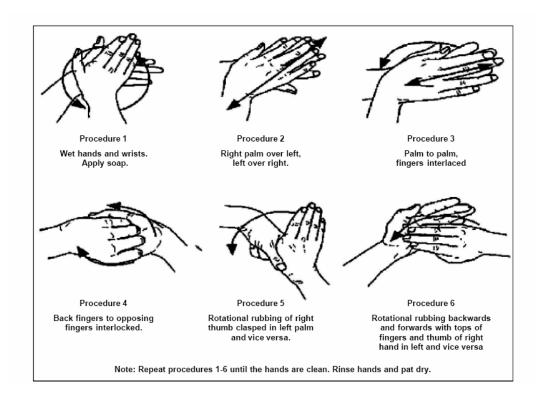


Figure 2

STANDARD OPERATING PROCEDURES: STANDARD PRECAUTIONS FOR OUTPATIENT SETTINGS

SOP 102:	Personal Protective Equip	pment
Prepared by: Date adopted: Reviewed by:		
Name/Grade	Signature	Date

Procedures: personal protective equipment

A. Use gloves, caps, masks, gowns, aprons, protective eyewear and other personal protective equipment for direct contact with blood or other body fluids.

1. When to wear gloves

- Use a new pair of gloves for each patient when contact with blood, body fluid(s), secretion and/or excretion(s) might occur during patient care.⁴
- Wash hands and change gloves between tasks if doing more than one thing needing gloves on the same patient (for example, drawing blood and performing a rectal exam).
- Always change gloves when they become visibly contaminated.
- Use a new pair of gloves for each new patient and task (for example, drawing blood, fingersticks, heelsticks, putting in an intravenous access device, training others on how to draw blood).
- Put on a new pair of gloves before drawing blood on each patient, even if the patients are family members or well-known patients.

-

⁴ Gloves do not need to be worn when feeding patients or wiping saliva from the skin.

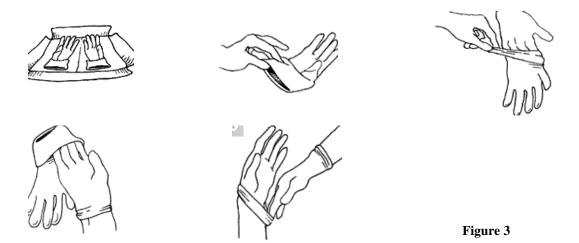
- Use a new pair of gloves for exams or procedures involving contact with non-intact skin and/or mucous membranes (for example, examining the inside of the mouth).
- Avoid direct patient contact and contact with contaminated equipment if you have open or weeping lesions or cuts on the hands.

2. How to apply gloves

- Select gloves that fit the caregiver's hand size.
- Check gloves for punctures prior to use and throw away gloves with visible holes or punctures.
- Place fingers into glove holding the glove at the cuff.
- Pull the glove's cuff all the way to the wrist.

3. How to remove gloves

- Remove gloves before other protective equipment (gowns and masks).
- Hold the cuff with one hand while easing out fingers, turning the glove inside out during the process. Repeat process to remove the second glove.
- Discard gloves in an appropriate container; avoid hand contamination by handling the inside part of the glove.
- Wash hands with soap and free-flowing water immediately after removing gloves and before touching anything else.
- Do not wash, disinfect or prepare gloves for reuse. **Do not reuse exam glove**.



4. When to wear a cap

- Wear a cap when splashes of blood, body fluid, secretions and/or excretions might touch the hair.
- Wear a new cap for each possible exposure to blood and/or body fluid.

Figure 4

5. How to apply and remove a cap

- Place cap on head; cover hair completely.
- Discard the cap in an appropriate container.
- After removing the cap wash hands with soap and free-flowing water.

6. When to wear a standard surgical splash-proof mask

• Wear a mask of this type to cover the nose and mouth when splashes or sprays of blood, body fluids, secretions and/or excretions might happen.⁵

7. How to apply a mask

- Wash hands with soap and free-flowing water and dry.
- Place and fit new mask securely on face covering the nose and mouth.
- If wearing glasses, ensure that upper edge of mask fits underneath glasses.
- Wash hands after the procedure/exam with soap and free flowing water.

