Republic of Rwanda



Ministry of Health

National Guidelines for Prevention and Management of HIV and STIs

Edition 2016





PREFACE

Today, evidence shows that starting eligible HIV-infected patients on antiretroviral treatment alleviates their suffering and reduces the devastating impact of the HIV pandemic. With more than 210,000 people living with HIV in Rwanda, the expansion of antiretroviral treatment to all patients is a priority.

However, the continued scaling up of antiretroviral treatment is a real challenge that can only be overcome by the participation of all partners, both national and international. Apart from the financial support that is clearly essential, there is the supply of drugs and the monitoring of the mechanisms that have to be set up. Healthcare providers must be trained, infrastructures must be set up or upgraded, education of the community and mobilization of different persons involved in the fight against HIV/AIDS so that they can play their roles, must be carried out.

The target audience for this guideline is primarily for health care providers nurses, doctors, social workers and other people involved in HIV response in Rwanda so that they are capable of offering quality care services to patients over a long time.

The new National Guidelines for Prevention and Management of HIV and STIs are articulated in accordance to treat all HIV+ patients regardless of CD4 count and a new service delivery model to support its implementation.

We are fully aware that in spite of the progress made, there is still a lot to be done in prevention and management of HIV and STIs towards a healthy people and wealthy nation. May this publication contribute to improve the knowledge on HIV/AIDS and STIs of all actors in the health sector and in improving the living conditions of our people.

Dr Diane GASHUMBA Minister of Health

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- The Centers for Disease Control and Prevention (CDC)/ Rwanda
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- The Partner In Health (PIH) Inshuti Mu Buzima/ Rwanda
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Dr Sabin NSANZIMANA

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MAIN ACO	CRONYMS AND ABBREVIATIONS		
3TC	Lamivudine		
ABC	Abacavir		
AES	Accident d'exposition au sang		
APRI	Aminotransferase Platelets Ratio Index		
ARV	Antiretroviral		
AZT	Azidothymidine		
CD4	Cluster of Differentiation 4 (Stands for T4 Lymphocytes)		
CDC	Centre for Diseases Control and Prevention		
CMV	Cytomegalovirus		
CTM	Cotrimoxazole		
ddI	Didanosine		
DNA	Deoxyribonucleic Acid		
EFV	Efavirenz		
FTC	Emtricitabine		
HBe Ag	Hepatitis B Envelop Antigens		
HBs Ag	Hepatitis B Surface Antigens		
HBV	Hepatitis B Virus		
HCV	Hepatitis C Virus		
HIV	Human Immunodeficiency Virus		
HTS	HIV Testing Services		
IDR	Intradermal Reaction		
IDV	Indinavir		
LDV	Ledipasvir		
NFV	Nelfinavir		
NNRTI	Non Nucleoside Reverse Transcriptase Inhibitor		
NRTI	Nucleoside Reverse Transcriptase Inhibitor		
NVP	Nevirapine		
OI	Opportunistic Infection		
PCR	Polymerase Chain Reaction		
PEG-INF	Pegylated Interferon		

PI	Protease inhibitor
PLHIV	Person living with HIV
PMTCT	Prevention of mother to child transmission
RNA	Ribonucleic Acid
RTV	Ritonavir
TDF	Tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
VZV	Varicella zoster virus
WHO	World Health Organization

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PART I. HIV PREVENTION

1. HIV PREVENTION

1.1. Introduction

This chapter offers background, definitions, summaries of service objectives, and a description of the package of activities associated with each aspect of prevention programming.

Prevention of HIV is part of the minimum package of services offered by health centres, specifically sensitization, HIV testing, counselling, and prevention of mother-to-child transmission services. This chapter describes the standards governing HIV prevention services in Rwanda. These standards cover the conditions a health centre must meet to provide HIV prevention activities. They include, among others, the location of activities and the conditions for opening prevention activities in a health facility.

1.2. Location of Activities

HIV prevention activities must be integrated into the package of services offered by all public health facilities and be included in outreach activities in the community. In addition, by agreement of the district hospital, private health facilities and some non-health structures may also carry out prevention activities.

1.3. Opening Prevention Activities in Health Facility

Authorization to open a site will be given through the district hospital to any health facility or organization recognized by the Ministry of Health located in its catchment area. The authorization will be offered by the Rwanda Biomedical Centre, after an assessment of the facility to ensure minimum standards are met.

During the assessment of the health facility, district hospital technicians must ensure that certain criteria are met, including the existence of trained personnel, required infrastructure, and equipment as further detailed below.

1.3.1. Training of the Personnel

To provide HIV prevention services, the health facility should have certified staff with relevant trainings. Healthcare providers are trained using standard training modules validated by the Rwanda Biomedical Centre. These trainings are integrated and must combine all HIV prevention strategies including HIV testing services (HTS), HIV prevention based on ART (PMTCT and PEP), Voluntary Medical Male Circumcisions (VMMC), Condoms, additional prevention services for key populations, and linkage to care and treatment services for those who test HIV positive. Refresher trainings of personnel should be organized every two years to ensure continuity of training of staff.

Every healthcare provider should be able to provide HIV prevention services. These include doctors, nurses, social workers, nutritionists, clinical psychologists, laboratory technicians, and pharmacists. The specific services provided will vary according to the professional's area of expertise.

1.3.2. Required Infrastructure

The infrastructure must enable the provision of high-quality services and be designed in such a way as to respect confidentiality and allow for easy dialogue. In order to offer HIV prevention services, a health facility must have at least one reception room, a counselling office, and a laboratory. Health facilities which offer PMTCT services must also have a maternity ward built and equipped according to MOH standards.

For details regarding the required infrastructure, refer to the "Health Facility Evaluation Form" available at "www.moh.rw"

1.3.3. Required Materials and Equipment

To provide clinical HIV prevention services, a health facility must have the suitable material and equipment according to the MoH.

Apart from office equipment, the health facility must have national guiding documents for reference:

- HIV Prevention guiding document including up-to-date guidelines and training manuals
- Health provider manuals and training manuals
- Standards operating procedures (SOP) for all HIV preventions strategies

• IEC materials and demonstration tools

For details regarding the required materials and equipment, refer to the "Health Facility Evaluation" at www.moh.rw

1.4. Ethical Considerations for Operating HIV Prevention Services

1.4.1. Consent for HIV Testing

The decision to be tested must be made by the person concerned. This person has the right to receive all the information related to HIV testing and all the possible outcomes prior to giving consent to be tested and counselled. Verbal consent is sufficient and written consent is not required.

Any person aged 12 and over may provide his or her own verbal consent for an HIV test. However, the counsellor should assess each child's capacity to consent to HTS. In order to consent to an HIV test, a child must be able to:

- 1. Understand information about the benefits, risks and social implications of HIV testing; and
- 2. Act accordingly (i.e., agree or refuse to test) based on that understanding; and
- 3. Understand and cope with his or her own seropositivity.

For children under 12 years of age, the consent of a parent or a legal guardian is required. Due to the young age at which first sexual activity may occur and children's vulnerability to HIV and other STIs, an exception can be made for specific cases such as key populations including sex workers, men who have sex with men, people who inject drugs, or for girls who are pregnant, etc.

If the person does not have all of his mental faculties to make an informed decision about the test, the procedure will be performed only when it is certified to be in his or her medical interest. Under these circumstances, the decision to test should be made by a family member or a legal guardian.

1.4.2. Confidentiality

Confidentiality is the client's right and an obligation of the provider. Confidentiality means to keep the client's information private. Patient information can only be shared with others when the patient has given consent to release the information. Confidentiality must be guaranteed at all stages of the counselling process. The client's confidentiality is protected by ensuring the following:

- Files and records of clients must be kept confidential.
- System of archiving and storing client files must be designed in a way that guarantees confidentiality.
- All personnel with access to medical records or test results are bound to confidentiality.

In case of referrals, it is mandatory to observe the rules of shared confidentiality.

1.4.3. Pricing

HIV counselling and testing services are offered free of charge at all public health facilities recognized by the Ministry of Health of Rwanda. Accredited private clinics can also offer HIV testing to individual adults or couples at a price determined by the MOH rules and regulations.

2. HIV DIAGNOSIS

2.1. HIV Testing and Counselling (HTS)

The overall goal of HTS is to identify as many people living with HIV as early as possible after acquiring HIV infection, and link them in a timely manner to appropriate prevention, care, and treatment services. The people tested who are not infected should receive appropriate counselling to remain HIV negative and be linked to appropriate prevention services.

HTS services include both voluntary HIV counselling and testing (VCT) and provider initiated HIV testing and counselling (PITC). VCT services are provided to the client who decides on his/her own to undertake HTS, while PITC are when the health care provider's offers HTS for a client who consulted for any other health problem. PITC is an important approach for increasing the uptake of HIV testing.

2.1.1. HTS Guiding Principles

All forms of HTS should be voluntary and adhere to the **five C's**:

- <u>C</u>onsent,
- <u>C</u>onfidentiality,
- <u>C</u>ounselling,
- <u>Correct test results and</u>
- <u>C</u>onnections to care, treatment and prevention services.

Mandatory or coerced testing is never appropriate, whether that coercion comes from a healthcare provider or from a partner or family member.

Connections to prevention, care, and treatment services should include the provision of effective referral to appropriate follow-up services as indicated, including long-term prevention and treatment support. Each positive case must have an enrolment number (for example TRACnet Number) in the HTS register as an observation.

2.1.2. Settings for HIV Testing and Counselling (HTS)

Diverse models of HTS service delivery are used with the aim to increase population's access to HIV testing. Services are available in health care facilities, non-health facilities (e.g. Youth Friendly Centres) and in the community. Each setting involves specific HTS approaches:

HIV Testing and Counselling in Health Facilities

It is recommended to routinely offer HTS in clinical settings through both VCT and PITC. VCT services are offered at hours by determination of the health facilities and follow the steps outlined above.

PITC is an efficient and effective way to identify people with HIV who could benefit from treatment. PITC in Rwanda is offered in both public and private facilities and it is recommended in the cases below:

- Adults, adolescents or children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including TB
- HIV-exposed infants, children born to women living with HIV, and children with suspicious symptoms
- PITC should be considered in services for sexually transmitted infections, hepatitis and TB
- In antenatal care services and services for key populations (notably sex workers, men who have sex with men, and people who inject drugs).

PITC activities are guided by the same principles of HTS outlined in section 2.1.1 (pre-test counselling, consent, testing, post-test counselling, and linkage to appropriate care and treatment or preventions services). For outpatients, the provider receiving the patient conducts HIV counselling and testing. For inpatients, it is recommended to have a team of HIV counsellors carrying out

the tests in all hospital services. See section 2.1.3 for detailed guidelines on pre-test counselling, testing, post-test counselling, and linkage to further services for treatment or prevention.

