



# **HIV TREATMENT AND CARE CENTERS: STANDARD OPERATING PROCEDURES**

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**THE NATIONAL AIDS CONTROL PROGRAM  
MINISTRY OF HEALTH  
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CONTENTS

ACKNOWLEDGEMENTS

INTRODUCTION	4
HIV TREATMENT AND CARE CENTER OBJECTIVES	5
REGISTRATION PROCESS NEW PATIENT FOLLOW UP VISITS	8
CONFIRMING HIV INFECTION STATUS	8
FIRST VISIT OBJECTIVES MEDICAL ASSESSMENT	10
FOLLOW UP VISIT OBJECTIVES MEDICAL ASSESSMENT	12
ART: ELIGIBILITY CRITERIA ADULT PEDIATRIC	13
COUNSELING OBJECTIVES INITIAL HIV/AIDS COUNSELING	15
PRE-TEST COUNSELING	17
POST-TEST COUNSELING	18
PRE-ART COUNSELING (1 <sup>ST</sup> SESSION) 2 <sup>ND</sup> SESSION	19
ART INITIATION 3 <sup>RD</sup> MEDICAL VISIT 3 <sup>RD</sup> COUNSELING SESSION	20
ART PROTOCOLS REGIMENS	21
MONITORING OF PATIENTS ON ART: SUBSEQUENT VISITS 1 <sup>ST</sup> WEEK 1 <sup>ST</sup> YEAR 2 <sup>ND</sup> YEAR	22
LABORATORY MONITORING SCHEDULE	
CHANGING ART CRITERIA	24
DRUG REACTION PROTOCOL	25
TREATMENT FAILURE	26
POST EXPOSURE PROPHYLAXIS ACTIONS TO UNDERTAKE PEP PROTOCOLS	26
MAINTAINING PATIENT RECORDS AND CONFIDENTIALITY	28

REFERRAL MANAGEMENT	29
ETHICAL CONSIDERATIONS	32
REFERENCES	33
ANNEXES:	34
1. WHO STAGING CLASSIFICATION	
2. APPOINTMENT CARD	
3. REGISTRATION FORM	
4. INFORMED CONSENT FORM (HIV CARE & TESTING)	
5. INITIAL VISIT	
6. FOLLOW-UP VISIT	
7. ART ELIGIBILITY FORM	
8. COUNSELING FORM	
9. LABORATORY DATA FORM	
10. REFERRAL FORM	

## ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal clinics
ARV	Antiretroviral
ART	Antiretroviral therapy
CBO	Community based organization
CDC	Centers for Disease Control and Prevention (US)
CO	Community Organization
ddI	Didanosine
EFV	Efavirenz
FHI	Family Health International
FPC	Family planning clinics
HIV	Human Immunodeficiency Virus
ID	Infectious Disease specialist
IDU	Injection Drug Users
NACP	National AIDS Control Program
NFV	Nelfinavir
NGO	Non-governmental Organization
NVP	Nevirapine
OI	Opportunistic infection
PACP	Provincial AIDS Control Program
PEP	Post-exposure Prophylaxis
PLWHA	People Living with HIV/AIDS
PI	Protease inhibitors
PMTCT	Prevention of Mother-Child Transmission of HIV
SOPs	Standard Operating Procedures
STIs	Sexually Transmitted Infections
TNF	Tenofovir
TB	Tuberculosis
TLC	Total Lymphocyte Count
WHO	World Health Organization
UNAIDS	United Nations Joint Co-sponsored Program on AIDS
VCT	Voluntary Counseling and Testing
3TC	Lamivudine
d4T	Stavudine
ZDV	Zidovudine

## INTRODUCTION

A number of countries in Asia are experiencing rapidly growing HIV/AIDS epidemics. An estimated million or more people living with HIV/AIDS need antiretroviral therapy (ART) but less than 6% are currently receiving it. Overwhelming evidence from developed countries, and more recently from developing countries, shows that ART reduces mortality/morbidity, improves the quality of life, rejuvenates communities affected by HIV, creates hope among people living with HIV/AIDS (PLWHA), and reduces the overall progression of the epidemic.

ART is expensive and requires health care systems that can effectively deliver treatment to HIV positive persons. Initiating ART programs without proper establishment of delivery systems and “best practices” to support treatment efficacy, and adherence monitoring will result in costly endeavors with little successful results. According to UNAIDS/NACP forecast models the number of PLWHA in Pakistan is estimated at 70000-80000 (0.1% overall prevalence). Of these 7000 (10%) are estimated to be in need of ART.

The scaling up of ART is a complex process, with multidimensional challenges. It demands the formulation of a carefully designed national strategy integrating ART at all levels in prevention and care programs, promoting voluntary counseling and testing, enabling laboratory diagnostics and support capacity, and ensuring treatment adherence through medical-social support systems and partnerships with PLWHA. While the need for ART remains critical in slowing down the HIV/AIDS epidemic in Pakistan, the importance of these factors must not be overlooked in our haste to establish HIV care programs.

## HIV TREATMENT AND CARE CENTER

### OBJECTIVES

- To establish a comprehensive HIV treatment and care centers that will provide antiretroviral therapy, management of opportunistic infections, voluntary counseling and testing (VCT) services and acute/chronic care of HIV related infections to people living with HIV/AIDS (PLWHA).
- Monitor treatment related adverse effects, toxicities and provide medical and psychological support in understanding both the disease and treatment demands.
- Establish and strengthen laboratory diagnostics support for HIV management and care including CD4 and HIV viral load testing (directly at the center or through local collaborations).
- Promote linkages with referral services (hospital based services), community organizations/NGOs and people living with HIV/AIDS (PLWHA) to enhance access to care and other support services (i.e nutritional, financial, social)
- To reduce stigma of HIV through acceptance of PLWHA and create awareness of HIV as a chronic medical condition.

## REGISTRATION PROCESS

### New Patient

A patient visiting the HIV treatment and care center (HTCC) for the first time will become a registered patient.

At the time of registration patient will receive:

- A unique patient identification number to maintain patient confidentiality. This unique patient identification number will be used for all patient related information and data generated from the HIV treatment and care center.
- An appointment card to document scheduled appointments, current medications, and investigations. This card should remain with the patient and be updated at each visit.
- Contact information on available Voluntary counseling and testing (VCT) services locally and nationwide.

Patients will generally access the HTCC from the following referral sources:

- Voluntary counseling and testing (VCT) centers
- Physicians
- Maternal Child Health services
- TB Clinics
- STI services
- Adult or pediatric Inpatient Hospital services
- Out-patient specialty clinics (Dermatology, Gynecology, Urology or others)
- Traditional or non-medical health care providers
- NGOs or other community out reach organizations
- Blood banks
- AIDS Control Programs
- PLWHA (People living with HIV/AIDS)
- Self-referral

## CONFIRMING HIV INFECTION STATUS

**Initial HIV test positive:** for person having a HIV positive test repeat testing should be done with a 2<sup>nd</sup> test (i.e ELISA, HIV rapid test and/or a Western Blot) on a new blood sample at the VCT center. Only after clear confirmation of a positive HIV status should continuation of care be carried out in the HTCC. **If the patient has clinical sign or symptoms compatible with advanced HIV (i.e AIDS, Annexe 1), the necessity of confirmatory testing for HIV positive status may be eliminated at the decision of the physician in charge of the HTCC. However, such practices should be discouraged to minimize the risk of misdiagnosis and unnecessary treatment.**

**Referral to VCT center for HIV Testing should be made in the following situations:**

- A patient with unknown HIV status, presenting with signs/symptoms suggestive of HIV/AIDS (e.g oral thrush, Herpes zoster, unexplained chronic diarrhea, unexplained fever, Kaposi's skin lesions)

- Person reporting behavioral risk factors for HIV infection (i.e sexual exposure, needle sharing, unscreened blood transfusions).
- Patients requesting VCT services with or without symptoms suggestive of HIV/AIDS.
- Patients referred to HTCC without a HIV-positive test result.

#### FIRST VISIT

- Registration process includes: documentation of patient's demographic information such as address, age, sex, occupation, source of referral, next of kin, and emergency contacts on the Registration Form. This form is filed in the patient's medical record file.
- Assignment of a patient identification number . The patient's identification number is entered into his/her medical record file. This number will remain the same throughout the patient's care at the HTCC.
- The patient's identification number is then entered into the HTCC Visit Register, which records their visits.
- A Patient Appointment Card for recording dates of patient's scheduled appointments and visits to the HTCC will be issued (Appendix )
- Contact numbers for the physicians working in the HTCC will be given to the patient.

#### FOLLOW UP VISITS

- At all subsequent follow up visits the patient' compliance with the scheduled visits will be entered in the HTCC Visit Register using the given patient identification number.
- At each visit patient contact information should be validated and updated if necessary.

## FIRST VISIT

### OBJECTIVES:

1. Establish initial contact with the patient.
2. Assess clinical status and treat any existing medical conditions or opportunistic infections (OIs)
3. Help familiarize patient with the diagnosis of HIV and AIDS
4. Categorize patient according to WHO clinical staging classification or CD4 cell count (if available)
5. Perform baseline laboratory and radiological testing.

In this visit the Physician should:

- Discuss and obtain **Informed Consent Form (Annexe)** for HIV care services. The patient should understand the importance for signing the informed consent forms. If HIV testing is undertaken at this visit the patient should be explained in detail the procedures and implications of HIV testing. These forms should be placed in the patient's medical file.
- Complete patient assessment using the **Initial Visit Form (Annexe)**
- Record vital signs (blood pressure, temperature, pulse) and weight in the Initial visit form.
- Complete a comprehensive baseline assessment including presenting complaints, risk factors for HIV, past medical history, OIs, and physical examination. It is important to record date and location of HIV testing.
- Discuss HIV/AIDS
  - what is HIV and AIDS
  - what are some key infections associated with HIV/AIDS
  - safer practices to avoid transmission of HIV to other susceptible persons
  - effective techniques for condom use
  - Ways in which HIV is not transmitted
  - Differences between treatment and cure
  - what is ART
  - Clinical indications for initiation of ART
  - Risks of prematurely starting ART
  - Benefits of ART deferral
  - determination of patient's understanding of HIV/AIDS and the need for additional support (emotional, financial, nutritional etc)
  - explain the importance of adherence in keeping appointments and the long term commitment for ART
- Classify the patient according to the WHO staging system.
- If CD4 testing is available, make arrangements for baseline CD4 testing (i.e sample collection date, procedures, report collection)

### **Additional Baseline Laboratory Testing:**

- HIV serology (if necessary)
- Complete blood count including total lymphocyte counts
- CD4 cell counts
- Pregnancy test (for women in child-bearing age)
- Hepatitis B and C serology
- Chest x-ray
- VDRL for syphilis

- Initiate treatment for acute symptoms and manage any existing treatable conditions (i.e diarrhea, TB, thrush)
- Initiate prophylaxis with Trimethoprim-Sulfamethoxazole (Co-trimoxazole) if patient is in Stage 3 or 4 and has no contraindications (e.g sulfa allergy, pregnancy, acute respiratory symptoms, acute liver symptoms), if CD4 count <200, or if patient has oral thrush.
- Instruct the patient to return in 1-2 weeks. The medical officer will write down scheduled appointment in the patients appointment card and in the clinic Appointment Register.
- Refer and assist the patient to the counselor for a detailed counseling session.
- Direct the patient to the laboratory or sample collection area for sample collection. It would be preferred if the samples can be collected safely (i.e observing proper infection control precautions) in the HTCC and then sent to the laboratory with proper labeling (i.e labeling stickers with patient unique identification numbers). If samples are collected in the lab then proper labeling stickers should be provided with the request form to minimize the risk of sample mix up in the lab.