8. How to remove a mask

- Remove mask using only the strings.
- Discard mask in an appropriate container.
- Wash hands after removing cap and before touching anything else.

⁵ Masks are also worn when patients have communicable diseases spread by droplets (tuberculosis). Many sources detail droplet precautions and other transmission-based precautions; see CDC and WHO guidelines respectively: http://www.cdc.gov/ncidod/hip/isoguide.htm, http://www.wpro.who.int/sars/docs/practicalguidelines/dec2004/Final_guidelines_Dec2004.pdf

9. When to wear a gown

- Wear a gown to cover the body when splashes of blood, body fluid, secretions and/or excretions are expected during patient care.
- Use clean, cotton gowns with a plastic apron underneath only if disposable gowns are not available.

10. How to apply a gown

- Wash hands with soap and free-flowing water and dry.
- Slide arms and hands inside the sleeves.
- Fasten ties at neck and waistband.

11. How to remove a gown

- Remove gown after removing gloves. Avoid contact outside of the gown.
- Turn gown inside out and discard in an appropriate container.



Figure 5

• Wash hands immediately after removal and before touching anything else.

12. How to clean a gown

- Machine-wash (or steam sterilization) reusable gowns using soap and hot water, followed by a clean water rinse.
- Use personal protective equipment when washing dirty items by hand if a washing machine is not available.
- Dry the gown in the sun or in a clothes drier, if available.
- Be careful of repeated washing of reusable gowns, which may breakdown the fabric and eventually reduce the gown's barrier strength.

13. When to use disposable, water-repellant aprons

- Use an apron of this type to cover the body when splashes of blood, body fluids, secretions and/or excretions are expected.
- Use reusable, plastic aprons only when disposable aprons are not available.

14. How to apply an apron

- Wash hands with soap and free-flowing water, and then dry.
- **Apply the apron** over uniform and tie around waist in the back.

15. How to remove an apron

- **Remove the apron**, avoiding contact with the outside of the apron:
- Turn the apron inside out and throw away in an appropriate container.
- Wash hands immediately and before touching anything else.

16. How to clean a reusable, plastic apron

• Wash with soap and water after each patient encounter.

17. What is protective eyewear?

- Disposable goggles.
- Face shields.

(Note: Providers' glasses do *not* provide sufficient protection.)

18. When to wear protective eyewear

• Wear protective eyewear when splashes of blood, body fluid, secretions and/or excretions onto caregiver's face and eyes may occur.

19. How to apply and remove protective eyewear

- Place goggles over the bridge of the nose and over the mask.
- Place goggles over prescription glasses.
- Remove goggles and discard or place in an appropriate container for decontamination.

STANDARD OPERATING PROCEDURES: STANDARD PRECAUTIONS FOR OUTPATIENT SETTINGS

SOP 103:	Aseptic Technique		
Prepared by: Date adopted: Reviewed by:			
Name/Grade	Signature	Date	

Procedures: aseptic technique⁶

- A. Before any procedure requiring aseptic technique, wash hands with anti-microbial soap and water using the following hygienic hand washing technique:
 - 1. Roll up sleeves, removing jewelry and watches.
 - 2. Wet hands under continuous and free-flowing water.
 - 3. For at least one minute with anti-microbial soap and water:
 - Rub palms together, right palm over left top and left palm over right top.
 - Rub palms together with fingers and backs of fingers interlaced.
 - Then, rub backs of fingers to opposite palms of fingers interlocked.
 - Then, rub the right thumb around in left palm and the left thumb around in right palm.



Figure 6

⁶ Aseptic: to prevent infection from pathogenic microorganisms. Technique applies to: minor clinical procedures such as suturing of lacerations, abscess incision and drainage, venipuncture, setting up and maintaining IV lines.