Community-Based HIV Testing and Counselling

HTS can be offered in a variety of settings in the community. The same principles for HTS outlined in section 2.1 also apply for community-based HTS (pre-test counselling, consent, testing, post-test counselling, and linkage to appropriate care and treatment or preventions services).

In Rwanda, community-based HTS (often referred to as **outreach or mobile HTS**) is recommended for key populations (specifically sex workers, men who have sex with men, mobile populations, etc.) with linkage to prevention, care, and treatment services.

Refer to section 2.1.3 for detailed guidelines on pre-test counselling, testing, post-test counselling, and linkage to further services for treatment or prevention.

2.1.3. HIV Testing and Counselling Procedures

HTS steps for both VCT and PITC include: (1) *Pre-test counselling*, including *information*, *education and communication*(IEC) for behaviour change; (2) *HIV testing* in the counselling room using rapid testing; (3) *Post-test counselling* and *delivery* of the results and its significance. During this session, clients receive appropriate counselling according to their results; (4) *Linkage to care and treatment* for those tested HIV positive *or ongoing prevention services* as appropriate for those who tested HIV negative.

Refer to **annex.1.0** HIV Testing and Counselling Procedures for each steps to be undertaken.

Pre-test Counselling

Pre-test counselling should be shortened as much as possible and be provided to all people seeking or requiring HIV testing. It may be provided individually, to a couple, to a group of people or, if necessary, to a parent or guardian (for children below 12 years, people not in command of all their mental faculties, and people with disabilities). Written/verbal informed consent is required according to the guidance outlined in section 1.4.1. In case of language problems, the counsellor may use an interpreter so that all steps of the counselling process are followed. This must be done with respect to confidentiality.

When pre-test counselling is provided in *a group*, it is an opportunity for Information Education and Communications/Behaviour Change Communications (IEC/BCC). Clients receive comprehensive information on HIV and AIDS, including the difference between HIV and AIDS, the importance of being tested, modes of transmission, means of prevention, possible results and their implications, availability of care and treatment services, as well as demonstration of male and female condoms. Then the clients have an opportunity to ask questions and receive answers.

Individual pre-test counselling takes place in the counsellor's office, where clients are received one by one. It must follow the pre-test approach, which includes

(1) Reception, presentation and screening for eligibility,

(2) assessment of the client's knowledge of HIV and AIDS,

(3) HIV risk assessment,

(4) discussion on sexual activities (encouragement of couple testing),

(5) HIV risk reduction plan (Abstinence, Being faithful to one partner,

Condom use, Don't share needles, Education and information for behaviour change (ABCDE),

(6) preparation for HIV testing and possible outcomes,

(7) provision of information on availability of care and treatment services in case of a positive result, and

(8) obtaining free and informed consent for testing according to consent guidelines in section 1.4.1.

HIV Testing

For HIV testing, blood is drawn from capillaries by pricking the finger (*"finger prick"* method) because this method is easy to use, less invasive than other blood draws, and better tolerated by clients. Health worker and non-health worker counsellors can be trained to perform HIV testing using the fingerpick method. In particular situations, like antenatal clinics, venepuncture might be the most appropriate option to ensure clients comfort given the number of blood-related tests to be performed.

The New HIV rapid testing algorithm comprises of 2 stage tests:

- Determine as First screening test (Determine TM HIV-1/2 Ag/Ab)
- Stat Pak as Second screening test (HIV 1/2 STAT-PAK)
- HIV Rapid Test Algorithm, version 2016, Rwanda



Notice: The Special Case for inconclusive results

Send samples of Elisa without waiting 4 weeks for the following groups:

- Pregnant women attending antenatal clinics and delivery room,
- Couples who seek HIV testing for marriage
- Rape cases

Quality control is ensured mainly by using *Proficiency Testing Panels*. The National Reference Laboratory (NRL) supervises this program. Verification (Retesting) is recommended to all HIV+ before initiation of ARVs.

The first HIV testing is performed by a nurse in different entry points using finger prick method. For the positive cases, a verification HIV test will be performed by a lab technician the same day, using the same algorithm but with a new blood sample.

Health Facilities are advised to follow the recommendations of the test manufacturer and the NRL regarding HIV testing (internal quality control and external quality control). HIV testing can only be performed by healthcare providers and counsellors trained on finger prick and the use of the above-mentioned algorithm. This test can be performed in various settings within a health facility (counsellor room, maternity, hospitalization wards, consultation room, OPD, etc.) or in the community during outreach activities.

Announcement of the Result

The results of an HIV rapid test are to be given within 10-0 minutes. The communication of the results is verbal.

Clients requesting written results for any reason must be taken/reviewed by to medical facilities authorized to deliver written results. Positive or negative results is temporary and may change depending on many factors (client exposure after previous test, window period, inconclusive results, sample and human errors) therefore written results should be interpreted with cautiousness.

For clients able to give their own consent per section 1.4.1, HIV test results should be given to the consenting individual or consenting couple.

For those under the age of 12 or those unable to provide consent for themselves, their results should be communicated to the parent or guardian. The client must himself or herself be present when the results are communicated and for minors appropriate counselling for their age must be given.

Post-Test Counselling

The same person who gave the pre-test counselling should provide post-test counselling. In case of language problems, the counsellor may use an interpreter so that all steps of the counselling process are followed. This must be done with respect to confidentiality.

In case the client is a child below 12 years or an adult not in command of all of his mental faculties, post-test counselling will be given to the parents or guardian in the client's presence.

In case of *negative results*:

- Post-test counselling will insist on the risk reduction strategies for HIV prevention and the counsellor should explain to the client about the seroconversion period and its implications. The counsellor should also encourage clients to bring their sexual partners for HIV testing.
- For high-risk clients who test HIV-negative such as commercial sex workers, men who have sex with men, or HIV-negative partners in discordant couples, the counsellor will encourage HIV risk

reduction behaviours and the importance of retesting every 12 months.

- Pregnant women in serodiscordant couple relationship should be encouraged to retest every 3 months until the end of PMCT follow up period of 24 months post-partum.
- Negative clients who are not at high risk of HIV infection should be advised to keep protecting themselves against HIV seroconversion and plan to retest only after any other risky contact.

In case of *positive results*:

- Post-test counselling will encourage on risk reduction and secondary prevention of HIV infection.
- HIV-positive clients will be referred to a comprehensive HIV care and treatment unit for follow-up and enrolment into the service. See section 8, below, on procedures for linkage to care and treatment.
- Initiation of ARVs should be as soon as possible, within a week preferably, except special cases that require more preparation of the clients.
- Clients must be encouraged to live positively, to reduce further exposure, and to avoid transmitting new infections to others.
- Clients are advised to disclose their status to their sexual partners and invite them for HIV testing. For clients who test positive and have children, they are encouraged to bring them in for testing as well.

2.1.4. HIV Testing and Counselling in Specific Cases

The following paragraphs describe the procedures for HIV counselling and testing in the case of couples, adolescents, children, key populations, blood transfusions, organ donations, mobile VCT, survivors of sexual assault, and body fluid exposure accidents.

Couples

The couples HTS model was proven acceptable, feasible and effective. It allows identifying sero-concordant positive couples who are then linked to care and treatment services. It also identifies couples with sero-discordant HIV test results that can benefit from HIV prevention interventions specifically for sero-discordant couples as well as HIV treatment for the HIV-positive partner.

Services should be offered to married and cohabiting couples, premarital couples, polygamous unions, and any other partnerships free of discrimination. It is important to ensure that the process is entirely voluntary and no member of the couple is forced to take the test. If the counsellor suspects any coercion on a member of the couple, the counsellor should encourage the couple to return after they have made the decision jointly and without any coercion.

The counselling and testing of couples involves a confidential dialogue between the two people in a couple and a counsellor to enable the couple to overcome stress, assess the risk of HIV transmission within the couple, and make decisions about adopting preventive behaviours.

In all settings, couples and partners should be offered voluntary HTS with support for mutual disclosure.

Pregnant Women

HIV testing and counselling for pregnant women as well as linkage to care and treatment are needed to promote the mother's health and prevent new paediatric infections (for details see PMTCT guidelines in section 3). All pregnant women who previously tested HIV-negative during ANC or with an unknown HIV status should be offered an HIV test during labour or 12 hours after delivery.

Infants and Children (young than 10 years)

HIV-exposed infants and children younger than 18 months should be tested within the first 6 weeks of birth so that those already infected with HIV can start ART. The follow-up testing schedule for HIV-exposed infants up to age 18 months is outlined in the PMTCT guidelines in section 2.2.1.

In HIV-exposed infants, HIV infection can only be definitively confirmed using virological tests because of the presence of persisting maternal HIV

antibody in the child up to 15–18 months of age will lead to reactive rapid tests (for details see PMTCT guidelines in section 2.2.1).

Children of school age (7 years and older) should be informed of their HIVpositive status in the presence of their parents or caregiver. The disclosure should be conducted after an attentive assessment of their cognitive and emotional maturity.

Adolescents (10-19 years)

Adolescents are often underserved and given insufficient priority in many HIV programs, leading to poor access and uptake of HTS as well as linkage to prevention and care.

Adolescents living with HIV include those surviving perinatal infection and those newly acquiring infection as they become sexually active. Infants infected by their mothers should be diagnosed through PMTCT programs and initiate antiretroviral treatment immediately. Sexually active adolescents are also vulnerable to HIV infection and would benefit from access to friendly, acceptable and effective HIV services, including HIV testing and counselling as well as HIV care and treatment for those who are HIV-positive. Youth friendly services are needed to provide a comfortable environment for youth to access HTS and other sexual health services. Consent issues may pose a barrier to access HTS services for adolescents for those under the age of 12. HTS with linkage to prevention, treatment and care, is recommended for adolescents from key populations in all settings. Adolescent must receive special post-test counselling from a trained counsellor about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose.

Key Populations

Innovative and tailored models for delivering HIV testing to key populations are needed (e.g., mobile services, home-based testing) to reach these groups at high-risk of HIV infection (commercial sex workers, men who have sex with men, and serodiscordant couples). Special consideration should be given to different testing models including voluntary, provider-initiated, and couples and partner testing. Use of rapid test kits with same day results paired with post-test counselling is recommended in all circumstances for key populations.

To reach the majority of key populations, healthcare providers, in collaboration with peer educators will plan and conduct outreach HTS targeting key populations in the catchment areas of the health facilities.

HTS is a gateway to other interventions which will be carried out in compliance with all the steps and procedures as described in this document.