## FOLLOW UP 2<sup>ND</sup> VISIT

### OBJECTIVES:

1. Establish rapport with patient regarding their medical condition.
2. Develop understanding of patients existing social support systems (i.e nutritional status, family support, financial situation etc).
3. Discuss the results/reports of initial visit.
4. Assess clinical status and/or follow up on the treatment of any existing medical conditions or opportunistic infections (OIs).
5. Categorize patient according to WHO classification system or CD4 cell count results.
6. Explore patients' readiness in initiating ART (if applicable) and discuss the eligibility criteria.

In this visit the physician should

- Discuss with patient the laboratory test results from the previous visit.
- Assess patient readiness to start ART in cases of diagnosed or suspected AIDS.
  1. Patient understands about the role and importance of ART
  2. Can follow the prescribed regimen
  3. Preferably has a close family member or friend who can serve as a "treatment assistant"
  4. Understands the importance and necessity of strict adherence with the prescribed regimen.
  5. Is willing to keep the recommended clinic appointments (i.e monthly for the 1<sup>st</sup> year).
- Counsel the patient about importance of ART adherence. Emphasis must be placed on the efficacy and convenience of the 1<sup>st</sup> line regimen in long term treatment success.
  1. The physician should clearly explain that a limited supply of 1<sup>st</sup> line regimens is available in Pakistan.
  2. Clearly explain the implications of non-adherence (i.e compliance needs to be greater than 95%) and irregular dosing (i.e missing > 3 doses per month). Patient should understand that such practices will quickly lead to HIV drug resistance (the medicines will stop working against HIV) and be harmful for the patient.
- Discuss in detail the eligibility criteria including the rationale for having selection criteria, the risks of prematurely initiating ART and concepts of resistance development.
  1. Clearly explain that there is no benefit in starting ART unless clinically indicated (Annexe : Eligibility Criteria)
  2. ART is life long and has toxicities/side effects and risk of resistance development. Therefore ART should be started only when clinically indicated.
  3. Repeatedly emphasize that ART is never an emergency and the response is not affected by starting it at a later stage.

- Refer eligible patient for Pre-Art Adherence Counseling Sessions.

**For patients not eligible for ART, the physician will discuss**

- In cases where CD4 count is >200 or patient is in clinically Stage 1 or 2 (WHO Classification), the benefits of postponing treatment needs to be clearly explained. **Please note that every patient with HIV positive person does not need or benefit from ART. It is critical for patients to understand this rationale and reasoning. One visit may not be enough to reinforce this concept. Physicians will need to exercise their clinical judgment in assessing patient comprehension.**
- Reasons for ineligibility (if other than CD4 > 200), including possible ways to overcome those barriers.
- Refer to appropriate services (VCT, nutritional support, social services etc)
- Define a follow up schedule i.e 3-6 monthly or sooner if signs/symptoms develop.
- Provide patient with contact numbers to call if there are additional questions.

## DETERMINING ELIGIBILITY FOR ART INITIATION

### ELIGIBILITY CRITERIA

#### Medical

- Confirmed HIV positive status (using 2 different tests ELISA, rapid tests or Western Blot) with CD4 counts less than 200/mm<sup>3</sup>
- WHO stages 3 or 4 regardless of CD4 count
- Asymptomatic patients (stage 1 or 2) with CD4 less than 200/mm<sup>3</sup>

#### Adherence

1. Must attend 2- 3 pre-ART counseling sessions. Attendance is mandatory for a minimum of 2 sessions. Additional counseling sessions may be needed based on the counselor or physicians assessment.  
*and*
2. Express firm commitment and readiness to following treatment regimen exactly as prescribed and attend the scheduled clinic visits. Patient should inform health care provider immediately of any unexpected adverse events or drug toxicities and/or when stopping the medications.

Note: Pre-Art counseling sessions are separate from pre and post test counseling or counseling for other HIV related issues.

### PEDIATRIC ELIGIBILITY CRITERIA

#### Medical

- WHO Pediatric Stage 3 or 4
- WHO Pediatric Stage 1 or 2 with CD4 <20% (if younger than 18 months) or CD4 <15% (if older than 18 months)
- Recurrent hospitalizations (>2 admissions/year) for HIV related disease or prolonged hospitalization (>4 weeks)

#### Adherence

1. An identifiable adult caregiver who is able to administer medication  
*and*
2. Demonstrated reliability in adult caregiver i.e has attended 2 or more scheduled counseling sessions.  
*and*
3. Caregiver must express firm commitment to follow the treatment regimen and attend the scheduled clinic visits.

The medical and adherence eligibility criteria must be met before ART initiation, while treatment should be deferred or not initiated in those who meet the medical or adherence ineligibility criteria.

## INELIGIBILITY CRITERIA

### Medical

- CD4 cell count greater than 200/mm<sup>3</sup>
- Asymptomatic patient and WHO stages 1 or 2 (unless CD4 count is less than 200/mm<sup>3</sup>)
- End stage liver disease (decompensated cirrhosis with recurrent ascites)
- End stage kidney disease
- Advanced stage cardiac disease (Stage IV cardiomyopathy)
- Advanced cancer or any other terminal medical condition (excluding HIV)
- Advanced HIV-related dementia or encephalopathy (these are irreversible conditions even with ART initiation)

### Adherence

1. Active injecting drug users (IDUs)\* who are unable to maintain regular clinic appointments and counseling sessions. A good predictor of adherence can be the regular utilization of harm reduction services by the IDU (i.e at least 5-6 times/week).

\* IDUs need to enroll in drug detoxification and drug rehabilitation programs and should be “drug free” for 3 months before initiating ART. The HTCC should link up with NGOs working with IDUs to ensure compliance.

## COUNSELING

### OBJECTIVES:

1. To educate and counsel patients about HIV/AIDS.
2. To identify and facilitate, patient needs for additional medical and social support services.
3. To assess patient readiness and commitment to ART
4. To promote linkages between medical, social and psychological aspects of HIV care.

### INITIAL HIV/AIDS COUNSELING

#### Defination:

Counseling is defined as “Confidential dialogue between a client and a counselor/care provider aimed at enabling the client to cope with HIV/AIDS (directly or through association) and take personal decisions in an informed manner. The counseling process includes an evaluation of personal risk of HIV transmission, encouraging preventive behaviors and other mechanisms of understanding the disease process in a way that empowers the client”

Counseling can be offered to individuals, couples, families and groups. Counseling involves helping people to define for themselves the nature of the problems they are facing and then enabling them to make realistic decisions about what they can do to reduce the impact of these problems on themselves and their family/friends. Therefore, helping people to achieve the confidence to make life-style changes is an integral part of the counseling process. In summary, counseling people about HIV/AIDS is important because:

1. Infection with HIV is lifelong and needs chronic management (i.e ongoing counseling)
2. A diagnosis of HIV infection can create enormous psychological pressures and anxieties, worsen illness, especially as the diagnosis of HIV is associated with fear, misunderstanding, stigma and discrimination.
3. Behavioral change and knowledge can prevent a person acquiring HIV infection or transmitting it to others.

Counselors should keep in mind two key objectives:

- 1) Provide psychosocial support in a non-judgmental manner
- 2) Prevent additional HIV infection by encouraging behavioral change through education and information (i.e promote preventive behaviors)

#### Psychosocial Support

People diagnosed as having HIV infection and HIV-related illness, including AIDS, and those close to them are confronted by a host of problems that require emotional and/or practical support. Anxiety about having spread infection, physical isolation, hospitalization, stigma/discrimination within the community and/or family, loss of housing, interruption of education, financial problems, the physical effects of illness, disease progression, loss of relationships, bereavement, anger, loneliness, and depression are all concerns that may have to be managed.

These problems may be periodic or come at different phases of the illness, both for the person with HIV/AIDS and for those providing care for them. The fact that they are not always constant and not always predictable produces physical and emotional stress. Counseling can be particularly helpful in identifying and addressing these concerns.

#### *Key components of the counseling process*

- Ensure passing-on of accurate information.
- Provide support at times of crisis
- Encourage change when change is needed for the prevention or control of HIV infection
- Help clients focus and identify their immediate and long-term needs. Propose realistic action plans suitably adapted to the different clients and circumstances.
- Assist clients to accept and act on information to promote their health and well being
- Help clients to be well-informed and appreciate the technical, social, ethical and legal implications of HIV testing.

Special Note: In the process of counseling it is essential to develop a cordial relationship between a client and a counselor. However the counselor's objective assessment in evaluating the client's case is extremely important. There is, however, a continuous gradation between objective detachment and closeness, within which the counselor must find the correct balance; this is important in promoting well-being and problem solving skills of the client. For a client talking to a stranger about personal matters may be frightening, intimidating or culturally not acceptable. The counselor should begin therefore, by finding out what the client already knows about counseling and the disease process and expects of the counselor. If necessary, the counselor should explain the process briefly, illustrating it with examples, discuss the client's fears about it, and then listen to the client's own account of the problem.