- Rotationally rub backwards and forwards clasping fingers of right hand and in the left palm and vice versa.
- 4. Do not splash clothing or the floor.
- 5. Rinse both hands carefully under free-flowing water, hold hands down to rinse.
- 6. Pat dry both hands with a clean paper towel or a clean cloth towel; turn off faucet with the towel and dispose of the paper towel in general waste disposal or dispose of the cloth towel in the laundry.

B. Use antiseptic and sterile gauze to disinfect the target areas of skin immediately prior to any clinical procedure that will puncture the skin.

- 1. Consider any of the following antiseptics:
 - 70-80 percent w/w ethanol.
 - 60-70 percent v/v isopropanol.
 - 10 percent w/v aqueous or alcoholic povidone-iodine (1 percent w/v available iodine) such as betadine.
 - Chlorhexidine in aqueous formulations (0.5-4 percent w/v) or in alcoholic formulations with chlorhexidine (0.5 to 1 percent w/v) in 60-70 percent isopropanol or ethanol (for example, Hibiclens)
 - Solutions containing 1 percent w/v diphenyl ether (triclosan).
- C. Do not use cotton balls stored wet in multi-use containers.
- D. Once clean, allow the area of skin to dry before the procedure.
- E. Do not touch or allow any other object to touch the skin area before the procedure.
- F. Perform procedure.
- G. When using scalpel blades in a procedure, always use forceps to hold the blade.
- H. When transferring blood from a syringe into a test tube:
 - 1. Make sure the test tube is in a test tube holder.
 - 2. Use only one hand to insert the needle into test tube.

STANDARD OPERATING PROCEDURES: STANDARD PRECAUTIONS FOR OUTPATIENT SETTINGS

SOP 104:	Injec	Injection Administration		
Prepared by: Date adopted: Reviewed by:				
Name/Grad	e	Signature	Date	

Procedures: injection administration

A. Always notify the patient that you plan to administer an injection.

B. Pre-procedure

- 1. Prepare each injection in a separate, clean area (without body fluids and blood).
- 2. Use a new, single-use, disposable needle and syringe for every injection administered and to reconstitute every medication unit.
- 3. Inspect syringe and needle packaging.
 - Ensure it is not torn, punctured or damaged.
 - Discard if damage is found.
 - Discard needles that had contact with non-sterile areas such as countertops.

- 4. Use single-dose vials to prepare medication.
 - If this is not possible, always clean the top of the multi-dose vial with available antiseptic, then puncture the septum of the multi-dose vial with a clean, sterile needle. Do not leave needles in the septum.
 - Do not remove or manipulate the needle from the syringe prior to disposal.



Figure 7

- 5. Avoid ampules that require a metal file to open.
 - If this is not possible, protect hands while opening the ampule by protecting fingers with a clean gauze pad or other clean barrier.
 - Discard medications that show evidence of tampering or expiration (cracks, tears, broken seals).

C. How to perform an injection

- 1. Wash hands prior to administration of the injection.
- 2. Avoid giving injections to patients with poor skin integrity (flaky, painful rash).
- 3. Wear single-use, disposable gloves if bleeding is anticipated.
- 4. Clean the area of skin to be injected.
 - Remove visible dirt with soap and clean water.
 - Use an antiseptic⁷ (clean, single-use swab) to disinfect the target area of skin immediately prior to injection. (Note: An antiseptic is preferred, but is not required if the skin has been cleaned with soap and clean water).
 - Do not use cotton balls stored wet in multi-use container.



Figure 8

• Allow the area of skin to dry prior to injection.

5. Be aware of and avoid sudden or jerking movements of the patient during and after injection administration.

⁷ See SOP 103.B.1. for procedure.

- 6. Do not recap needle(s) after use and prior to disposal.
- 7. Immediately dispose contaminated needle and syringe in sharps container.
- 8. Remove gloves, wash hands with soap and free-flowing water and dry.