Healthcare providers must address the specific needs of these groups while also respecting the principles of HTS outlined in section 2.1.1 (obtain the informed consent of clients, offer pre-test and post-test counselling, ensure confidentiality and ensure proper client follow up). Linkage to care is essential for those testing HIV-positive and outreach testing requires additional effort for linking and enrolling those who test HIV positive into HIV care and treatment services. HIV negative individuals in key populations should receive strong risk reduction counselling and be encouraged to get tested for HIV every 12 months. They should be supported to linked to other prevention services such as VMMC, access to condoms, STI screening and treatment.

Who to Test	When to Test	Where to Test
People with signs or symptoms of HIV infection	Integrate in health care encounter	In all healthcare settings
Partners of people with HIV	As soon after partner diagnosis as possible; For the negative person in serodiscordant couples, offer retesting every12 months	In all healthcare settings, VCT
Families of individuals testing HIV-positive	As soon as possible after the family member is diagnosed	In all healthcare settings, homes, community outreach
Key populations: Men who have sex with men and sex workers	Every 12 months	In all healthcare settings, outreach services for key populations, and harm-reduction services
Pregnant women and their partners	At the first antenatal care visit, offer retesting for HIV negative during labor	In antenatal care services, maternity services
Infants and children <18 months old	Early infant diagnosis at 6 weeks for all infants whose mothers are living with HIV, HIV-negative mothers with HIV positive partners or if maternal HIV status is unknown; Determine the final infant HIV infection status after 18 months and/or when breastfeeding ends.	In clinical services for dried blood spot testing, Maternal and child health services, Paediatric clinics, Immunization clinics
Children with signs or symptoms of HIV infection or who have a family member living with HIV	Integrate in health care encounter	In all healthcare settings
Adolescents from key populations	Every 12 months	Youth-friendly services, STI clinics, outreach.

Table 1: Summary of HIV Testing & Counselling Recommendations

3. PREVENTION OF MOTHER TO CHILD TRANSMISSION

3.1. Prevention of Mother-to-Child Transmission of HIV

In countries where breastfeeding is a common practice like in Rwanda, the probability of transmission of HIV from the mother to her child (MTCT) is very high in the absence of prevention interventions with ART. Probability of transmission varies between 20-45%, with 5-10% % chance of transmission during pregnancy, 10-20% during delivery and 5-20% during breastfeeding. In developed countries where PMTCT programs are well implemented and where the most efficacious ART is provided to HIV-positive pregnant women with limited breastfeeding, the level of mother to child transmission for HIV is below 2% at 18 months.

Since 2012, Rwanda has been implementing WHO Option B+ which means starting ART for all HIV positive pregnant women regardless the level of CD4 count, exclusive breastfeeding protected by ART, and mothers continuing ART as a lifelong treatment. The implementation of Option B+ has reduced the MTCT rate at 18 months, recent data show an MTCT rate of 1.8% in a cohort of exposed infants.

3.1.1. PMTCT Package of Services

The PMTCT program is based on a comprehensive four-pronged approach including:

- (1) Primary prevention of HIV infection among women in childbearing age
- (2) Preventing unintended pregnancies among women living with HIV
- (3) Preventing HIV transmission from women living with HIV to their infants
- (4) Providing appropriate treatment, care and support to mothers living with HIV, their children and families

HTS is recommended for pregnant women as a key component of the package of care in all antenatal services. All pregnant mothers attending ANC will receive HTS preferably with their partners, at the time of their first visit to ANC. Strong emphasis will continue being put in male partners' involvement in PMTCT cascade, starting by attending ANC together and couples HIV counselling and testing.

In addition to testing at the first ANC visit, it is recommended that retesting occur for the couple again at the time of labour. The rationale of re-testing is the risk of acquiring HIV infection during pregnancy and a possibility of seroconversion before delivery. Refer to **annex 1.1**. Table summarizing a package of activities in PMTCT.

3.1.2. ARVs for Women of Reproductive Age

All HIV-positive women should be provided with counselling on family planning. The use of condoms among women who are HIV-positive remains an important strategy for preventing transmission of HIV to uninfected partners. Contraceptives are an important part of a woman's reproductive rights and are an important strategy for PMTCT and every PMTCT site should also provide family planning services.

It is safe to use all contraceptive methods with ARVs. The patient's clinical status should be reviewed and an IUD should not be newly inserted if the patient is in clinical stage 3 or 4. However, a patient with a current IUD in clinical stage 3 or 4 can continue using their IUD.

3.1.3. Pregnancy Desire

It is necessary to regularly discuss pregnancy desires with HIV-positive female patients during follow up because most patients will not talk about it spontaneously. Ultimately, it is the woman's right to choose whether or not she would like to become pregnant.

The healthcare provider together with the client should have more than one counselling discussion, preferably together with the male partner, focusing on the pregnancy desire, associated risk on mother's health, and the risk of mother-to-child HIV transmission. The healthcare provider should accompany the woman/couple in their decision making process. If the woman/couple decides to bear the pregnancy, the healthcare provider will conduct close follow up of the mother in order to ensure good biological indicators (viral load suppression, absence of opportunistic infection and sexually transmitted infections) and decide the less risky time for conception. Counselling on infant nutrition, HIV testing and follow up is also a key component.

In a discordant couple, the desire for pregnancy should consider seriously the risk of HIV transmission to the HIV-negative partner. The health care provider should assist the couple to identify the woman's fertile period. It is recommended that conception is attempted during this period, in order to limit repetitive attempts that increase the risk of HIV transmission. Additionally, early initiation of ART and special adherence follow-up for the HIV-positive partner should be provided.

In summary, the points to be evaluated when a HIV-positive woman wishes to become pregnant are:

- Is the partner's HIV status known?
- Is the disease stable for the HIV-positive partner? Check for:
 - Viral load suppression
 - Good evolution in CD4
 - Good clinical evolution
- Is the ARV treatment available and correctly taken?
- Information on the risks to the mother, baby and the partner.
- What is the social support that the patient is receiving?

3.1.4. Guidelines on ART Drugs in HIV Positive Pregnant Women

It is recommended that any HIV-positive pregnant woman receives all care including ART in the same health facility. This will be possible since the process of delegation of powers **(task shifting)** from physicians to the nursing staff is being implemented in our health system since 2009. The district hospital must do the maximum to oversee this approach.

Initiation of ART for pregnant women should start as early as possible following the guidelines outlined in the Treatment and Care section below.

The following situations are possible among HIV-positive pregnant women:

- The first line regimen is composed of TDF + 3TC + EFV
- Any woman with impaired renal function or likely to have impaired renal function will receive **ABC** + **3TC** + **EFV**
- In case EFV is contraindicated, Nevirapine can be given only to those with CD4 cell count below 350. For those above 350 CD4 cells, Atazanavir is recommended but can be replaced by Kaletra

• If a woman has already started ART for her own health, there is no need to change the regimen except in case of side effects. The woman should continue the same regimen.

There are three particularities of provision of ART to pregnant women:

- Adverse side effects are more common and may influence the choice of the ARV drugs (e.g. risk of severe rash with NVP treatment is seven times higher than for men).
- Lactic acidosis and hepatic steatosis are more common when using nucleoside analogues/NRTIs (83% of the first 107 cases that were reported).

NB: Doses are the same as in adults HIV Treatment (see details in care and treatment chapter). Monitoring of renal function is important.

3.1.5. HIV-Negative Pregnant Women in a SDC

An HIV-negative woman in a serodiscordant couple (i.e., the partner is HIVpositive and the woman is HIV-negative) will need to be tested for HIV every three months, as well as at the onset of labour.

- If she is shown to be HIV-positive: refer to the section on ART for HIV-positive pregnant women (see section 3.1.5).
- If she remains HIV-negative, she will receive during labour: A single dose of TDF + 3TC + EFV and continue with TDF + 3TC (one combined tablet per day) for one week after delivery.

3.1.6. HIV Exposed Infant Prophylaxis

<u>Prophylaxis in Children Born in a SDC where the mother is newly diagnosed</u> <u>HIV</u>

If the mother is shown to be HIV-positive at the time of breastfeeding, she should be put on ART and the child should start combined AZT and NVP for six weeks after initiation of the mother's ART. Adherence to ART has to be reinforced.

ARV Prophylaxis for Infant Born to HIV+ Mothers

All children born to HIV-positive mothers, whether the mothers breastfeed or not, will receive Nevirapine (NVP) syrup from birth for the first six weeks of life. The baby will start Cotrimoxazole syrup at the age of 6 weeks and will be discontinued after final confirmation of HIV negative status at 24 months post breastfeeding.

3.1.7. Postnatal Consultation for the Mother-Child Pair

The follow up of the mother-child pair will include:

- 1. Counselling on infant feeding and nutrition
- 2. Routine follow-up of the mother's HIV
- 3. Infant growth monitoring and evaluation of nutritional status

Infant feeding and nutrition:

Advice on a healthy and balanced diet for the child and the mother must be given continuously to the mother. Counselling on nutrition and infant feeding should have begun as soon as pregnancy test results were announced and will continue through postnatal counselling.

The recommended feeding method for the infant is as follows:

- Exclusive breastfeeding until 6months
- Introduction of healthy, balanced, and appropriate complementary food at six months and continuation of breastfeeding without exceeding the maximum recommended duration of 18 months
- Weaning should be done gradually over a period of 2 months; then a final confirmation test should be done at 24 months; advice and nutritional support are necessary during this period.

If a mother chooses not to breastfeed, the following is recommended:

- Make sure that safe and adequate replacement food is available.
- The health care provider should give appropriate advice on substitute milk to use, healthy and balanced complementary foods to offer starting at six months.
- If the mother chooses replacement feeding, the child must be fed exclusively by replacement feeding and never breastfed. It is important to give clear explanations on how to clean the feeding bottles or cups and how to sterilize them using boiling water. Access to clean water is an important factor and must be evaluated before considering artificial feeding.

The success of artificial feeding depends on:

- The quality of the counselling that was given: the issue of infant feeding should be discussed as early as possible following the disclosure of seropositivity.
- The family and/or community support received by the mother.
- The quality of mother and infant follow-up done by the health care team.

Routine Follow-up of Mother's HIV

Follow-up of the mother's HIV should continue per usual care guidelines outlined in the care and treatment section.

- Regular clinical follow up of the mother and child will occur together
- ARV adherence should be continuously ensured
- Ensure mother's biological regular follow up

Infant Growth Monitoring and Evaluation of Nutritional Status

The first 2years of life are a period of rapid growth in children. The average child's weight at birth is about 3kg. The child doubles his/her birth weight after 6months and triples it after one year. At 2years, he/she weighs about 12kg on average.

The size of the child is about 50cm at birth. It increases to about 75cm after one year and to 85cm after two years. Head circumference is between 33cm and 36cm at birth. It increases to about 45cm after one year and to 47cm after two years.