#### **PRE-TEST COUNSELING**

Prior to administering the voluntary HIV testing the counselor should cover certain topics to ensure that the client understands the medical, legal, and social implications of HIV testing:

- Reason for attending the counseling
- Reason for HIV testing
- Assessment of the level of risk
- Client understanding of HIV virus and its modes of transmission
- Correcting misconceptions
- Essential information on the HIV infection
- HIV test procedures and limitations
- Implications of a positive and negative test
- Importance of post-test counseling
- Additional discussion on possible modes of transmission if the report turns to be positive
- Client's marital status and risk behaviors
- The importance to prevent infection and re- infection;

Counselor should take care of the following points in the Pre Test Counseling.

- Establish rapport: take relevant intake information, make eye contact, accept the client with unconditional positive regard, inform about confidentiality and ensure mechanisms to observe patient confidentiality.
- Explain pre test counseling
- Ask client about his knowledge about STIs and HIV/AIDS.
- Give more information verbally and make sure that you do not frighten them.
- Tell them about the test and possible outcomes and test results.
- Ask client about his possible reaction of the results so that you prepare him for the results.
- Find out the support systems of the client.

### Generic Guidelines for Counseling

- Place of counseling should be friendly environment with adequate privacy
- You should have ample time and give undivided attention to the client.
- If possible, same counselor should do the pre as well as post counseling.
- In the initial visit see the client alone and involve family/spouse later.
- Encourage the client to ask more questions and you should be familiar with local terms for sexuality, sexual behaviors.
- **Give information; do not preach to the client.**
- Encourage the client to comeback within 2-3 weeks or sooner.

### POST TEST COUNSELING

#### When a person is diagnosed with HIV:

- Support the process of anticipatory grief,
- Planning for continued involvement of the client in self care;
- Establishing or reestablishing a support network to provide physical and emotional care

#### During the disease process:

- How to tell others about HIV infection status or AIDS
- Handling hostility, fear and feelings for having HIV infection or having AIDS.
- Exploring ways of taking care of survivors;
- Accepting fear of death and need of repeated counseling.
- Discussion on personal, family and social implications.
- Discussion on personal risk reduction plan.
- Dealing with immediate emotional reactions.
- Checking availability of adequate immediate emotional and medical support.
- Plan of immediate action on behalf of client.
- Follow-up plan for counseling.
- Referral linkages

#### When the patient is HIV negative

- Explain 'Window Period'. It is defined as a duration of 3 to 6 months after HIV infection when the HIV tests may be negative because adequate antibodies have not developed to be detected by the testing strategies in spite of the

blood being infected by the virus. The person can transmit infection during this time.

- For client with high level of risk assessment; voluntary retesting after 3 months should be advised.
- Client should be encouraged to take necessary precautions to prevent HIV infection in the future i.e condoms, avoid needle sharing

### Generic Post Test Counseling Guidelines

- Establish rapport, spend a few minutes.
- Present the test results.
- Wait for the client to respond, you remain calm.
- Be empathetic, not sympathetic, if results are positive.
- Try to assess the mental status of the client.
- Discuss the meaning of the test results.
- Discuss the future health plan or actions (if client appears composed to do so)
- Look for the silent reactions and symptoms, which may require intense medical or psychological interventions.

### PRE-ART COUNSELING SESSION

After the physician has determined potential eligibility for ART and discussed treatment initiation, the patient is then referred to the counselor for pre-ART counseling sessions. It is mandatory that prior to ART initiation, the patient must attend a minimum of 2 counseling sessions. Additional sessions may be required based on individual situations as assessed by the counselor or physician.

The counselor will:

- Register the patient, collect detailed demographic-social information on the Counseling Form (Annexe).

#### *Assess*

- *Existing knowledge and understanding of HIV/AIDS*
- *Expectations for ART*
- *Future plans following response to ART*

- The importance of adherence and the consequences of failing to take the regimens as prescribed.
- The necessity for strictly following the prescribed 3 drug regimen. Patients should be educated about not accepting any ART regimen that does not have 3 drugs in it except in prophylaxis situations (i.e PEP, MTCT prevention)
- Discuss potential barriers in taking the prescribed treatment. Also assist the patient in possible ways of overcoming the barriers. Address the issues of stigma and discrimination openly in the counseling sessions and enable the patient to express their fears and concerns.

- Identify with patient a close family member or friend to function as a “treatment assistant” to increase adherence.
- Schedule appointment for the 2<sup>nd</sup> counseling session within 1-2 weeks of the first session. This session should preferably be attended by 1-2 close family members to whom the patient has disclosed his/her HIV positive status.
- Answer any patient concerns and questions. Ask the patient to write down any questions for the next visit.
- Document all information obtained on the Counseling Form.

## 2<sup>nd</sup> COUNSELING SESSION

The patient will report to the Registration and be entered in the HTCC Visit Register. If there are any medical concerns or signs/symptoms that require medical attention the counselor should bring them to the attention of the HTCC physician and the patient should be seen by the physician. Otherwise he/she will be directed to the counselor.

In this session the counselor will:

- Review the previous counseling session and answer the patient’s questions.
- Clearly identify “Treatment Assistant” and their role in ART adherence including accompanying on clinic visits. Assess the commitment and social support available to patient in this regard.

### *Explain*

- *ART is not a cure for HIV/AIDS*
- *ART is a lifelong commitment*
- *Even with ART the HIV test remains positive*
- *Resistance to HIV drugs will develop if the patient does not follow their prescribed ART.*
- *ART does not prevent the transmission of HIV infection to other susceptible persons.*
- *Practice of safer behaviors i.e condoms and avoiding needle sharing is necessary even when on ART.*

- Discuss the benefits, risks and side effects of 1<sup>st</sup> line regimen.
- Encourage the patient to develop strategies that will help him/her adhere to the ARV regimen.
- Schedule appointment for the 3<sup>rd</sup> counseling session on the day when the patient will visit physician to initiate ART.
- Document information obtained on the Counseling Form.

### 3<sup>RD</sup> MEDICAL VISIT: ART INITIATION

#### OBJECTIVES:

1. To prepare patient for ART initiation, discuss drug side effects and dosing schedules.
2. Issue prescription for ART.
3. Review and treat any additional medical problems.

In this visit the physician will:

- Assess signs/symptoms since last visit and treat as needed.
- Review any laboratory tests from prior visit.
- Counsel patient on ART regimen, adherence, side effects, possible remedies, and ART monitoring schedule.
- Provide a written schedule of the prescribed medicines
- Schedule an appointment in 2 weeks or earlier if needed.
- Document the clinical assessment and ART regimen in the Follow up Form.
- Direct the patient to attend the 3<sup>rd</sup> counseling session.

### 3<sup>RD</sup> COUNSELING SESSION: ART INITIATION

In the 3<sup>rd</sup> counseling session the counselor will:

- Review the patient's medication regime, including:
  - Schedule of each medication
  - Dose of each medication
  - Food requirements of each medication
- Stress the importance of 100 % regimen adherence and strategies to assist in treatment adherence.
- Discuss possible side effects:
  - Which side effects to report to the HTCC health staff immediately
  - Which side effects can be managed at home and simple remedies how to do so
  - To continue taking the medications despite which side effects and when stopping to stop all medicines simultaneously if side effects are intolerable. Also to inform HTCC physician immediately if stopping medications. The patient should have contact number of HTCC physicians to report any concerns to.
- Explore ways of living positively: the importance of a positive attitude, social support, healthy food and spiritual aid.
- Identify needs (the patient's and the household's) that have not been addressed before; provide referrals to appropriate services.
- Discuss ongoing prevention, including specific strategies to prevent transmission of the virus to sexual partner(s) and possible re-infection.

- Schedule an appointment with the counselor in 48-72 hours to assess possible side effects and medication adherence. This appointment can be done on the phone if transport issues are present.
- Direct the patient to the pharmacy to obtain the ARVs.

## ART REGIMENS

The ARV regimens will be prescribed in a triple drug combination therapy (except for PMTCT and certain cases of PEP) according to the National Guidelines for Antiretroviral therapy.

<u>ARV Regimens:</u>
<p><b>1<sup>st</sup> line:</b></p> <ul style="list-style-type: none"> <li>• Zidovudine + Lamivudine + Nevirapine (preferred 1<sup>st</sup> line) <i>Or</i></li> <li>• Stavudine + Lamivudine + Nevirapine <i>Or</i></li> <li>• Zidovudine + Lamivudine + Efavirenz <i>Or</i></li> <li>• Stavudine + Lamivudine + Efavirenz</li> </ul>
<p><b>2<sup>nd</sup> line:</b></p> <ul style="list-style-type: none"> <li>• Didanosine + Tenofovir + Nelfinavir <i>or</i></li> <li>• Abacavir or Tenofovir + Didanosine + Saquinavir/ritonavir or Lopinavir/ritonavir <i>Or</i></li> <li>• Didanosine + Stavudine + Nelfinavir (HIV resistance testing is recommended prior to changing just 1 drug)</li> </ul>

## MONITORING PATIENTS ON ART: SUBSEQUENT VISITS

### 1<sup>ST</sup> WEEK

The patient and family member or friend identified as “treatment assistant” will contact and/or visit the HTCC within 2 weeks of initiating treatment to discuss any concerns or side effects from ART. The purpose of this visit is

- Discuss patients experience with the medications
- Reinforce adherence
- Provide support and adherence to continue ART

- Discuss the dangers of sharing ART with other infected family members or friends.

The conversation and/or visit must be documented on the ART adherence counseling form or the Follow up visit form.

## **CLINICAL MONITORING SCHEDULE FOR PATIENTS ON ART**

### **1<sup>st</sup> Year:**

Month 1: schedule visit every 2 weeks

Month 2 to 12: schedule visit every month (11 visits)

**Note:** It is strongly recommended not to give more than one months supply of ART to the patient at each visit. This will ensure closer supervision and monitoring of treatment adherence and drug side effects. For patients having transport/travel issues (i.e costs, distance, and inconvenience) it is critical to reinforce that monthly assessments are mandatory to ensure effective response to ART and detect resistance early on. Efforts can be made to explore options for cost-sharing of travel expenses incurred by the patient by the national/provincial AIDS programs or NGOs working with PLWHA.

### **2<sup>nd</sup> Year - onwards:**

If the patient has been medically stable and compliant with ART during the 1<sup>st</sup> year then for the 2<sup>nd</sup> year the clinic visits can be scheduled every 3 months and ART can be given for 3 months. However, it is strongly preferred that some communication strategy be defined between the patient and community NGO working with PLWHA to follow up on adherence in the interim time period.