SOP 105:	Housekeeping	
Prepared by: Date adopted: Reviewed by:		
Name/Grade	Signature	Date
		

A. Procedures: cleaning patient-care rooms⁸

1. At the start of each day:

- Use a damp cloth to remove dust from examination tables, trolleys, lamps and other office furniture.
- Use a damp mop to remove excess dust from the floors.

2. Between patients:

Clean examination tables, counters, lamps, blood pressure cuffs and other patient care equipment, and other surfaces at risk for contamination:

- First, clean with soap and water then dry.
- Then, use a disinfectant solution, such as JIK, permanganate de potassium, or Dakin, or any 1-2 percent sodium hypochlorite or 70 percent alcohol solution, on a damp cloth and wipe off the dirty item.
- Do the same thing to clean floors, ceiling and/or walls if contaminated. If these areas are soiled with blood or body fluids, see SOP 105.B.

⁸ Includes patient-care rooms, instrument processing area and laboratory; excludes waiting areas.

3. At the end of each day:

- Use a disinfectant solution (such as JIK, permanganate de potassium, or Dakin) to clean all counters, floors, tables, sinks, lights, door handles, walls, blood pressure cuffs and other patient-care equipment.
- For facilities with toilets/commodes, clean the seat and other areas with warm water and soap using cleaning cloth or sponge and then dry. Then use the disinfectant solution and dry again.

4. Weekly:

• Use a mop or other appropriate tool dampened with a disinfectant solution (such as JIK, permanganate de potassium, or Dakin) to clean ceilings in patient consultation areas if soiled.

B. Procedures: spills of blood or body fluids

1. Smaller spills (less than 10cm in diameter)

- Use standard precautions and personal protective equipment as described in SOP 102 as appropriate. Use heavy-duty or utility gloves when addressing spills and cleaning surfaces.
- Apply dry, absorbent paper towels or a cloth saturated with a disinfectant solution directly to contain the fluid spill.
- Dispose of the paper towels and/or cloth by following the procedures for infectious, non-sharps, clinical waste disposal as outlined in SOP 107.
- Immediately clean with soap and water to remove surface dirt and contaminants within the spill.
- Use a disinfectant⁹ such as bleach (0.5 percent chlorine solution) after cleaning with soap and water when:
 - Spills are contaminated with blood or body fluids.
 - There is risk of bare skin contact with the spill area.
 - Cleaning is difficult.

• Wash hands with soap and free-flowing water.

⁹ Disinfectants can usually kill bacteria and/or viruses whereas detergents usually cannot.

2. Larger spills (more than 10cm in diameter)

- Use standard precautions and personal protective equipment described in SOP 102.
 Wear disposable cleaning gloves, heavy-duty or utility gloves when cleaning spills and surfaces.
- Coat the area with a disinfectant (0.5 percent chlorine) solution.
- Wipe spill with dry, absorbent paper towels, a damp cloth, sponge or a mop to contain the majority of the spill.
- Immediately clean area(s) with water and soap using dry, absorbent paper towels, a cleaning cloth, sponge or mop.

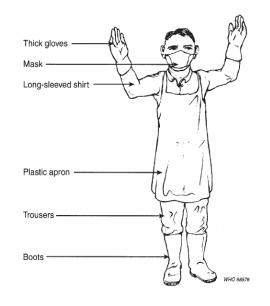


Figure 9

- Next, disinfect the area with at least 0.5 percent chlorine solution and allow complete drying time.
- Dispose of all paper towels, damp cloth(s) or mop using procedures for infectious, non-sharps, clinical waste disposal described in SOP 107.
- Wash hands with soap and free-flowing water.

C. Procedures: linen and exam room item handling

1. How to handle linens

- Use paper or protective liners to keep bed and exam table linen clean.
- If protective liner is unavailable, remove used linen from exam tables after each patient encounter and store for cleaning in a labeled bag or container.
- Wear gloves when removing and placing dirty linen in marked, leak-proof biohazard bags if linen is contaminated with blood or other body fluids.
- Separate blood-contaminated linen from other items; then clean using soap and bleach.
- Separate and clean all used and soiled linens away from patient consultation areas.
- Wash used/soiled linens with laundry soap and water heated to approximately 75 degrees C for at least 25 minutes. Items may dry in the sun.