The anthropometric parameters most commonly used for growth monitoring of children are as follows:

- Weight: The naked or lightly dressed (without shoes) child is weighed with a well-calibrated scale. Height: Children under two years should be measured lying down; older children should be measured upright using a height board. Never use a tape measure.
- Head circumference: This should be measured in all children under five years every time they have contact with the health centre. A tape measure should be used and should be passed around the frontal and occipital bones.

Regular growth monitoring is critical to following an HIV-exposed or infected child and can allow for early detection of weight, height, and head circumference abnormalities. If any, the exact cause will be sought to undertake appropriate treatment and allow the child to realize his full growth and development potential.

Completing growth charts: <u>At each consultation</u>, the weight, height, and head circumference should be recorded on the growth chart in the child's file.

- All HIV-exposed infants should be completely examined (weight, size, neurological development, suspicious signs of infection) every month until they reach 18 months.
- If the child shows growth or neurological problems, or suspicious signs of infection (fever, impaired general condition, dyspnoea, etc.), he will be immediately referred to a doctor.
- Assess nutritional status monthly, and interpret the results to offer appropriate advice and nutritional care given that HIV-exposed children are at risk of malnutrition.

Infant Follow up Schedule

HIV exposed children will be closely monitored, clinically and biologically, in order to diagnose and provide early treatment to those needing ARVs before 24 months. The biological follow-up includes PCR at 6weeks and serological tests at 9, and 24 months. Refer to **annex 1.2.** HIV testing Among HIV Exposed Infants.

The first appointment is after 6weeks (child vaccination, PCR, Cotrimoxazole initiation, monitoring of growth and psychomotor development), and monitoring will continue every month following the vaccination schedule. The appointment at 6weeks is crucial. The identification of HIV-exposed children in the vaccination service will be facilitated by the immunization card integrating information about the mother's HIV status and interventions in the PMTCT program.

After the vaccinations, monitoring will continue every month until 24 months, and for at-risk cases (non-cessation of breastfeeding at 24 months, malnutrition, HIV-infection, etc.), it will be prolonged and overseen by the relevant services

It is important to harmonize follow-up appointments of the child with those of the mother to avoid multiple visits.

It is worth noting two important instructions:

- When an HIV-exposed infant tests indeterminate on serological tests used at the health facility, the health care provider should collect immediately a DBS/PCR for confirmation.
- At completion of the follow up period in PMTCT (24 months), the health care provider should be certain of the infant's serostatus. When the infant tests negative on rapid tests used at the health facility, but the result accuracy is suspected for any reason (e.g. suspected that mother did not stop breastfeeding 3 months earlier) the health care provider should estimate a date when the 3 months will have been completed to perform another rapid test for final confirmation and declare the infant' status upon reception of the result.
4. HIV PREVENTION AMONG SERODISCORDANT COUPLES

Evidence-based interventions package for HIV serodiscordant couples can be provided through facility based and/or community interventions. Although these interventions are delivered in a package, providers must ensure that they contextualize the specific, particular needs of the couple since different couples may have different needs.

Overall, the intervention package for discordant couples consists of the following:

- (1) Risk reduction counselling and condom provision.
- (2) Family planning counselling and service provision.
- (3) Repeat HIV testing for the uninfected partner every 12 months.
- (4) Care and treatment for the HIV-positive partner.
- (5) STI screening and treatment.

The objectives of these interventions are:

- (1) To protect the negative partners from HIV infection.
- (2) To provide care and treatment to HIV positive partners.
- (3) To protect future children from HIV infections.
- (4) To get the sexual partners and children of HIV-positive individuals tested for HIV.

5. ART FOR POST-EXPOSURE PROPHYLAXIS (PEP)

Every person who has experienced accidental exposure to blood/body fluids, is a survivor of sexual assault, or who has had accidental sexual exposure (i.e., condomless sex with a known HIV-positive person; condom breakage) must have access to an early evaluation of the risk of HIV infection and antiretroviral prophylaxis if indicated. This is why it is necessary to have functional services that work 24 hours a day. It has been shown that initiating ART prophylaxis soon after exposure to HIV diminishes the risk of HIV infection by about 80%.Post-exposure prophylaxis (PEP) is short-term ART to reduce the likelihood of acquiring HIV infection after potential exposure either occupationally or sexually. Post-exposure prophylaxis should be

provided within 72 hours of exposure and ideally within 48 hours. An HIV serology test should be performed on the exposed individual as soon as possible (ideally *within 4hours*) following the HTS procedures outlined in section 2.1.3. If the test result is negative, the guidelines below should be followed for the administration of PEP. Serologic monitoring will be continued, in particular after three months and before the end of the sixth month.

5.1. Special Considerations in Cases of Accidental Exposure to Blood (AEB) or Other Biological Fluids

In case of accidental exposure to blood, always clean the exposed area immediately. In case of exposure through *needle stick or skin injury*, clean the wound immediately with clean water and soap. In case of *splash on the mucous membranes (particularly the conjunctiva)*, rinse at least for 5 minutes with copious amounts of water or preferably physiological saline and do not apply disinfectant on the mucous membranes.

The actual risk for a given patient must be evaluated by one of the health care providers from the health facility. This evaluation includes:

- The severity of the exposure, which is directly linked to the depth of the wound and the type of needle that was responsible for the injury (Venepuncture needle, needle for injection, non-sharp instrument).
- (2) External contact of secretions with the skin or mucosa (splash), the risk is higher with blood than with any other body secretions (amniotic fluid, serous fluid).

The source person of the exposure should be assessed on his or her HIV status, clinical and immunological status and history of ART. If the HIV status is not known, it is important to establish it with his/her free consent per guidelines outlined in section 2.1.3. If the HIV status of the source person cannot be obtained within 4hours, prophylaxis should be started immediately. If eventually the source person of the exposure is proven to be HIV-negative, then ARV prophylactic treatment should be stopped.

The post-exposure prophylaxis (PEP) depends on degree of exposure, and HIV status of the source of exposure as per the following table:

Source	Exposure Severity			
	Massive	Moderate	Minimum	
HIV-positive with low	Recommended	Recommended	Recommended	
CD4 or Opportunistic				
Infections				
HIV-positive and	Recommended	Recommended	Recommended	
asymptomatic				
HIV status unknown,	Recommended	Recommended	Discuss	
but risk factor for HIV				
$(\geq 1 \text{ risk factor})$				
HIV status unknown	Recommended	Discuss	Discuss	
or unknown source				
without risk factors				

 Table 2: Recommendations on Post Exposure Prophylaxis in Cases of

 Occupational Exposure

Prior to initiation of PEP an informed consent form should be signed by the client.

5.2. Special Considerations in Cases of Sexual Assault or Rape

In case of rape, the provider must first follow the HIV counselling and testing steps described in the above paragraphs (section 2.1.3) before giving prophylactic treatment. PEP should be offered to the sexual assault victim once the clinician has assessed all the factors involved in the likelihood of HIV transmission (probability of HIV positivity in the assailant, probability of HIV transmission, PEP might help the victim gain a sense of control and decrease their anxiety about acquiring HIV .Consider HIV post-exposure prophylaxis for survivors of sexual assault presenting within 72 hours of the assault. In addition to HIV post-exposure prophylaxis, women should be offered emergency contraception to prevent unintended pregnancy within 1 week of exposure.

Source	Exposed	Recommendation
Person HIV	Person HIV	
Status	Status	
Positive or	Known	No prophylaxis is indicated, ensure
negative	positive	enrolment in HIV treatment and care
		Provide emergency contraception if the
		exposed is female and accepts.
Known	HIV-negative	Immediate HIV Rapid test done on the
positive	or unknown	exposed person.
		- If HIV-negative, then counsel and
		offer prophylaxis
		- If HIV-positive, ensure linkage to
		HIV treatment.
		Provide emergency contraception if the
		exposed is female and accepts.
Unknown	HIV-negative	Immediate HIV Rapid test done on the
	or unknown	exposed:
		- If the exposed is HIV negative, then
		counsel and offer prophylaxis;
		- Provide emergency contraception if
		the exposed is female and accepts.

Table 3: Management of Sexual Exposure to HIV

5.3. ART Prophylaxis

The current recommended duration of post-exposure prophylaxis for HIV infection is 28 days. Treatment should start as early as possible, within the first 4 hours following the exposure, without waiting for results of HIV serology of the source person. A limit of 72hours is reasonable in seeking maximum efficacy, however the sooner the better. The recommended post-exposure prophylaxis drugs are based on the current second and first line regimen:

- 1. TDF + 3TC / FTC + ATV/r
- 2. AZT + 3TC/ FTC + ATV/r (If no TDF or a contraindication)

NB: The recommended ART Prophylaxis is the same in rape/sexual assault and exposure to biological fluids

Date	Not on Prophylaxis	On Prophylaxis	
Initial	HIV Test (Serology)	- HIV Test (Serology)	
		- Creatinine (Renal Clearance)	
		- Pregnancy Test (if female)	
Week 2	N/A	- Creatinine (Renal Clearance)	
M1	HIV Test (Serology)	ology) - HIV Test (Serology)	
		- Creatinine (Renal Clearance)	
M3	N/A	- HIV Test (Serology)	
M6	HIV Test (Serology)	- HIV Test (Serology)	

Table 4: Follow-up of Person on Post-Exposure Prophylaxis

6. HIV PREVENTION AMONG KEY POPULATIONS

Key populations are persons with behaviours that put them at risk of contracting and/or transmitting STIs including HIV, particularly because of multiple partners and the low rate of condom use. They are often affected, stigmatized and marginalized, and disproportionately affected by HIV.

Classic key populations for HIV include men who have sex with men and transgender persons, people who inject drugs, and male and female sex workers (M/FSWs); while vulnerable populations include prisoners, uniformed personnel, mobile populations (migrant workers, truck drivers), people living with disabilities and refugees.

In Rwanda, key populations are defined as female sex workers and their clients, men who have sex with men, vulnerable youth (young women 15-24 years) and serodiscordant couples. Other vulnerable groups include prisoners, mobile populations (long distance truck drivers and their assistants, fishermen in Lake Kivu) refugees and internally displaced population and people in uniform.

Minimum package of services for key populations:

- **1.** *HIV Testing and Counselling:* Described in HTS chapter (see section 2.1), with key populations discussed under special cases (section 2.1.4).
- 2. *Peer education and outreach services*: Peer outreach service relies on community members to reach key and vulnerable populations with HIV prevention information and linkage to clinical services. These services emphasize on risk reduction counselling and provisioning of supplies (e.g. condoms, lubricants, family planning commodities).
- **3.** *Sexual and drug use assessment, and risk reduction counselling*: Taking a sexual and individual drug using history ensures that service providers know and do not assume the needs of their clients. Risk reduction counselling is an effective intervention for key populations, whether delivered through peer outreach or in health facility settings and can address both drug and sexual risk behaviours, as appropriate.
- 4. Condom and water based lubricant promotion and distribution: Programs need to ensure a consistent supply and availability of quality condoms as well as water based lubricants compatible with condoms especially for men who have sex with men.
- 5. *STI screening and treatment*: Existence of an STI may facilitate sexual transmission and acquisition of HIV. Routine STI assessment and treatment should be an integral component of key population package of services. Key populations (especially for female sex workers and men who have sex with men) should get screened for STIs every 3 months.