## **SUBSEQUENT FOLLOW UP VISITS: POST ART**

### **OBJECTIVES:**

1. Assess clinical status and improvements after initiation of ART.
2. Early detection and treatment of any existing medical conditions or new opportunistic infections (OIs)
3. Monitor for any adverse drug events.
4. Reinforce treatment adherence.
5. Perform laboratory and radiological testing as needed.

In these visits the Physician will:

- Complete patient assessment using the Follow up visit forms.
- Record vital signs (blood pressure, temperature, pulse) and weight
- Documentation of medical assessment including presenting symptoms, drug toxicities, response to ART, and diagnostic testing.
- Discuss on going preventive behaviors (i.e condoms, HIV status disclosure)
- Refill prescriptions and inquire about the addition of new medicines for possible drug-drug interactions.



## LABORATORY MONITORING SCHEDULE FOR PATIENTS ON ART

1 <sup>st</sup> Year					
Pre-ART initiation baseline labs	Month 1	Month 3	Month 6	Month 9	Month 12
<ol style="list-style-type: none"> <li>1. complete blood count (CBC)</li> <li>2. LFTs (preferred but optional if cost is an issue)</li> <li>3. Renal functions (preferred but optional if cost is an issue)</li> <li>4. Chest x-ray</li> <li>5. VDRL</li> <li>6. Hepatitis B** and C</li> <li>7. CD4</li> </ol>	LFTs (if symptomatic) Hepatitis B vaccination for HBV negative patients.	<ol style="list-style-type: none"> <li>1. HIV viral load (Strongly recommended)*</li> <li>2. CBC (particularly for ZDV based regimens)</li> <li>3. LFTs (if symptoms)</li> <li>4. other tests as needed.</li> </ol>	Testing on as needed basis	Testing on as needed basis	<ol style="list-style-type: none"> <li>1. CD4 counts</li> <li>2. HIV viral load (Strongly recommended once a year)*</li> <li>3. CBC</li> <li>4. LFTs</li> <li>5. other tests as needed.</li> </ol>
2 <sup>nd</sup> Year and Following Years					
Annual Labs	Month 1	Month 3	Month 6	Month 9	Month 12
<ol style="list-style-type: none"> <li>1. Repeat Chest x-ray</li> <li>2. HIV viral load</li> <li>3. CD4 counts</li> <li>4. Hepatitis B and C</li> <li>5. VDRL</li> </ol>	As needed	As needed	CD4 HIV viral load LFTs	As needed	CD4 HIV viral load LFTs

- \*HIV viral load is strongly recommended where available. After 6-12 weeks of ART, the viral load should be less than 400 copies/ml. In situations where HIV Treatment and Care Centers do not have facilities for obtaining HIV viral loads, short term arrangements should be made with other laboratory facilities that can perform the test. Preferably the test should be available to the patient free of cost (through government provided access) or at low subsidized rates.
- \*\* For patients who are Hepatitis B antigen and antibody negative, HBV vaccination to prevent future HBV infection is recommended.
- For HIV patients not on ART annual labs as indicated by the HTCC physician should be carried out .

## SPECIAL NOTE

For patient who is not responding to treatment after confirmed patient adherence to ART, HIV viral load and HIV resistance testing (genotyping to detect viral mutations) is mandatory. An Infectious Disease specialist should be consulted for input in patient management when resistance is suspected or known to be present.

Facilitation for HIV genotyping is available through the National AIDS Control Reference Laboratory. For details please contact NACP 051-9255367-8 (Dr. Ayesha Khan)

## CHANGING ART CRITERIA

### DRUG REACTION PROTOCOL:

- The presence of a drug reaction secondary to ART will be documented when
  - i) A patient experiences a severe reaction or side effects that have been associated with one of the antiretroviral drugs.
  - ii) In cases where strategies to manage the severe reaction or side effects do not work and the patient experiences increased morbidity, worsened quality of life and increased risk of mortality, ART will need to be stopped.
- The offending medication will be identified and stopped. Another drug in the same class and according to the National Guidelines on ART will be started to replace the stopped drug.
- The patient will be counseled on the new drug, regarding dosing schedule and side effects.
- The reason for change of therapy will be documented in the patients medical record.

### TREATMENT FAILURE PROTOCOL:

Treatment failure will be defined according to the National Guidelines for Antiretroviral therapy based on the following criteria:

- i) **Clinical failure:**
  - occurrence of OIs, wasting or dementia after being on treatment for >3 months
  - recurrence of OIs
  - failure to resolve pre-treatment OIs despite being on ART
- ii) **Immunologic and Virologic failure**
  - A decrease in CD4 cell count to below baseline while on ART.
  - Failure to reduce viral load to undetectable (i.e <400 copies/ml or <50 copies/ml) after 6-12 weeks of triple regimen ART.
  - Consistent and sustained increase in Viral load >1000 after initial suppression.

- Repeated increases in viral load after virologic suppression.

When treatment failure is suspected or known despite appropriate adherence all ART should be immediately stopped.

- Genotype testing will be done for resistance to guide in changing the ART regimen. Till the time that arrangements for genotyping are being made the patient should continue ART regimen.
- In situations where genotyping is not available a completely new 3 drug regimen will be selected according to the National Guidelines on ART.
- The reasons for changing therapy will be documented in the patients medical record file.

#### SPECIAL NOTE

For patients who continue to be non-adherent to ART despite adherence counseling and strategies to increase adherence, ART should be stopped.

## POST EXPOSURE PROPHYLAXIS AFTER EXPOSURE TO HIV

### What is PEP?

Prophylaxis means disease prevention. PEP means taking ARV as soon as possible after exposure to HIV, so that the exposure will not result in HIV infection. PEP should begin within 24-36 hours and should continue for 4 weeks.

### Who Should Use PEP?

#### Occupational Exposure:

An workplace exposure is defined as one that may place a worker at risk of HIV infection through percutaneous injury, contact of mucous membrane or skin (chapped or abraded) with blood, tissue or other body fluids to which universal precautions apply from a person known or suspected to be HIV positive.

Most exposures do not result in infection. Average risk of HIV infection after an occupational exposure is generally low:

Clinical Situation	Risk
Risk with Small amount of blood on intact skin	no risk
Risk with needle stick injury	1 in 300 (0.003%, dependent on type of needle i.e solid versus hollow bore, percutaneous)
Exposure of mucous membrane	1 in 1000 (0.001%)
Risk with broken skin	1 in 1000 (0.001%)

#### Other Non- Occupational Exposure:

Are generally considered to be the following:

- Sexual assault or rape
- Infants exposed to breast milk from HIV infected mothers

#### Factors Affecting Transmission:

- Amount of blood in the exposure
- Higher viral load >100,000 (greater risk)
- Advanced AIDS in source patient

### What Actions to Undertake Upon Exposure?

- DO NOT PANIC. MAJORITY OF EXPOSURES DO NOT RESULT IN HIV INFECTION.
- Do not put the cut/pricked finger into your mouth.
- Immediately wash the exposed area thoroughly with soap and water. No added benefit in using bleach or anti-septic.
- Promptly report exposure to your HIV Treatment and Care Center or (NACP) 051-9255096, 9255367-8. Reporting after 72 hours or 3 days is useless to initiate PEP.
- Determine the HIV status of the exposure source person (i.e HIV viral load, CD4, HIV +, HBV and HCV)
- Decision to initiate PEP must be assessed by the HIV physician or an Infectious Disease specialist.
- If yes to initiating PEP then recommend starting Post exposure prophylaxis as soon as possible within 72 hours (<3 days)

## Regimens for PEP:

For low risk exposures as assessed by the physician:

2 drug regimen:

- ZDV+3TC

For high risk exposure :

Expanded 3 drug regimen :

- ZDV + 3TC + EFV (for men or women in whom pregnancy is definitely ruled out)  
or
- ZDV + 3TC + Nelfinavir (can be given to both men and women)

Decisions to initiate PEP should be made after carefully evaluating the exposure and preferably in consultation with an Infectious Disease specialist. Particularly in rape cases the use of EFV is contraindicated and an Infectious diseases specialist must be consulted. The following table 4 and 5 will assist in categorizing the type of exposure and the need for PEP :

**TABLE 4. Recommended HIV postexposure prophylaxis for percutaneous injuries**

Exposure type	Infection status of source				
	HIV-Positive Class 1*	HIV-Positive Class 2*	Source of unknown HIV status <sup>†</sup>	Unknown source <sup>‡</sup>	HIV-Negative
Less severe <sup>§</sup>	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors <sup>¶¶</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe <sup>¶¶</sup>	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors <sup>¶¶</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted

\* HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

<sup>†</sup> Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

<sup>‡</sup> Unknown source (e.g., a needle from a sharps disposal container).

<sup>§</sup> Less severe (e.g., solid needle and superficial injury).

\*\* The designation "consider PEP" indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

<sup>¶¶</sup> If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

<sup>¶¶¶</sup> More severe (e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein).

**TABLE 5. Recommended HIV postexposure prophylaxis for mucous membrane exposures and nonintact skin\* exposures**

Exposure type	Infection status of source				
	HIV-Positive Class 1 <sup>†</sup>	HIV-Positive Class 2 <sup>†</sup>	Source of unknown HIV status <sup>‡</sup>	Unknown source <sup>§</sup>	HIV-Negative
Small volume**	Consider basic 2-drug PEP <sup>¶</sup>	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP <sup>¶</sup> for source with HIV risk factors <sup>¶¶</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP <sup>¶</sup> in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume <sup>¶¶</sup>	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP <sup>¶</sup> for source with HIV risk factors <sup>¶¶</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP <sup>¶</sup> in settings where exposure to HIV-infected persons is likely	No PEP warranted

\* For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

<sup>†</sup> HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

<sup>‡</sup> Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

<sup>§</sup> Unknown source (e.g., splash from inappropriately disposed blood).

\*\* Small volume (i.e., a few drops).

<sup>¶</sup> The designation, "consider PEP," indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

<sup>¶¶</sup> If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

<sup>¶¶¶</sup> Large volume (i.e., major blood splash).

Special Note: for additional details please consult the National ART Guidelines 2005.

## MAINTAINING PATIENT RECORDS AND CONFIDENTIALITY

Each patient will be given a unique patient identification number and will have a medical record file at the HTCC. The file will contain the following forms:

- Registration form
- Informed consent
- Clinic visits attendance
- ARV Eligibility checklist
- Initial Visit Form
- Follow up Visits
- Laboratory data form
- Counseling form

### Security:

The medical record files will be kept securely in a locked cabinet in the HTCC. On the scheduled clinic days the receptionist will ensure that the medical record files for scheduled patients are available in advance.