• Keep fresh, clean linen in a separate clean linen area to avoid contamination.

2. How to handle exam room items

- Wipe examination tables/mattresses/pillows that have plastic covers with soap and water after each patient encounter.
- Steam-clean mattresses without plastic covers when exposed to body fluids.
 - If steam-cleaning is unavailable, wash mattress manually with soap and hot water while wearing personal protective equipment.
 - Alternately, the contaminated mattresses may be thrown away.
- If contaminated with body fluids, pillows without plastic covers should be dry cleaned or, if dry cleaning is unavailable, washed manually with soap and hot water while wearing personal protective equipment.
 - Alternately, the contaminated pillow may be thrown away.
- Clean curtains when there is visible dirt using technique described immediately above in C.1 (bullets three through five).

SOP 10	06:	Instrument Processing	
	red by: dopted: ved by:		
	Name/Grade	Signature	Date
			

Procedures: instrument processing (applies to reusable items such as specula, containers and glass bottles)

A. Pre-procedure

- 1. Avoid hand-to-hand transfer of sharp, reusable instruments.
- 2. Place reusable items/instruments in marked containers immediately after use.
- 3. Transport equipment to designated area for reprocessing.
- 4. Use a separate room or bench space to keep clean and dirty equipment separate.

B. How to process instruments

- 1. Wear heavy-duty or utility gloves, protective eyewear and a mask.
- 2. Disassemble instruments in non-patient care areas.



Figure 10

- 3. Use warm water in a dedicated instrument-processing sink to rinse instruments and remove any blood or body fluids.
- 4. Thoroughly wash and clean the instruments in free-flowing water with a mild alkaline soap (ph 8.0-10.8) using a soft brush or non-abrasive scouring pad. Keep the brush and utility gloves in clean and serviceable condition.
- 5. Carefully rinse instruments under free-flowing warm or hot water to remove all soap and dry prior to disinfection or sterilization procedures.¹⁰



Figure 11

- 6. Use steam sterilization, high-level disinfection or low temperature automated chemical sterilant systems to clean instruments that contact intact mucous membranes. Refer to facility for potential resources and capabilities.
- 7. Instruments that puncture sterile tissue, enter the vascular system or are otherwise contaminated with blood or body fluids should undergo steam or chemical sterilization;¹¹ choose the sterilization process based on the intended use of the equipment.
- 8. Store instruments in a dry, clean, dust-free, and covered space until next use.

C. Syringes

Do not sterilize syringes or needles for reuse. Each injection or blood draw should occur with a new, disposable syringe and needle.

¹⁰ After cleaning with soap (removal of surface contaminants) and disinfection (partial microorganism killing), instruments are ready to undergo sterilization (removal or inactivation of all microorganisms).

¹¹ Sterilization process removes all microorganisms through chemical, steam (autoclave) or dry-heat (electric oven) methods. Chemical: low-temperature chemical sterilant systems or ethylene oxide sterilization; steam: moist heat under pressure; dry-heat: high heat for a fixed time period.

SOP 107:	Clinical Waste Disposal	
Prepared by: Date adopted: Reviewed by:		
Name/Grade	Signature	Date

A. Procedures: clinical waste¹² disposal — sharps

1. When to dispose

• Immediately after use, at the point of use. Do not recap syringes/needles.

2. Where to first dispose

- Immediately after use, place all sharps, including syringes and needles, scalpel blades and other items for disposal, in leak-proof, puncture-proof sharps containers, regardless of whether or not they are contaminated.
- Keep sharps containers as close as possible to clinical use area.

3. How to dispose

• Place uncapped, used syringe directly into the nearest leakproof, puncture-proof sharps container.

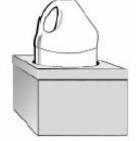


Figure 12

¹² Applies to waste created during examination, diagnosis and preventive/curative treatment of patients.