STI services are also useful in attracting key populations into services/programs, providing an opportunity to reach key populations with other HIV prevention services.

6. *Referrals to HIV care and treatment, including PMTCT*: Initiation of ART at the earliest possible point is a critical intervention for key populations. Female sex workers and men who have sex with men should be rapidly linked to friendly ART services upon diagnosis with HIV, and should start ART immediately upon enrolment in HIV services. Key population programs should include support for adherence and retention designed around the needs of these populations. Good treatment adherence

has been demonstrated among key populations when approaches are implemented to facilitate access and acceptability. Innovative approaches to increasing successful linkage into PMTCT, care and treatment services should be implemented. All key population programs need to ensure adequate monitoring of linkages to services. Prevention programs for key populations need to link up and help facilitate training for clinical PMTCT and ART service providers to make existing services friendly, accessible, and non-discriminatory for key populations.

- 7. **Referrals to substance abuse treatment**: although substance abuse seems to be very low in Rwanda, substance abuse treatment reduces the frequency of drug use, which in turn reduces HIV risk behaviours. It also improves adherence to disease treatment regimens. Treatment modalities include non-pharmacological and pharmacological approaches; often, a combination of the two is used.
- 8. *Linkages to other health, social, and legal services*: key populations and other vulnerable populations should be provided with or referred to other health services including family planning, primary health care as well as psychosocial and legal support.

Service delivery models (e.g., mobile versus fixed sites, hours of operations, type of health service provider, etc.) for these core prevention interventions may need to be adapted to reach, engage and retain key populations.

7. COMBINATION PREVENTION

7.1. Biomedical Prevention

7.1.1. Condoms

Condom use is a critical element in a comprehensive, effective, and sustainable approach to HIV prevention across the continuum of response. Condom distribution and promotion should be key components of all packages of interventions for all populations, where appropriate. Male condoms reduce heterosexual transmission by at least 80% and offer 64% protection in anal sex among men who have sex with men, if used consistently and correctly.

Fewer data are available for the efficacy of female condoms, but evidence suggests they can have a similar prevention effect.

Condom programming should engage the public, social marketing and private sectors in condom distribution and promotion and should include a plan for increasing sustainability of condom programming. Social marketing programs should provide subsidized and marketed commodities to poor and vulnerable populations where the private sector does not supply these commodities. Free public sector condoms should primarily be distributed to population segments lacking disposable income and/or those most at risk of HIV transmission or acquisition.

Specifically for key populations (female sex workers and men who have sex with men), condom programming and distribution should go hand in hand with the distribution of water-based lubricants.

7.1.2. Voluntary Medical Male Circumcision (VMMC)

Three randomized controlled trials have demonstrated that VMMC reduces men's risk of HIV acquisition by approximately 60 percent, making it an effective HIV prevention intervention. WHO/UNAIDS issued normative guidance in March 2007, recognizing that VMMC is an additional important intervention to reduce the risk of male heterosexually acquired HIV infection and that VMMC should always be implemented as part of a comprehensive HIV prevention package.

The minimum VMMC package includes:

- (1) The provision of HTS services;
- (2) Clinical evaluation of the client,
- (3) Administration of 2 doses tetanus vaccination (unless proof of updated vaccination), and
- (4) Informed consent.

Also the package may include the treatment for STIs; the promotion of safer sex practices, such as abstinence from penetrative sex, reduction in the number of sex partners, and delay in the onset of sexual relations; and the provision of condoms, and promotion of their correct and consistent use.

7.1.3. VMMC Setting

VMMC package is offered in public and private health facilities fulfilling the conditions required by the Ministry of Health:

- 1) To have an operation room for at least minor surgery,
- 2) To have at least one health care provider trained on VMMC procedures
- 3) To have necessary equipment for sterilization of materials
- 4) To have necessary materials for the performance of male circumcision (depending to the VMMC method),
- 5) To respect scrubbing and infection prevention principles

VMMC can be provided by using classic surgical methods or a device based method. In Rwanda, the PrePex device has been tested and found to be safe and effective as a means of performing bloodless adult male circumcision that can be carried out by non-physician staff without need for anaesthesia, suturing, or sterile settings.

After the VMMC procedure, the client should receive all the information regarding possible complications (bleeding, important pain, difficulty urinating, swelling or local infection). The client is advised to avoid any sexual intercourse or masturbation for at least 4-6 weeks after VMMC. When the VMMC is device based, the counselling is based on the manufacturer recommendations. In case of complications beyond the health facility competencies or by the client's request, transfer should be done according to the referral system applicable in Rwanda.

7.1.4. New-born Circumcision

Rwanda is a traditionally a non-circumcising society and the prevalence of male circumcision among men age 15-59 is only 13%. These data are mainly applicable to the adult population and data on children are not yet available.

Efforts to increase the male circumcision prevalence in the country took into account all age groups of the population. For young children, these efforts sometimes face obstacles such as pain related to the procedure and parents' fear of potential side effects for their children. The introduction of an infant specific program in the country aims at breaking such barriers and normalizing male circumcision.

The Early Infant Male Circumcision (EIMC) in the country is using Mogen clamp procedure. This is a clamp-based procedure validated by the WHO and performed on infants between 7 and 60 days of life. It has several advantages as it takes less time to be performed, the wound heals quickly, the procedure is cost effective, and it causes less pain to the infant.

7.2. Prevention with People Living with HIV

HIV prevention with people living with HIV, referred to as prevention with positives (PWP), integrated into routine care is a core component of a comprehensive and integrated HIV prevention, care and treatment strategy. Prevention services for HIV-positive persons include both behavioural and biomedical activities aimed at reducing the morbidity and mortality experienced by HIV-positive individuals and reducing the risk of transmission to HIV-negative partner(s) and infants.

By focusing on partner and couples HIV testing and counselling (HTS), PWP service provision can contribute to the identification of HIV-positive individuals as well as serodiscordant couples and partnerships. Partners who are newly identified as HIV-positive can then be linked into HIV prevention, care and treatment services.

PWP activities are summarized below:

STEP 1: Give prevention recommendations to the HIV-positive patient during each visit

STEP 2: Evaluate the patient's adherence to ARV treatment and other treatments at each visit

STEP 3: Evaluate the patient for possible signs and symptoms of STIs at each visit.

STEP 4: Evaluate the state of pregnancy and the intention of the patient or and the patient's partner to have a child.

STEP 5: Give condoms to the patient at each visit

STEP 6: Assess for specialized care needs and refer patients to the appropriate services.

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7.3. Behavioural Interventions

The goal of behavioural interventions is to reduce HIV risk behaviours and the frequency of HIV transmission events. To reach this goal, interventions attempt:

- (1) to decrease the number of sexual partners,
- (2) to increase the number of sexual acts that are protected,
- (3) to encourage adherence to clinical strategies for preventing HIV transmission

Programs use various communication approaches – for example, school-based sex education, peer education/counselling, community-level education, and interpersonal counselling – to disseminate behavioural messages designed to encourage people to reduce behaviour that increases the risk of HIV and increase the behaviour that is protective (such as safer drug use, delaying sexual debut, reducing the frequency of unprotected sex with multiple partners, using male and female condoms correctly and consistently and knowing own and partner's HIV status).

7.4. Structural and Supportive Interventions

Structural approaches aim to mitigate the impact of HIV by altering structural factors, which include physical, social, cultural, organizational, community, economic, legal or policy aspects of the environment that determine HIV risk and vulnerability. Structural interventions involve more than the service providers and beneficiaries; it includes working with various stakeholders including governmental and non-governmental agencies and addressing the factors that impede or facilitate efforts to prevent HIV infection.

These interventions affect access to, uptake of and adherence to behavioural and biomedical interventions. Such interventions address the critical social, legal, political and environmental enablers that contribute to HIV transmission. This includes legal and policy reform, measures to reduce stigma and discrimination, the promotion of gender equality and prevention of genderbased violence, economic empowerment, access to schooling and supportive interventions designed to enhance referrals, adherence, retention and community mobilization.

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8. LINKAGE TO CARE AND TREATMENT

Knowledge of HIV status allows people to make informed decisions about HIV prevention and treatment. Strong linkages to effective HIV prevention, treatment, care and support services are essential if people are to carry out these decisions.

8.1. Linkages to Care and Treatment for Individuals Testing HIV-Positive

HIV-positive individuals should be referred for ART. For those who test HIV positive, the HTS provider should:

- 1. Provide clear **information on ART** and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to obtain ART.
- 2. Provide information on how to **prevent transmission of HIV**, including information of the reduced transmission risk when viral suppressed on ART.
- 3. Make an **active referral** for a specific time and date. An active referral is one in which the tester makes an appointment for the client or accompanies the client to an appointment, including an appointment for co-located services, and enrolment into HIV clinical care.
- 4. Arrange for follow-up of clients who are unable to enrol in HIV care on the day of diagnosis.
- 5. Provide condoms, contraception, and lubricants and guidance on their use.

For couples who are serodiscordant, HTS provides access to HIV treatment for his/her own health and also to reduce the chance of HIV transmission to the uninfected partner. It is critical for people living with HIV to enrol in care as early as possible in order to benefit from immediate offer of ART as well as access to interventions to prevent the further transmission of HIV, prevent other infections and comorbidities and to minimize loss to follow-up. Several good practices are proposed to improve linkage to care. These include:

- (1) Integrating HIV testing and counselling and care services;
- (2) Involving the community to identify the people lost to follow-up;
- (3) Ensuring support from peer patients;
- (4) Using new technologies, such as mobile phone text messaging for follow-up.

Connecting individuals and couples that have been tested for HIV to prevention, care and treatment services is one of the guiding principles of HTS conduct.

8.1.1. Recommendations for Retesting Individuals Prior to ART Initiation

To ensure that individuals are not needlessly placed on life-long ART (with potential side-effects, waste of resources, psychological impact of misdiagnosis), all individuals will be retested to verify their HIV status prior starting ART.