### Confidentiality:

"Patient Confidentiality means that only certain individuals will have the right to access patient information that is secure from others". In other words what you see or hear as part of your hospital/clinic duties shall not be discussed without proper permission of the involved person/patient".

How can we ensure confidentiality?

- Understand that patient information that is provided to us in confidence **can not be used or disclosed** without informed consent from the patient. This information can not be disclosed to even close family members or friends without permission from the patient.

### Confidentiality Model

- **Protect**-patient's information
- **Inform**-patients how this information will be used
- **Provide choice**- allow patients to select without pressure.
- **Improve**-think of new ways to protect, inform and provide choice.

## REFERRAL MANAGEMENT

In the context of HIV, a referral is the process by which patient needs for specialized or comprehensive HIV care services are assessed and assistance/facilitation is provided to gain access to such services. Referral should also include reasonable follow up efforts to obtain a feedback on the referral process.

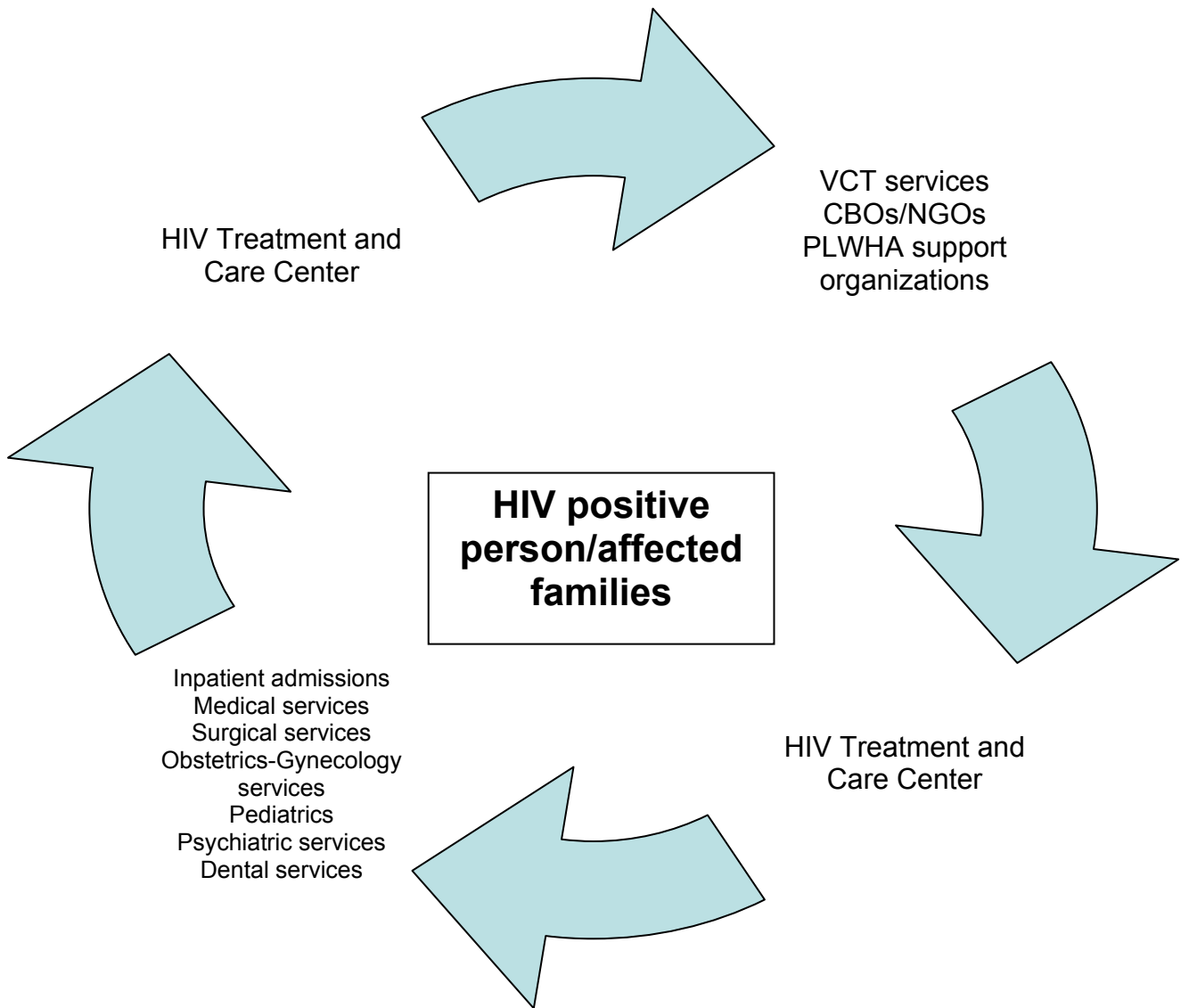
- The physician will determine the need for referral and fill out the referral form.
- The physician/nurse will guide the patient on how to obtain the necessary consultations. Facilitation will be provided by the medical officer or clinic nurse (as applicable)

- Documentation of referral will be put in patient's medical file. At the next visit the physician will inquire about the results of the referral and document them in the medical record follow up form.

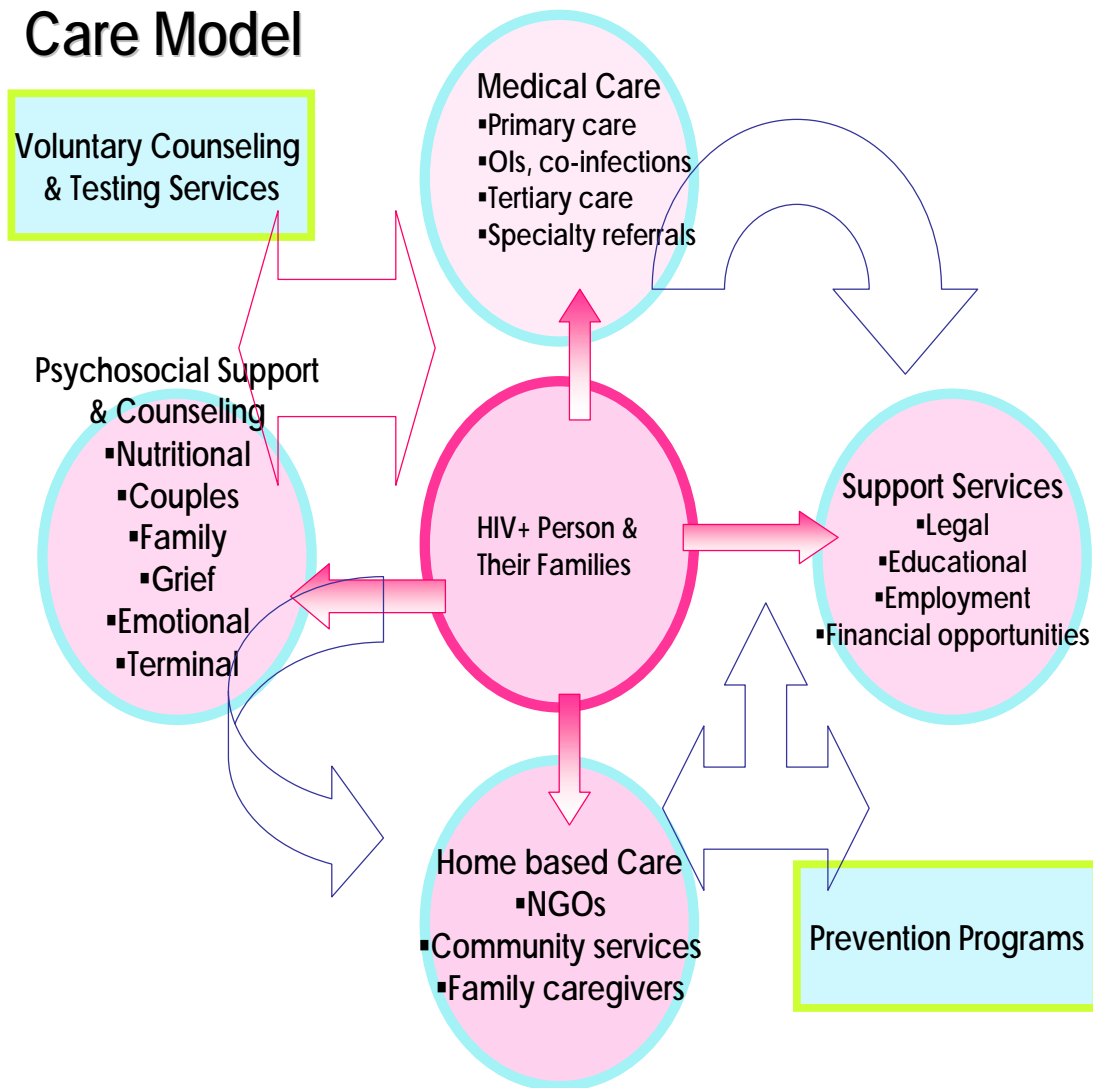
*Referral Services that should be available are:*

- Specialty medical services (i.e pulmonary, cardiology, nephrology, gastroenterology etc)
- Surgical services (adult and pediatric)
- Obstetrics-Gynecology
- Pediatric services
- Psychiatric services
- Dental services
- Others (including social support services)

# Referral Process



# Care Model



## HIV TREATMENT AND CARE CENTER COMMITTEE

The principles of fair process, which should always guide decision making, are particularly important in provision of HIV care services and ART management because they make decisions more acceptable and legitimate. The HTCC should establish clear policies on ART initiation and management so as to avoid decision making that is subjective, biased towards vulnerable and marginalized populations and based on arbitrary criteria. The formation of an HTCC committee to oversee ART management would assist in ensuring that the HIV Treatment and Care Center goals and the national ART selection criteria are being followed in an open and transparent manner.

### **Committee Membership:**

The committee should preferably meet once a month and membership should consist of:

- An Infectious disease physician (in places where available)
- 1 physicians working in the HTCC (can alternate between physician in-charge and medical officer)
- 2 physician working in the hospital preferably from pediatrics and obstetrics-gyn departments.
- 1 Provincial AIDS Control Program Staff member
- 2 PLWHA or 1 PLWHA and 1 PLWHA NGO member

### **Key Responsibilities:**

- Review the patient records and ART Initiation checklist of those started on ART. Patient confidentiality will be maintained and no names will be disclosed.
- Oversee that the National Selection Criteria is being followed
- Discuss relevant concerns or issues regarding the functioning of the HTCC.
- Discuss ways of improving the quality of care services and expanding access to the HTCC.