- Do not remove or manipulate the needle from the syringe prior to disposal.
- Do not hand the contaminated sharp to another person for disposal; the person who uses the sharp object throws it away.
- Do not try to recap the needle/syringe prior to disposal.

4. Making a sharps container

- Make the container from metal or high-density plastic and fit with a cover.
- Use a dense cardboard safety box if metal or plastic is unavailable.
- Seal the puncture-proof, leak-proof container when it is three quarters full.
- Do not reopen or empty the sharps disposal container once it has been sealed.

5. Where to finally dispose of sharps

- Place filled, sealed sharps disposal container in disposal bag.
- Label or color-code bag "Highly Infectious Waste" before removal from clinical use area.



Figure 13

- Three options for final sharps disposal:
 - On-site incineration, if possible.
 - Transport labeled disposal bags to a distant, appropriate facility.
 - Burial, per WHO recommendations (WHO, December 2004).

B. Procedures: clinical waste disposal — non-sharps

- 1. Place non-infectious waste in general garbage disposal stream.
- 2. Put highly infectious, non-sharps material (items containing blood, vomit, urine, body fluids, soiled or used wound dressings) in leak-proof, biohazard bags.
- 3. Label and color code waste disposal bags by waste category (WHO, 1999):
 - Hazardous for non-sharp infectious waste (yellow).
 - Highly hazardous for highly infectious non-sharp waste (yellow and marked "Highly Infectious").
 - Sharps (Yellow and marked "Sharps").

- 4. Tightly seal **all** waste disposal bags when three quarters full.
 - Light gauge bags may be tied at the neck.
 - Seal heavier bags with a plastic sealing tag (self-locking).
 - Do not staple bags.
- 5. Do not reopen any closed or sealed biohazard bags or containers.
- 6. Mark all designated biohazard areas. Keep all bagged, biohazardous material in an area protected from public access (scavengers, children).
- 7. Consider burning or burying waste as designated by the facility protocol if clinical disposal is not taken to a designated place on a regular basis.

SOP 108:	Resuscitation	
Prepared by: Date adopted: Reviewed by:		
Name/Grade	Signature	Date
	<u> </u>	

Procedures: resuscitation

- A. Use ventilation devices (for example, AMBU bag and mask) to provide positive pressure ventilations during resuscitative efforts, instead of mouth-to-mouth resuscitation methods.
- B. When performing cardiopulmonary resuscitation (CPR) in the clinic setting, wear disposable, latex examination gloves and other relevant personal protective equipment as described in SOP 102.
- C. Clean AMBU bag and mask with soap and water, allow to dry completely, then send for appropriate disinfectant and/or sterilization procedures.

FIGURE LIST

Figure 1:	http://siri.uvm.edu/graphics/Personal Protection/Hands/
Figure 2:	http://www.wpro.who.int/sars/docs/interimguidelines/Image51.gif
Figure 3:	www.engenderhealth.org/ ip/surgical/sum4.html
Figure 4:	http://www.fotosearch.com/thumb/PHD/PHD532/AA051322.jpg
Figure 5:	http://www.sifi.it/it/farmaci/strumenti/img/mon2.jpg
Figure 6:	http://www.drlam.com/pictures/washhand.jpg
Figure 7:	http://www.michna.com/kenya2002/image/212c.jpg
Figure 8:	http://whyfiles.org/150alt_med2/images/injection.jpg
Figure 9:	http://www.who.int/water_sanitation_health/medicalwaste/140to144.pdf
Figure 10:	http://www.podiatryonline.com/images/cclean4.jpg
Figure 11:	http://www.sterling-products.com/sterile%20tray.jpg
Figure 12:	http://www.wpro.who.int/sars/docs/practicalguidelines/dec2004/Final_guidelines_Dec2004.pdf
Figure 13.	http://www.wpro.who.int/sars/docs/practicalguidelines/dec2004/Final_guidelines_Dec2004.pdf

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