Retesting before ART initiation should follow the following procedures:

- Testing of a new specimen for each newly diagnosed individual
- Retesting is to be conducted by a different provider, ideally this will be the health care provider
- Retesting must use the same testing algorithm

8.2. Linkage to Further HIV Prevention for Individuals Testing HIV-Negative

For individuals identified as HIV-negative and sero-concordant negative couples, HTS provides access to HIV prevention services. The health care provider should provide the following to those who test HIV negative:

- Education on methods to prevent HIV acquisition and provision of condoms, contraceptives, lubricant and guidance on their use;
- Emphasis on the importance of knowing the HIV status of sexual $\ensuremath{\mathsf{partner}}(s)$

- Information about the availability of partner and couples testing services;
- Referral and linkage to relevant HIV prevention services, including voluntary male medical circumcision (VMMC) for HIV-negative men and PEP
- For adolescents in particular, provide information and education about healthy behaviours, such as:
 - Correct and consistent condom use
 - Reduction of risk-associated behaviours and prevention of HIV and unwanted pregnancy
 - Retesting if they have new sexual partners
 - Referred to appropriate prevention services, such as VMMC for males and contraception.

8.2.1. Recommendations for Retesting for Individuals who Test HIV-Negative

The vast majority of individuals do not require retesting to verify an HIVnegative status, particularly in the absence of any ongoing risk. However, it is important to accurately identify individuals who test HIV-negative and may require retesting in certain circumstances:

- Individuals from key populations
- Individuals with a known HIV-positive partner
- Individuals with known recent HIV exposure
- Individuals seen for a diagnosis or treatment of STIs
- Individuals with TB
- Outpatients with clinical conditions indicative of HIV infection
- Individuals taking PEP.

In the absence of linkages to these services, HTS will have only a moderate impact on HIV prevention.

PART II. HIV CARE AND TREATMENT

9. GENERALITIES ON CARE AND TREATMENT

9.1. Introduction

This section offers different 3 chapters, which concentrate HIV infection treatment & management for three age groups: children young than 10, adolescent 10-19 years of age; and adults with more than 19 years of age. This guidelines call upon and recommend the commencement of the antiretroviral therapy (ART) for everyone living with HIV – regardless of their CD4 count. ART is the combination of several antiretroviral medicines used to inhibit HIV replication and therefore slow the progression of HIV disease to AIDS, thereby improving the clinical status and quality of life of patients.

9.2. Goals and When to Start Antiretroviral Therapy

Initiation of ART has several different goals: (1) to reduce the amount of virus in human body (viral load) to a undetectable levels with current blood tests, (2) to improve the immune reconstitution, (3) to -reduce the transmission of HIV (4) to minimize the risk of resistance as well minimizing long term toxicity and, (5) to minimize the cost of care.

10. DIFFERENTIATED MODEL FOR ART DELIVERY FOR STABLE PATIENTS

10.1. Definition of Differentiated ART Model

With Treat All recommendations and expanding availability of ART, people are presenting to care earlier and require less intensive clinical care. This increase number of patients taking ART and tend to increase the burden on health systems, particular at sites with high number of patients on ART and also unnecessarily clinical visits. To reflect the preferences and expectations of various groups of PLHIV and to reduce unnecessarily burdens on the health system and multiple clinical visits for patients, HIV national program has adopted a differentiated model for ART service delivery.

A differentiated model for ART service delivery aims to decrease patient clinical visits to six months and pharmacy pick-up for medications (ARVs and OIs prophylaxis) visits to three months. This model applies only for patients who have been on ART for at least 18 months demonstrating good adherent to program and proven to have a successful and sustainable viral suppression (at least two consecutive times including the last visits).

10.2. Preparation for enrolment in differentiated ART model for ART

Preparing clients for new ART model is anticipated to take a month of preparation. High volume sites will enrol patients in cohorts (group of patients attending the clinics at the same time), these facilities will take maximum three months to enrol all patients in cohorts.

Patient classifications and synchronizations of different visits:

Health providers, at health facility level, will use patient registers and patient charts to classify patients receiving ART in different categories including:

- 1. Patient's eligible for new model,
- 2. Patients non-eligible for new model
- 3. Special consideration.
 - Pregnant and breastfeeding women
 - Adolescents
 - Patients with NCDs
 - Patients with other co-infections
 - Others

Health providers supported by mentor have to coordinate routine clinical consultations, planned medicine pickup with laboratory visit to reduce visit frequencies for patients. Also, in the preparation phase, health provider will map stable patients (patient eligible for spacing model) who have same day visits and group them as a cohort. These patients will be required to attend clinic the same day to receive same services.

Education and counselling sessions: Patients eligible for new ART delivery model should participate in an education and counselling sessions, at least two sessions. Health providers have to explain different details and steps to be taken to the patients eligible for the model. This includes assessment of willingness to participate in the model, the benefits and risks related to the model and operation of the model (how patients will be seen, either separately or in cohorts/groups, coordination for different visits, community providers' interventions, when patients moves from one group to another etc..). Patients not eligible for the model will not be mixed with unstable patients in the same education and counselling sessions. Before the education and counselling sessions, health care workers have to assess the willingness of clients to participate in the model. Health providers have to explain to the patient's community services (packages, frequencies, other...) and membership of community services. If eligible patients are pregnant women, adolescents, patients with any chronical diseases that has a different schedules, education sessions are adapted to a particular groups focusing on challenges for that specific group and how ART model will be aligned with the exiting conditions

10.3. Targeted clients

10.3.1. Eligible patients for the model:

HIV patients on ART at least 18 months should be screened for eligibility to differentiated ART Service delivery model. Patients are eligible for the model:

- All adult clients on 1st line ART with two consecutive viral load tests showing viral suppression (< 20 RNA copies/mm3) including the last visit. The last viral load will be considered as recent if the results were reported at least after 2 months after blood collection for the test.
- All adult clients on 2nd line requesting to be part of differentiated ART model, and fulfil the eligibility criteria. Health provider will assess other conditions, if a patients has been on 2nd line for several years, adherent to treatment and showing viral suppression, s/he will be enrolled in new ART model.
- 3. All key population with all eligibility criteria (see above)

- 4. Respect all pharmacy, laboratory and clinic appointments during at least the last 6 months (adherence to the program schedules)
- 5. Clients willing to be part of differentiated ART delivery model. Proposed model for this group:
 - (1) Reduce medical consultations at every six months
 - (2) Reduce medication pick up at every three months
 - (3) Adherence counselling and Psychosocial support at every three months
 - (4) Increase community visits and support at every months between two pharmacy visits,
 - (5) For other medical needs, clients will follow the current ART guideline recommendations.

10.3.2. Non-eligible patients for the model

Patients non eligible model include:

- 1. All PLHIV clients on ART less than 18 months
- 2. Patients on 2^{nd} and 3^{rd} line ART
- 3. Co-infected patients with NCDs (Diabetes, cancers, heart diseases, etc....), this apply for patients who are intensive period of treatment, these patients will be moved to new ART model at six months after the last dose of co-infection treatment.
- 4. For patients with NCDs or other chronical conditions; clinical, pharmacy visit and laboratory visits will be coordinated with visits of their chronical conditions until patients is stabilized for that conditions.
- 5. Malnourished PLHIV in nutrition follow up services
- 6. All HIV positive clients who have TB and/or Hepatitis coinfections(C and B), until after six months from the last dose of co-infection
- 7. Children under 15 years. For children attending boarding schools, there will be considered as adolescents (see special consideration).

Patients in this category will follow the standard ART guidelines:

- (1) Medical consultations every three months
- (2) Medication pick up every month
- (3) Adherence counselling every month
- (4) Psychosocial support every three months
- (5) Community intervention as needed.

10.3.3. Population considerations

- 1. Pregnant or breastfeeding mothers on ART will require different followup and health providers will have to coordinate their clinical and pharmacy visits with ANC or PMTCT visits. This different model will be used from the beginning of pregnancy until the end of the breastfeeding period.
- 2. At the end of breastfeeding period, pregnant and breastfeeding mothers (Eligibility for the model) will be enrolled to new ART model.
- 3. Due to school routines and competing priorities, adolescents at schools will be scheduled for pharmacy and clinical visits evert three months, this period have to correspond school break period.
- 4. All adolescents in schools will continue in this model until the end of their secondary education and at least 19 years of age.
- 5. After secondary educations and adolescents 19 years of age, if eligible for model they will be moved to spacing model as adult patients.

When a non-eligible patient will be eligible the model, and when eligible patient will be considered as failing for the model (See algorithm)

10.4. Adherence assessment and counselling for patients enrolled in the model

Non adherent patients: Adherence to treatment for this group will be assessed using standard procedures. This means will assess if patients have taken all proscribed drugs. Poor adherent patients encompass the following conditions:

Poor adherence may encompass any of the following:

- 1. Missing more than 5% of prescribed dosed during the last three months.
- 2. Missing appointments (at least one clinical/pharmacy visits without any notification).
- 3. Missed by a community provider between two pharmacy visits
- 4. And Viral load detectable two consecutive times

10.5. Lost to follow up definition for patients enrolled in model

Lost to follow-up: Patients are considered as lost to follow up, if this patients has missed one pharmacy visit and was not seen for the lasts 3 months from the last drugs pickups by a peer educator and the health providers were not able to reach him by any communication mean (telephone call and home visit) within one month from the time he/she was anticipated to attend the clinic.

High risk of Lost to follow up: is considered as high risk of lost to follow up any patient not reached by community at least two consecutive times and did miss the last clinical or pharmacy visits.

11. HIV CARE AND TREATMENT FOR CHILDREN YOUNG THAN 10 YEARS OF AGE

11.1. Psychosocial evaluation and support of children young than 10 years living with HIV

It is important to remember that successful and sustained administration of ART to children is dependent upon the agreement and support of their parents/caregivers. Appropriate counselling is ultimately the responsibility of the team providing care to the children living with HIVA psychosocial needs assessment should be conducted on the same day of HIV testing in order to evaluate all psychological and social needs and priorities of clients and their families and provide appropriate counselling and link them to relevant community services and resources. Psychosocial assessment is done during

enrolment in ART services and at every visit for ensuring a good adherence, and appropriate counselling offered.

For younger children under 7 years (before the child has concrete thinking) the psychosocial assessment is done through their parents /caregivers as the successful and sustained administration of ART to children is dependent upon the agreement and support of their parents/caregivers. For children aged 7 and above (7-11) the psychosocial assessment considers not only caregivers needs but also child needs.

The below table presents what to be covered during psychosocial assessment at enrolment and at every visit by categories of age:

= 4810 01 1 57	chosocial assessment at enronment
Categories	At enrolment
of age	
Children	Through counselling session health care providers assess
aged 0-6	psychological and social status of caregivers.
years	 In assessing psychological and mental status of caregivers, health providers will use the mental health screening tool (see annex 2.9) and assess especially the depression and continue counselling in assessing other psychiatric symptoms and history of sexual violence and drug abuse. At baseline, the health care provider should also assess the social problems which can affect adherence of the child and address them accordingly. Caregiver's social status is assessed in getting information related to : Sexual life which include: Is the caregiver married or does the caregiver have sexual partner? Is the couple stable? In the case of discordant couple or HIV positive concordant couple, is the doing the protected sexual activity? Does the caregiver disclosure his/her HIV result to the partner?