It should be noted that the HTCC physician will facilitate the monthly committee meeting and prepare a report/minutes of the meeting to share with the committee members. A copy of that report will be sent to the National AIDS Control Program.

## ETHICAL CONSIDERATIONS

The HTCC staff should follow the guiding principles of:

1. **Respect:** for the patient as an individual regardless of HIV status or reasons for having acquired the infection.
2. **Equality:** treat all patients with respect and dignity regardless of social status, religion, education level or occupation.
3. **Gender Equity:** the HTCC policies and staff behaviors should encourage and promote women and children to have equal access to HIV Care and Support.
4. **Quality of care:** strive to provide the best quality care through continuous efforts at improving HIV care delivery systems and referral linkages.
5. **Confidentiality:** maintain patient confidentiality in all aspects of HIV care and support.
6. **Access and Availability:** assist and facilitate the patient in obtaining access to appropriate and timely care when needed.
7. **Maximize Efficiency:** aim to utilize limited resources in ways that maximize the provision of benefits to the greatest number of PLWHA without compromising on quality of care.
8. **Sustainability:** it is the combined obligation of the Ministry of Health/Government of Pakistan, National and Provincial AIDS Control Programs, HIV Treatment and Care Center Staff, PLWHA and other key stakeholders to ensure that effective Care and Support programs continue to develop means to sustain them on a long term basis. Innovative approaches must be considered in resource limited settings as the HIV epidemic grows.

## Appendix 1:

### **REVISED WHO CLINICAL STAGING OF HIV FOR ADULTS AND ADOLESCENTS**

(For use in those 15 years of age or more with positive HIV antibody test or other laboratory evidence of HIV infection)

<b>PRIMARY HIV INFECTION</b>
Unrecognized Acute retroviral syndrome <sup>i</sup>
<b>CLINICAL STAGE 1</b>
Asymptomatic Persistent generalized lymphadenopathy (PGL)
<b>CLINICAL STAGE 2</b>
Moderate unexplained weight loss (<10% of presumed or measured body weight) Recurrent upper respiratory tract infections (sinusitis, bronchitis, otitis media, pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulcerations Papular pruritic eruptions Seborrhic dermatitis Fungal nail infections of fingers
<b>CLINICAL STAGE 3</b>
<b><i>Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations</i></b> Severe weight loss (>10% presumed or measured body weight) Unexplained chronic diarrhoea for longer than one month Unexplained persistent fever (intermittent or constant for longer than 1 month) Oral candidiasis Oral hairy leukoplakia Pulmonary tuberculosis <sup>1</sup> (diagnosed in last two years) Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia ) Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
<b><i>Conditions where confirmatory diagnostic testing is necessary</i></b> Unexplained Anemia (<8gm/dl), neutropenia (<1,000/mm <sup>3</sup> ) or thrombocytopenia (<50,000/ mm <sup>3</sup> ) for more than 1 month
<b>CLINICAL STAGE 4</b>
<b><i>Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations:</i></b> HIV wasting syndrome Pneumocystis pneumonia Recurrent severe or radiological bacterial pneumonia Chronic Herpes simplex infection; (orolabial, genital, or anorectal of more than 1 month duration, or visceral of any duration ) Oesophageal Candidiasis Extrapulmonary tuberculosis Kaposi's sarcoma CNS toxoplasmosis HIV encephalopathy
<b><i>Conditions where confirmatory diagnostic testing is necessary:</i></b> Extrapulmonary Cryptococcosis including meningitis Disseminated non-tuberculous mycobacteria infection Progressive multifocal leukoencephalopathy (PML) Candida of trachea, bronchi, or lungs Cryptosporidiosis Isosporiasis Cytomegalovirus infection (retinitis or of an organ other than liver, spleen, or lymph nodes) Any disseminated mycosis (e.g. Histoplasmosis, Coccidiomycosis, Penicilliosis) Recurrent non-typhoidal salmonella septicaemia Lymphoma (Cerebral or B cell non-Hodgkin's)

Invasive cervical carcinoma  
Visceral Leishmaniasis,

<sup>1</sup> Acute retroviral syndrome : Acute febrile illness 2-4 wks post-exposure often with lymphadenopathy and skin manifestations, pharyngitis.

<sup>2</sup> TB may occur at any CD4 count, and this must be considered where available. If CD4 is less than 200 it should be considered as a stage 4 event. Diagnosis and treatment of both pulmonary and extrapulmonary TB should be in line with international and national guidelines.

## Appendix 2: WHO Classification in Children < 13 years old

(For use in those under 15 years with confirmed laboratory evidence of HIV infection; HIV Antibody where age >18 months, virological or P24 Ag testing for those age <18 months)

STAGE 1
Asymptomatic Persistent generalized lymphadenopathy (PGL)
STAGE 2
Hepatosplenomegaly Papular pruritic eruptions Seborrhoeic dermatitis Extensive Human papilloma virus infection Extensive Molluscum contagiosum Fungal nail infections Recurrent oral ulcerations Lineal Gingival Erythema (LGE) Angular cheilitis Parotid enlargement Herpes zoster Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis.)
STAGE 3
<b>Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations</b> Moderate unexplained malnutrition <sup>n</sup> not adequately responding to standard therapy Unexplained persistent diarrhoea (14 days or more ) Unexplained persistent fever (intermittent or constant, for longer than 1 month) Oral candidiasis (outside neonatal period ) Oral hairy leukoplakia Acute necrotizing ulcerative gingivitis/periodontitis Pulmonary tuberculosis <sup>iii</sup> Severe recurrent presumed bacterial pneumonia
<b>Conditions where confirmatory diagnostic testing is necessary</b> Lymphoid interstitial pneumonitis (LIP) Unexplained Anaemia (<8gm/dl), neutropenia (<1,000/mm <sup>3</sup> ) or thrombocytopenia (<50,000/ mm <sup>3</sup> ) for more than 1 month Chronic HIV associated lung disease including bronchiectasis
STAGE 4
<b>Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations:</b> Unexplained severe wasting or severe malnutrition <sup>v</sup> not adequately responding to standard therapy Pneumocystis pneumonia Recurrent severe presumed bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) Chronic Herpes simplex infection; (orolabial or cutaneous of more 1 month duration, visceral of any duration) Extrapulmonary tuberculosis Kaposi's sarcoma Oesophageal Candidiasis CNS Toxoplasmosis (outside the neonatal period) HIV encephalopathy
<b>Conditions where confirmatory diagnostic testing is necessary:</b> CMV infection (CMV retinitis or infection of organ other than liver, spleen, or lymph nodes onset at age 1 month or more) Cryptococcal meningitis (or other extrapulmonary disease) Any disseminated endemic mycosis(e.g. extra-pulmonary Histoplasmosis, Coccidiomycosis, Penicilliosis) Cryptosporidiosis Isosporiasis Disseminated non-tuberculous mycobacteria infection Candida of trachea, bronchi or lungs Acquired HIV related rectal fistula Cerebral or B cell non-Hodgkin's Lymphoma Progressive multifocal leukoencephalopathy (PML) HIV related cardiomyopathy or HIV related nephropathy

Presumptive Stage 4 diagnosis in children less than 18 months

The presumptive diagnosis is designed for use where access to confirmatory diagnostic testing for HIV infection using virological or P24 Antigen for infants and children less than 18 months is not readily available. It is not recommended for use by clinical care providers who are not trained on ART , accredited or certified and experienced in HIV care, and must be accompanied by immediate efforts to confirm the HIV diagnosis with the best nationally or locally available test.

### **A Presumptive diagnosis of Stage 4 clinical disease should be made if**

An infant is HIV antibody positive (ELISA or rapid test), aged under 18 months and symptomatic with two or more of the following:

- +/-oral thrush,
- +/- severe pneumonia,
- +/- severe wasting/malnutrition,
- +/-severe sepsis

CD4 values where available may be used to guide decision making, CD4% below 25 requires ARV treatment

Other factors that support diagnosis of clinical stage 4 HIV infection in an HIV seropositive infant are:

- recent HIV related maternal death
- advanced HIV disease in mother.

Confirmation of the diagnosis of HIV infection should be sought as soon as is possible

### **Explanatory Notes**

The clinical staging system for infants and children is designed to:

1. Be used where HIV infection is confirmed by HIV antibody testing in children over 18 months of age, virological or P24 Antigen testing in those < 18 months of age.
2. Provide greater consistency between adult and pediatric staging and harmonize with HIV/AIDS surveillance definitions.
3. Classify disease in a progressive sequence from least to most severe, with each higher clinical stage having a poorer prognosis. Once a stage 3 clinical event has occurred, the prognosis remains that of stage 3 and does not improve, even with resolution of the original condition.
4. Provide simple guidance to assist clinical care providers in when to start, substitute, switch or stop ARV therapy in HIV infected infants and children, or trigger referral as outlined in WHO ART guidelines for a public health approach.
5. Be largely used with reference to CURRENT clinical events, meaning clinical events that have been diagnosed or are being managed at this episode.
6. Be considered in relation to previous clinical events, such as reported TB, severe pneumonia, PCP or other conditions. This is RETROSPECTIVE clinical staging and requires caution. **Note:** Reported history of a stage 3 or stage 4 clinical event should have immediate assessment by, or referral to, HIV care providers able to initiate ARV treatment.
7. Be used to guide clinicians in assessing the response to ARV treatment, particularly where viral load and or CD4 counts/or percent are not widely or easily available. However further evidence is required to determine the significance of staging events once on ART.

<sup>1</sup> Moderate malnutrition: Defined as very low weight for age - up to - 2SD for age [http://www.who.int/child-adolescent-health/publications/CHILD\\_HEALTH/WHO\\_FCH\\_CAH\\_00.1.htm](http://www.who.int/child-adolescent-health/publications/CHILD_HEALTH/WHO_FCH_CAH_00.1.htm) or page4 [http://www.who.int/nut/documents/manage\\_severe\\_malnutrition\\_eng.pdf](http://www.who.int/nut/documents/manage_severe_malnutrition_eng.pdf)

<sup>1</sup> As for footnote 2. TB is particularly difficult to diagnose in infants and young children.