Table 5. Psychosocial assessment at enrolment

	Professional , financial and economic status of the caregiver and the family		
	 Does the caregiver have a job? Is the schedule of the caregiver's job facilitating the time to take the medication? How does the caregiver arrive to health centre? Does she /he have transport fees from home to health facility? How is the spiritual life of the caregiver? What is his/her religion? How is his/her accommodation? Do they access to clean water and sanitation? How many other dependents in the household? Does the family have the medical insurance? 		
	In case of HIV positive caregiver, health care provider have to assess the following:		
	 Challenges which can affect his/her own adherence Availability of the treatment supporter Disclosure plan to the child and to others in the family Food security 		
Children aged 7-10 years	 For this age category, a psychosocial assessment is given to the caregivers as well as to the child. Health care providers assess all above mentioned psychological and social needs of caregivers but also asses to the child the following key elements: Level of understanding of the child School performance of the child Physical, emotional and behaviour state of the child Discussion on disclosure process with the caregiver (For more details on the disclosure see the chapter on the disclosure) N.B: 		
	 These children have to be accompanied with their parents or caregivers in the enrolment process All information related to psychosocial assessment have to be documented in patient file 		
	✓ To fixe next appointment for ART education and preparation		

11.1.1. Disclosure

HIV disclosure is not a one-time event. It must be individually not in a group setting. The provider has to assess the child's and family's understanding of general illness, HIV specific knowledge, and disease progression. He have to discuss the importance of privacy and who are "safe" people for the child to talk to about HIV:

- Clarify how much information the parent wants to share about their own history
- Build on child's understanding and knowledge
- Correct and clarify misinformation
- Provide basic education over several discussions that lead up to diagnosis after child understands the virus, role of meds, etc.(*refer to child disclosure tool*)
- Prepare for difficult questions that may come later

Why is disclosure important?

Disclosure may increase social support available to child and family, may increase a child's willingness to adhere to treatment regimen. Disclosure helps children understand the illness and avoids an accidental disclosure from occurring (e.g., child overhears caregiver discussing it). The children have the chance to ask questions about their illness.

Who should disclose to a child?

The disclosure process should be done by the parents or caregivers at home. During the preparation process, health care providers help parents to prepare and assist them during disclosure session. In the case of parents / caregivers are not comfortable to disclosure to their child, health providers do the disclosure and the parents/caregivers assist the process.

When to announce the diagnosis to a child?

The choice of the best moment to announce the result to the child is decided together with parents/guardians taking into account several factors such as: the level of understanding of the child, its questioning regarding medical care,

the health status of the child and other events that have marked the life of the child. It is preferable to provide complete announcement (HIV/AIDS) before 14 years.

Factors to Consider & Assess before disclosure

Parental issues:

- Available social support
- Potential conflicts/safety issues
- Readiness to tell extended family/siblings
- Adjustment with HIV parents status
- Communication skills with child
- Right time

Child issues:

- Age/developmental level
- Child/ Adolescent's current knowledge/understanding of illness
- Child/Adolescent's health status
- Child/Adolescent's emotional status
- Support system
- Child/Adolescent's readiness

What are the steps of disclosure?

0-4 years old: No disclosure yet

The aim of this step is to build up confidence of child in health workers and taking medicine. It will depend on adult for all needs and information. Child needs comfort, support and most of all security. The caregiver has to carry on consultation with child present. The child is too young for direct information about HIV but to give the explanations to caregiver about how HIV which can affect the child remain important. It's a good opportunity to provide ideas to help caregiver support child taking medicine, to congratulate child on taking medicines well; to address caregiver anxieties; to build relationship with the child through play/singing and to provide a safe and welcoming clinic.

5-7 years Old: Early disclosure

At this age the aim of the early disclosure to allow to children to understand that medicines support the body to keep well.

In general the child needs to learn about illness but not HIV by name yet. The provider can introduce ideas of good and bad health by eating healthy food, keeping clean, exercising, looking after teeth etc. He can explain how medicines help to keep a body healthy and strong. He can introduce infections as 'germs' that can hurt or damage the body/make you sick or hurt. He can introduce (white) blood cells as the part of the body that look for and kill infections or germs hide therefore child needs to take medicines to help fight the germs.

8-10 years: Partial disclosure

At this step the aim will be to name the infection as HIV Virus. The provider will explain that the germ concerned is a virus which can damage white blood cells. If medicines are not taken correctly, the virus can get stronger and stop the medicines working (resistance). During the session, naming of virus as HIV should occur but not essential. The provider will explain that information is private and should only be shared with those agreed with the caregiver(s). He will help the child to identify who they can to talk with about their health or HIV with.

11-14 years old: Full disclosure

The HIV full disclosure can be done at this age. The child has the full understanding, right and responsibilities the ability to negotiate own health care. The provider checks understanding of health, medicines, sexual development and HIV infection. He assess the need to understand responsibility for not transmitting HIV i.e. safer sex, and their rights i.e. family planning, confidentiality. He prepares the teenager for future, encourages direct involvement in discussions and decisions. The provider promotes the benefits of attendance at adolescent support group.

Post-Disclosure

The provider discuss the pain and distress after disclosure to:

- Assess emergent psychological symptoms regularly,
- Offer your continued support and availability;
- Discuss the importance of having continued counseling sessions on a regular basis;
- Encourage teenager to always ask questions and discuss his/her concerns and fears and
- Explore the teenager's hopes, ambitions and plans for the future using questions addressing wishes.

Notice:

- As soon as they are able, children above 12 years old have the right to give their opinion about HIV testing and to continue the process for getting antiretroviral treatment
- 2) Disclosure can be a difficult process for all concerned, effective conversations are dependent on the age and understanding (developmental level) of the child
- 3) The first steps to find out what the child already knows (often more than adults think)
 - Failure of full disclosure by early teenage years can lead to:
 - Poor adherence
 - Emotional difficulties
 - Poor school performance
 - HIV transmission if sexually active

What can be barriers to disclosure?

Parents' fears of child's reaction to diagnosis:

- Child is not old enough to understand illness or death
- Child can't keep a secret
- May bring more social isolation or peer rejection
- Child may become more anxious during medical procedures and hospitalizations
- Child may become depressed and give up

How to deal with the barriers?

- Discuss the following with caregivers on an ongoing basis:
- Caregivers' concerns about disclosure
- The importance of ongoing communication with child regarding health issues
- Benefits and risks of disclosing the diagnosis of HIV infection to children and adolescents
- Potential harm that can result from long-term nondisclosure

Possible feelings after disclosure

- Shock
- Anger
- Sadness/Depression
- Embarrassment
- Fear
- Confusion
- Loss
- Rejection, Isolation

General Principles for Disclosing HIV Status

- Date of disclosure should not coincide with other events such as birthdays, holidays, graduation, etc.
- Use clear and developmentally appropriate explanations of the disease/diagnosis
- Share the diagnosis quickly, do not delay or stall
- Promote sharing of feelings, but also accept silence
- Always allow the child to ask questions
- Give developmentally appropriate educational materials
- Both the healthcare team and caregivers should be involved throughout the process

How is the child coping?

After the HIV diagnosis has been disclosed, follow-up calls or visits should be made to assess the child/adolescent's understanding of the illness and emotional and psychological adjustment. At each visit after disclosure, health care providers assess child/adolescent's emotional well-being and functioning in the following areas:

- School functioning
- Family and peer relationships and support
- Interests and activities
- Mood and behaviour
- Health care providers work closely with caregivers to monitor for changes in functioning that may signify poor adjustment

How to report the disclosure?

After the disclosure, the provider relates the following information; date, tracnet, name, age, sex, family status (orphan or have one parent or two parents), reason of disclosure, reaction, next step

11.1.2. ART Adherence among children

ART Adherence refers to a client's ability to follow an ART treatment plan. This includes the client's ability to take medication as prescribed, and to follow any prescribed dietary restrictions. In the context of ART medication, adherence should be at least 95% of doses for maximizing the long term benefits of ART. For this, health care providers make attention to all possible factors that could affect adherence and reinforce the counselling for achieving adherence rates at least as high as 95%.

Barriers of adherence among children

For addressing adherence among children, health care providers should know what could be the barriers of adherence success. Different studies grouped barriers related to adherence among children in 4 categories:

o Drug related issues

Pill burden (with concomitant medications) Poor palatability Adverse events to ARV drugs

• *Patient related issues*:

Age: difficulty in administration of medication to a young

child

Lack of age-appropriate disclosure to the child Poor expectation from therapy

- Child refusal
- Child-caregiver relationship
- o Caregiver related issues

Disruption in Family unit as a consequence of adverse

health or economic conditions Ill health of parents/ caregiver

Absence of committed responsible caregiver

Uneducated/unmotivated care-giver

- Forgetfulness
- *Poverty (lack of food)*
- System related issues:

Inconsistent availability of medications

Difficult to access the health centres Poor quality of relationship between patient/care-giver and health care providers Unavailability of appropriate and on-going counselling&

support services

In individual counselling session with parents /caregivers, health care providers use open- ended questions for exploring specific issues of each child or caregiver which could affect the adherence

ART Adherence Assessment

Continuously assessing adherence is vital to a comprehensive and sustainable approach to ART delivery. Adherence monitoring should be the duty of every health care provider participating in the care of HIV-infected children. It should be performed whenever there is a visit to a health centre, in order to identify children in need of the greatest support for adherence. Once a child is taking ART medication, at each health facility visit, in each service (pharmacy, consultation, nutrition and social services) health care workers assess the adherence. In a non-judgmental manner, health care providers use open ended question to assess the adherence with the following methods.

Pill identification test (in Pharmacy service):

1. could you share with me the name or show me the medication that your child takes?

2. Explain more how and when these medication are taken

Pharmacy record form review (in pharmacy service)

Health care providers check if the caregivers respect the appointment for picking the medication, if he/she does not experience any medication stock out.

Pill count methods in pharmacy

when the child is receiving tablets, caregivers bring the remaining pills and in collaboration with health care workers they calculate the proportional of adherence.

% Adherence = (Dispensed – Returned x 100)/ Expected to be taken

When the child is taking the syrup, the caregivers bring the bottles and in collaboration with health care providers they compare the remaining quantity with of syrup bottles with bottles.