<sup>1</sup> Severe Malnutrition: Defined as : visible severe wasting or oedema of both feet and weight for height of -3SD Ref: [http://www.who.int/child-adolescent-health/publications/CHILD\\_HEALTH/WHO\\_FCH\\_CAH\\_00.1.htm](http://www.who.int/child-adolescent-health/publications/CHILD_HEALTH/WHO_FCH_CAH_00.1.htm)

**Annexe 1: Medical History: Initial Visit**

Institution \_\_\_\_\_

Date: \_\_\_\_\_

1. Name: \_\_\_\_\_ Medical Record # \_\_\_\_\_

DOB: \_\_\_\_\_ Age: \_\_\_\_\_ Sex: M  F  Occupation: \_\_\_\_\_

Address: \_\_\_\_\_

Phone #: \_\_\_\_\_ Guardian's name: \_\_\_\_\_

Referral: 1. Self  
 2. NGO/CBO \_\_\_\_\_  
 3. Physician \_\_\_\_\_  
 4. Other \_\_\_\_\_

HIV Test: ELISA (Laboratory \_\_\_\_\_ Dates \_\_\_\_\_  
 HIV test not done or pending \_\_\_\_\_  
 Other .....

**2. Presenting Complaint**

<b>Medical History</b>	
------------------------	--

**3. Personal History**

<b>Education</b>	<input type="checkbox"/> Illiterate <input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> College +
<b>Work (current)</b>	<input type="checkbox"/> Unemployed <input type="checkbox"/> Employed <input type="checkbox"/> Housewife Worked Abroad <input type="checkbox"/> Yes, Country _____ <input type="checkbox"/> No
<b>HIV Exposure</b>	1. Sexual contact <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Sex worker 2. Injecting Drug Use <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Blood transfusion <input type="checkbox"/> Yes <input type="checkbox"/> No 4. Mother-child transmission <input type="checkbox"/> Yes <input type="checkbox"/> No 5. Occupational exposure <input type="checkbox"/> Yes <input type="checkbox"/> No 6. Rape <input type="checkbox"/> Yes <input type="checkbox"/> No 7. Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Substance Use</b>	<input type="checkbox"/> None <input type="checkbox"/> Cigarette <input type="checkbox"/> Alcohol <input type="checkbox"/> Injecting Drugs <input type="checkbox"/> Charas/Bhang <input type="checkbox"/> Other _____
<b>History of STDs</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Gonorrhoea <input type="checkbox"/> Chlamydia <input type="checkbox"/> Syphilis <input type="checkbox"/> Herpes Simplex <input type="checkbox"/> Genital Warts <input type="checkbox"/> Other _____
<b>Marital Status</b>	<input type="checkbox"/> Unmarried <input type="checkbox"/> Married <input type="checkbox"/> Divorce/Separated <input type="checkbox"/> Widow
<b>Spouse HIV Status</b>	<input type="checkbox"/> HIV + <input type="checkbox"/> HIV - <input type="checkbox"/> Unknown <input type="checkbox"/> N/A

Children	Age (years)	Sex (M/F)	HIV Status (+/-)	On ART (Y/N)
Last child (youngest)				
2 <sup>nd</sup>				
3 <sup>rd</sup>				
4 <sup>th</sup>				
5 <sup>th</sup>				

#### 4. Clinical History

Opportunistic Infections		Constitutional Symptoms															
<input type="checkbox"/> TB <input type="checkbox"/> Pulmonary <input type="checkbox"/> Extra-pulmonary (site .....) <input type="checkbox"/> Pneumocystis pneumonia <input type="checkbox"/> Herpes zoster <input type="checkbox"/> Cryptococcal meningitis <input type="checkbox"/> CNS Toxoplasmosis <input type="checkbox"/> Diarrhea <input type="checkbox"/> Candidiasis (Thrush) <input type="checkbox"/> Kaposi's sarcoma <input type="checkbox"/> CMV retinitis <input type="checkbox"/> Lymphoma (NHL or HL) <input type="checkbox"/> Other _____		1. Unexplained fever..... 2. >10% weight loss..... 3. Cough/Shortness of breath..... 4. Diarrhea > 1 month..... 5. Excessive fatigue > 1month..... 6. Neuropathy..... 7. Other _____	<table border="1"> <thead> <tr> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>.....</td> <td>.....</td> </tr> <tr> <td>.....</td> <td>.....</td> </tr> <tr> <td>.....</td> <td>.....</td> </tr> <tr> <td>.....</td> <td>.....</td> </tr> <tr> <td>.....</td> <td>.....</td> </tr> <tr> <td>.....</td> <td>.....</td> </tr> </tbody> </table>	Yes	No	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
Yes	No																
.....	.....																
.....	.....																
.....	.....																
.....	.....																
.....	.....																
.....	.....																
<b>Clinical Examination</b>	Weight ..... Temperature..... BP ..... Pulse..... Respiratory rate..... <input type="checkbox"/> Pallor/Anemia <input type="checkbox"/> Lymphadenopathy <input type="checkbox"/> Oral thrush <input type="checkbox"/> Edema feet <input type="checkbox"/> Rash  Respiratory.....  CVS.....  CNS.....  GI.....  Other.....																

<b>Special Note</b>	1. Currently pregnant? If yes, trimester of pregnancy..... 2. Currently on TB treatment? If yes, date started _____ and regimen..... 3. Drug allergies? Medication name..... 4. Patient consent obtained and signed
<b>Investigations (current or past results)</b>	1. Hemoglobin 2. White blood cells 3. Platelets _____ 4. BUN _____ Creatinine _____ 5. Blood glucose _____ 6. LFTs : Bilirubin _____ ALT _____ AST _____ 7. Hepatitis B _____ Hepatitis C _____ 8. Chest x-ray _____ 9. Sputum AFB smear and culture 10. Syphilis ( VDRL or RPR) _____ 12. CD4 cells _____ HIV viral load 13. Urine analysis 14. Stool O&P

	15. Biopsy .....
	16. Other .....
<b>Current Prescriptions (please include ongoing Ols prophylaxis)</b>	1. _____ 2. _____ 3. _____ 4. _____ 5. _____

**5. Antiretroviral Therapy Record (only for those patients with prior history of ART)**

<b>ART received before?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, duration ..... Regimen ....., prescribed by.....	
Currently on _____	Date started _____	
<b>Reasons for Stopping ART</b>	1. Severe side effects (describe.....) 2. Treatment failure <input type="checkbox"/> Non-adherence <input type="checkbox"/> Resistance 3. Lost to follow up 4. Patient unable or unwilling to continue (financial or personal reasons) 5. Concurrent TB treatment 6. Other _____	
<b>Actions Taken this Visit</b>	<b>Investigations</b> 1. _____ 2. _____ 3. _____ 4. _____	<b>Prescriptions</b> 1. _____ 2. _____ 3. _____ 5. _____

**6. Assessment and Plan**

<b>Assessment</b>	
<b>Plan</b>	
<b>Appointments</b>	1. Counseling <input type="checkbox"/> Yes    Date ..... If no, please state reason..... 2. Next appointment _____

Name of Physician \_\_\_\_\_ Signature \_\_\_\_\_

**Annexe 2: Medical History: Follow up Visit**  
**Institution \_\_\_\_\_**

Date: \_\_\_\_\_

1. Name: \_\_\_\_\_ Medical Record # \_\_\_\_\_

<b>Presenting Complaint</b>	<b>Opportunistic Infection</b> <input type="checkbox"/> <b>No</b> If yes, then specify 1..... 2..... 3.....
-----------------------------	-------------------------------------------------------------------------------------------------------------------------

**2. Constitutional Symptoms**

Constitutional Symptoms		
	Yes	No
8. Unexplained fever	.....	.....
9. >10% weight loss	.....	.....
10. Cough/Shortness of breath	.....	.....
11. Unexplained chronic diarrhea > 1 month	.....	.....
12. Excessive fatigue > 1month	.....	.....
13. Neuropathy	.....	.....
14. Other _____	.....	.....

<b>Special Note</b>	Currently pregnant? If yes, trimester of pregnancy..... Currently on TB treatment? If yes, date/regimen ..... Drug Allergies? Medication ..... .....
---------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------

**3. Clinical Examination**

Weight ..... Temperature ..... BP..... Pulse..... <input type="checkbox"/> Pallor/Anemia <input type="checkbox"/> Oral thrush <input type="checkbox"/> Lymphadenopathy <input type="checkbox"/> Edema feet <input type="checkbox"/> Rash Respiratory.....  CVS.....  CNS.....  GI.....  Other.....
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

**4. Investigations**

	Date	Results
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

**5. Antiretroviral Therapy**

Indications: CD4 count \_\_\_\_\_

WHO Stage 3 or 4 disease \_\_\_\_\_

ART Regimen	Start Date	Stop Date	Switching/Side Effects	Comments/Plan
<b>Actions Taken this Visit</b>	Investigations 6. _____ 7. _____ 8. _____ 9. _____		Prescriptions 1. _____ 2. _____ 3. _____	

**6. Assessment and Plan**

<b>Assessment</b>	
<b>Plan</b>	
<b>Appointments</b>	1. Counseling <input type="checkbox"/> Yes Date _____ If no, please state reason _____ 2. Referral _____ 3. Next appointment _____

Name of Physician \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

**Annexe 3: HIV Treatment and Care Center: ARV Eligibility Form**

Institution \_\_\_\_\_

Date \_\_\_\_\_

Name: \_\_\_\_\_ Medical Record #: \_\_\_\_\_

Age \_\_\_\_\_ Date of Birth \_\_\_\_\_ Sex : Male/Female

Eligibility Criteria	Yes	No
<b>Medical Criteria:</b>		
1. HIV test positive		
2. WHO clinical stage:		
a) Stage III:		
▪ Weight loss > 10% of body weight		
▪ Unexplained diarrhea > 1 month		
▪ Unexplained fever > 1 month		
▪ Oral thrush		
▪ Pulmonary TB		
▪ Other _____		
b) Stage IV:		
▪ HIV Wasting syndrome		
▪ PCP pneumonia		
▪ Extrapulmonary TB		
▪ CMV retinitis		
▪ Toxoplasmosis of the brain		
▪ PML		
▪ Lymphoma		
▪ Kaposi's sarcoma		
▪ Other _____		
3. CD4 count < 200		
4. Date of test _____ 5. Laboratory _____		
6. Completed intensive phase of TB therapy (i.e 1 <sup>st</sup> two months)		
<b>Adherence Criteria</b>		
1. Attended Pre-ART counseling session # 1 (date _____)		
2. Attended Pre-ART counseling session # 2 (date _____)		
3. Attended Pre-ART counseling session # 3 (date _____)		
Eligible for ARVs: Comments _____		
Physician Name _____		
Signature: _____ Date _____		



**Annexe 5: HIV Treatment and Care Center: ART Pre-counseling Form**

Institution \_\_\_\_\_

Date \_\_\_\_\_

Name: \_\_\_\_\_ Medical Record #: \_\_\_\_\_

Age \_\_\_\_\_ Date of Birth \_\_\_\_\_ Sex : Male/Female

Counseling Session # : \_\_\_\_\_ Counselor Name \_\_\_\_\_

Topic	Patient level of Understanding of HIV/AIDS	
1. Patient/Caregiver knowledge of HIV/AIDS: 1. Strong (knows modes of transmission, prevention, signs and symptoms) 2. Basic (knows some modes of transmission, signs and symptoms) 3. Weak (no knowledge of modes of transmission, prevention, signs and symptoms)		
2. HIV/AIDS Information Discussed Today	Yes	No
i) Basics of ART		
• What is ART?		
• What are the benefits and risks of ART?		
• What is ART adherence?		
• Why is ART adherence so important?		
• What is a treatment assistant? Importance of having one.		
• Why is on-going prevention necessary while on ART?		
• Other _____		
ii) Patient Concerns & Barriers to ART		
• Stigma (i.e family, friends will find out, no social support)		
• Anxiety about medicine availability (i.e costs, long term)		
• Depressed about HIV/AIDS		
• Long term commitment to ART?		
• Afraid of ART side effects (i.e toxicities, poison)		
• Financial concerns (job opportunities, social support)		
• Logistical issues of collecting ART (transport issues, travel)		
• Other _____		
iii) Strategies to Cope/Overcome Barriers to ART		
• Disclosure to close family or friends		
• Management of ART side effects		
• Treatment assistant or other medication aides		
• Ongoing counseling (family, friend, patient)		
• Other _____		

Next Counseling appointment \_\_\_\_\_

## Annexe 6: Voluntary Counseling and Testing Form

Institution.....

Date: .....

Patient Name: ..... Medical Record # .....

Age: ..... Sex: M  F  Occupation:.....

Type of visit:  1<sup>st</sup> visit  Follow up visit  Pre-ART visit  Post ART Follow up visit  Other .....

<b>Referral By</b> <input type="checkbox"/> Self <input type="checkbox"/> Physician <input type="checkbox"/> NGO/CBO <input type="checkbox"/> TB Clinic <input type="checkbox"/> VCT <input type="checkbox"/> Other.....	<b>Prior HIV Test</b> <input type="checkbox"/> Yes, date..... Reason.....  <input type="checkbox"/> No	<b>Reason for this visit</b> <input type="checkbox"/> Spouse HIV + <input type="checkbox"/> Spouse death <input type="checkbox"/> STD history <input type="checkbox"/> Risk behavior <input type="checkbox"/> Baby of HIV + mother <input type="checkbox"/> Opportunistic infections <input type="checkbox"/> TB <input type="checkbox"/> Prolonged illness <input type="checkbox"/> Other.....	<b>Education</b> <input type="checkbox"/> Illiterate <input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> College +	<b>Marital Status</b> <input type="checkbox"/> Unmarried <input type="checkbox"/> Married <input type="checkbox"/> Divorce <input type="checkbox"/> Widow	<b>Living Situation</b> <input type="checkbox"/> Alone <input type="checkbox"/> Family <input type="checkbox"/> Friend <input type="checkbox"/> Hostel <input type="checkbox"/> Hotel <input type="checkbox"/> Other	<b>HIV Exposure</b> <input type="checkbox"/> Sexual contact <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Sex worker <input type="checkbox"/> Rape <input type="checkbox"/> IDU needle sharing <input type="checkbox"/> Blood product <input type="checkbox"/> Needle stick injury <input type="checkbox"/> Baby of HIV + mother <input type="checkbox"/> Unknown
<b>Willingness for HIV test</b> <input type="checkbox"/> Yes, <input type="checkbox"/> No	<b>Scheduled Date for Post-test counseling</b>	<b>Test Results</b> <input type="checkbox"/> HIV + <input type="checkbox"/> HIV - <input type="checkbox"/> Indeterminate <input type="checkbox"/> Other.....	<b>Date when Post-test counseling was completed</b>	<b>Who did the person share the test result with</b> <input type="checkbox"/> Spouse <input type="checkbox"/> Friend <input type="checkbox"/> Parents <input type="checkbox"/> Brother/sister <input type="checkbox"/> Partner <input type="checkbox"/> Other	<b>Patient agreed to bring spouse or partner for VCT</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<b>Patient accepted condom</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<b>Type of support required</b> <input type="checkbox"/> Individual counseling <input type="checkbox"/> Family counseling <input type="checkbox"/> Nutritional <input type="checkbox"/> Job placement <input type="checkbox"/> Social/communit y support	<b>Referral to</b> <input type="checkbox"/> Physician <input type="checkbox"/> NGO/CBO <input type="checkbox"/> TB clinic <input type="checkbox"/> STD clinic <input type="checkbox"/> PLWHA linkage <input type="checkbox"/> Other	<b>Patient counseled on</b> <input type="checkbox"/> Test result <input type="checkbox"/> Transmission <input type="checkbox"/> Spouse notification <input type="checkbox"/> Safe sex /condom use <input type="checkbox"/> IV needle cleaning <input type="checkbox"/> Pregnancy <input type="checkbox"/> Repeat testing <input type="checkbox"/> Brochures given <input type="checkbox"/> Other	<b>Follow up date</b>	<b>Key issues discussed</b>	<b>Follow up date</b>	<b>Key issues discussed</b>

<input type="checkbox"/> Mental health services <input type="checkbox"/> Medical services <input type="checkbox"/> Other						
<b>Follow up date</b>	<b>Key issues discussed</b>	<b>Observed or stated change in</b> <input type="checkbox"/> Acceptance of HIV status <input type="checkbox"/> Denial of HIV status <input type="checkbox"/> HIV activism <input type="checkbox"/> Practices safe sex/condom use <input type="checkbox"/> Spouse tested for HIV <input type="checkbox"/> Client depressed <input type="checkbox"/> Social support systems <input type="checkbox"/> Job loss <input type="checkbox"/> Financial situation <input type="checkbox"/> Home situation <input type="checkbox"/> IV needle cleaning <input type="checkbox"/> ..... <input type="checkbox"/> ..... <input type="checkbox"/> .....	<b>Date.....</b> <b>Additional remarks</b>	<b>Date.....</b> <b>Additional remarks</b>		
Next Follow up appointment	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, date .....					
Signature of .....			Date .....			

## Annexe 7: HIV Testing Consent Form Institution.....

Date: .....

I, \_\_\_\_\_ state that I have been counseled about the **HIV tests** (i.e HIV ELISA, CD4,HIV Viral Load PCR, Genotype) to be conducted on me or my son/daughter. Before taking this test I understand that

1. The Human Immunodeficiency Virus (HIV) is responsible for the disease AIDS (Acquired Immunodeficiency Syndrome)
2. The implications of the test results when positive, negative or indeterminate.
3. The details relating to HIV, its transmission, testing procedures, and limitations of the tests including interpretation of results.
4. The tests may require up to 6 months after HIV exposure/infection to turn positive and that repeat testing may be advised upon obtaining a negative or indeterminate result.
5. The test is not diagnostic of AIDS.
6. Results of these tests are confidential and can only be conveyed to the person tested.

I agree that the above mentioned points have been explained to be in a manner that I can understand and that all my questions have been answered. **I hereby give my consent for the test to be conducted on me or my son/daughter to determine the HIV status.**

**I consent to return in person to receive my test results from the physician/counselor in the clinic. I understand the significance of this test and take it voluntarily.**

Name \_\_\_\_\_ Signature \_\_\_\_\_

Date \_\_\_\_\_ Location \_\_\_\_\_

Self/Relation with Patient \_\_\_\_\_

Physician/Counselor Signature \_\_\_\_\_

**Note:**

1. In case of children consent should be obtained from the parents
2. In case of unconscious patient where there is a need for diagnosis of HIV for the management of the patient consent should be obtained from the parents, spouse or the closest relative available at that time.
3. In case no attendant is available, the test if necessary for management may be carried out on the recommendations of two attending physicians.
4. Please note that the general consent obtained for carrying out procedures in hospital does not include HIV consent.

## Annexe 7a: HIV Care Consent Form Institution.....

Date: .....

It is hereby stated that I, \_\_\_\_\_ am voluntarily seeking HIV care at the HIV Treatment and Care Center at \_\_\_\_\_.

By signing this form I understand:

7. The Human Immunodeficiency Virus (HIV) is responsible for the disease AIDS (Acquired Immunodeficiency Syndrome)
8. That I am HIV positive or have AIDS.
9. My medical records will be kept confidential and in a secure place.
10. Disclosure of my HIV status will not be made to anyone without my informed consent.
11. The HIV Treatment and Care Center will provide HIV related medical care including specialty and/or referral services regardless of my HIV positive status. If such services are not available within the hospital premises, I will be informed and given other available options.

I agree to the above mentioned points and all my questions have been answered. **I hereby give my consent for receiving HIV Care at the HIV Treatment and Care Center.**

Name \_\_\_\_\_ Signature \_\_\_\_\_

Date \_\_\_\_\_ Location \_\_\_\_\_

Self/Relation with Patient \_\_\_\_\_

Physician/Counselor Signature \_\_\_\_\_

**Note:**

5. In case of children consent should be obtained from the parents
6. In case of unconscious patient where there is a need for HIV care the patient consent should be obtained from the parents, spouse or the closest relative available at that time.
7. In case no attendant is available, if HIV care is urgent i.e life threatening, HIV medical/surgical care may be carried out on the recommendations of two attending physicians.
8. Please note that the general consent obtained for carrying out procedures in hospital does not include HIV consent.

## Annexe 8: Registration Form

Institution \_\_\_\_\_

Date: \_\_\_\_\_

Name: _____	Medical Record # _____		
DOB: _____	Age: _____	Sex: M <input type="checkbox"/> F <input type="checkbox"/>	Occupation: _____
Address: _____ _____			
Phone #: _____	Guardian's name: _____		
Emergency Contact: _____ _____			
Relationship: _____			
Registration By _____			

Date: _____	
Address: _____ _____	
Phone #: _____	Guardian's name: _____
Updated By _____	

Date: _____	
Address: _____ _____	
Phone #: _____	Guardian's name: _____
Updated By _____	

Date: _____	
Address: _____ _____	
Phone #: _____	Guardian's name: _____
Updated By _____	

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