Self-report (consultation, counselling and pharmacy room)

Through individual counselling, health care workers asked the caregivers or child aged 7 and above the following question:

1. Some parents /caregivers find it hard to always remember to give the child's medicine due to different reasons, thinking back over the past four days, have you forgotten or delayed to give any of child's doses? What about the last two weeks? What about last four weeks? If yes, what causes this to happen?

2. What support or reminder do you have that helps you to remember to give the medicine to your child at the right time?

3. Is there any other person(s) who can give the medication to the child when you are not around?

4. What support or reminder do you have that helps you to remember to give the medicine to your child at the right time?

5. Does the child know why he/she is taking the medicine? (For children above 7 years) that helps you to remember to give the medicine to your child at the right time?

6. Have you or your child noticed any undesirable drug effect related to the medication? What are they? What do you do to help your child to prevent / minimize those effects?

7. Some parents/caregivers have problems with giving the child medicines every day at the right when they don't have food, do you ever

not give the child the medicine because you don't have food to give with medicine?

At every visit, check the results the information from self-report and pill count if it is associated with viral loads results.

<u>N.B:</u>

All information captured during ART adherence are recorded in patient file in psychosocial part.

Strategies for promoting and supporting the adherence among children

As the ART medication is long life treatment, patients who are taking these medication have to be helped and encouraged to maximize the adherence. The adherence is dynamic, there is a period where adherence is excellent and other periods it fails due to many circumstances occurred in the life of the child and the whole family. In multidisciplinary approach, addressing the adherence is the tasks of every health staff working in ART services (physicians, nurses, social workers, psychologist and nutritionist).

Table 6. Strategies	for	promoting	and	supporting	the	adherence	among
children							

Strategies	What to do
Client friendly services	 Make the environment pleasant and comfortable, with not-too-long wait times and a shady waiting area, convenient hours, and welcoming staff Prioritize young children In the case of HIV positive parents/caregivers, ART visits for caregiver and the child occur on the same day Arrange appointments for other support services (nutritional and social)on the same day as health facility visits
Good communication	Show respect and dignity to the patientsFollow good communication and active listening skills

	 with the caregivers. Never judge the children as well as their caregivers that you are counselling. Be Honest; never lie to a child! For the children under five: Ask open-ended questions to caregivers about adherence to help them share. Example: "Some people find it hard to come at the health centre every month because they have so much to do at home. How has this been for you?"
Confidentiality	 Remind caregivers that care and treatment information of their children may be shared among the multidisciplinary team but will not be disclosed outside that group. Make sure all clients understand that what is said at the health facility is confidential. Assure caregivers that HIV status of their children will not be disclosed without their consent. Remind parents/caregivers that they might see other community members at the health centre and help them prepare for this.
Ongoing Education, counselling and peer support group	 At every visit, Provide ongoing education session to caregivers in group or individual and insist on the following key points Importance of early HIV testing among children Importance of ART medication to their health life (in case the caregiver is HIV positive) as well as to child In the case of HIV positive caregivers, health providers insist on the importance and participation in peer support group In the case of HIV positive caregivers , health care provider assess their adherence

	on ART medication		
	 Through counselling session, health care providers assess 		
	 the psychological and mental health status of caregivers 		
	• Remind how to take the medication properly		
	• Disclosure the HIV status to the child at the right time		
	 Encourage the caregivers to have and participate in peer support group. 		
	For children aged 7 and above, heath care providers have to		
	assess the following ;		
	• Does the child know their HIV status or is the		
	Disclosure process started?		
	• Level of understanding:		
	Does the child know the treatment he takes?		
	Does the child know the biological tests done		
	and their periodicity?		
	School performance of the child: How does the		
	child perform in the class?		
	Support group: Does the child participate in a		
	peer support group? Is there any one also who		
	knows the HIV status of the child in family?		
	Advise caregivers to use phones reminders, calendar, radio		
	and watches for helping them to remind them to give the		
	medication or go to their next medical appointment		
Linkage to	Managing severe and non-severe adverse effects		
other services	• Identifying a backup caregiver to be involved in		
and follow up	providing care		
	• When caregiver(s) is HIV positive, encourage them		
	to have treatment supporters who might help when		
	the caregivers is unwell		
	• Use an appointment system to track which patients		
	are supposed to come to the clinic each day, and for		

•	which services. Give clients reminder cards (carte de rendez vous) so they know when to come back to the clinic.
•	
•	Keep contact information updated and organized for each client
•	Link HIV positive caregivers with PLHIV associations and nongovernmental organizations (NGOs) in the community that can help support adherence.
•	For children who have missed appointments: conduct home visits and conduct counselling for assessing caused related to appointment missed
•	

11.2. Psychosocial support group

The aim of psychosocial support group (PSG) is to provide safety, empathy, validation, and essential support. The PSG enables participants to learn new coping strategies and decreases isolation and a sense of alienation. The PSG allow members to meet others who are dealing with similar experiences. Therefore they can restore a member's spirit of hope and self-confidence; increases self-awareness and focus on strengths.

TOPICS: They are proposed depending on the previous sessions and due to progress level of the group.

<u>0-4 Years Old:</u> At this age the role of PSG is to Support the caregivers by: - Sharing some problems they are facing at home of taking ART every day and at time

- Preparing the child and his family to overcome a lot of emotions provoked by the announcement of the diagnosis of HIV/AIDS.
Topics to be discussed include

- HIV/AIDS, transmission and prevention
- Drugs taking treatment monitoring for the child
- Medical and biological follow up
- Life experience for children
- Daily life
- Education of children

<u>5-7 Years Old:</u> At this age the role of PSG is too for caregivers support. The aim is for strengthening adherence to prophylactic and antiretroviral treatment, and facing the problems that crop up when psychosocial needs of the child are not met. Topics to be discuss should be the same that those for 0-4 years but the providers have to be attentive for any question from caregivers.

<u>8-10 Years Old:</u> The aim is to promote emotional support and exchange of experience and to strengthen compliance to prophylactic and antiretroviral treatment for children.

Topics to be discuss:

- Define HIV
- The body, the role of blood, immunity
- Taking drugs
- Life hygiene

In additional to the discussion, the following should also be done for the 8-10 Years Old range category:

- Evaluate expectations and proper needs of children aged between 8 10 years old.
- Support the integration of children in school, social and family life.
- Help children to express themselves through leisure activities.
- Sensitize children on the importance of regular taking of drugs.

11.3. Nutritional evaluation and support of children young than 10 years living with HIV

The purpose of this section is to equip health care providers with skills and knowledge and a general understanding of nutrition, care and support of children living with HIV.

11.3.1. General recommendations

- HIV-infected children should be routinely assessed for nutritional status. This includes weight and height at scheduled visits, particularly after initiation of ART.
- HIV-infected children who are moderately or severely malnourished should be managed as per the current national guidelines for nutrition
- HIV-infected infants and children between 6 and 59 months of age should receive high-dose vitamin A supplementation every 6 months as per the national guidelines for nutrition.
- HIV-infected infants and children between 6 and 23 months of age should receive 2 to 3 sachets a week of Micronutrient Powders (MNP) supplementation
- HIV-infected children who have diarrhoea should receive zinc supplementation
- For infants and young children known to be HIV positive, mothers are strongly encouraged to exclusively breastfeed for 6 months and continue breastfeeding as per recommendations for the general population (at least up to two years of age.)

Note:

- Weight/height by gender is the indicator of acute malnutrition for children under 5 years
- Weight/Age by gender is the indicator of underweight for children under 5 years
- Height/Age by gender is the indicator of stunting for children under 5 years
- BMI-for-age by gender is the best indicator of malnutrition for 5-19years

Note: If the Weight/Height is ≥ 3 SD: overweight or obesity. Identify the possible causes and provide appropriate dietary counseling to prevent obesity and complications

Consider the two others indices of malnutrition that are the Underweight (Weight for Age) and the stunting (Height for Age) and manage them according to the national protocol for

11.3.2. Nutritional management for children (under 5years) living with HIV

Table 7. Nutritional management for children under 5 years old

For the nutrition assessment of children under five refer to WHO charts that are found in the patient file.

Assessment	Diagnosis	Action Plan
 Measure the height, weight and MUAC of the child, note the age in months Observe the signs of malnutrition and record 	Severe acute malnutrition if weight/ Height= <- 3Zs, MUAC <12 cm or bilateral Oedema	If medical complications (e.g., infection, severe anaemia, dehydration) Admit/Refer the child to Hospital. Treat urgently complications Give theF75, F100orRUTF and continue breast feeding if the child is under18 months If no medical complications: Treated as an outpatient with RUTF and continue breastfeeding if the child is under 18 months
	Mild / moderate acute malnutrition if weight / height >-3ZS-2Zs/2 ZS- 1Zsand MUAC between12cmand1 3cmPB Good nutritional status if W/H>- 1ZS and MUAC>- >-13cm	If medical complications, admit the child and treat these complications Give the CSB+ and continue breast feeding if the child is under18 months. Praise the mother and encourage him. Continue breastfeeding if the child is below 18 months

11.3.3. Nutritional management for children (5-10 years) living with HIV

Assessment	Diagnosis	Action Plan
Measure the height and weight, know the age Calculate BMI: weight / height in m ² Observe the signs of malnutrition and record	Nagions Refer to WHO 2006 growth charts. Severe malnutrition if BMI / Age <= -	If medical complications (e.g., infection, severe anaemia, dehydration) Admit/Refer the child to Hospital. Treat urgently complications Give theF75, F100orRUTF and continue breast feeding if the child is under18 months If no medical complications: Treated as an outpatient with RUTF and continue breastfeeding if the child is under 18 months. If medical complications, treat these complications
	3ZS-2Zs Good nutritional status if BMI/Age > - 1ZS	If medical complications, treat these complications Give the CSB+. If no complications give CSB + and continue counselling.

 Table 8. Nutritional management for children between 5-10 years

11.4. Initial clinical and laboratory evaluation of children young than 10 years living with HIV

11.4.1. Clinical evaluation

- Comprehensive physical examination
- WHO HIV staging in children
- Growth assessment and malnutrition screening
- Neurodevelopment and intellectual assessment
- Drug history for the child and mother

11.4.2. Laboratory evaluation

• Baseline:

- CD4% preferred if < 5years old
- Hepatitis B surface antigen,
- Hepatitis C antibody,
- Liver Function (ALAT*, ASAT*)
- Renal Function (Creatinine and calculation of creatinine clearance, formula see below)
- Cryptococcus antigen (if CD4 count < 200cells/mm3) < 5years old consider CD4<20%.
- Additional lab exams as clinically indicated

Creatinine clearance (CrCl) in children (except infants) is calculated using the following formula (Schwartz equation):

CrCl (ml/min) = [length (cm) x k] / Creatinine [Umol/l]

To get the absolute CrCl, the value obtained from Schwartz must be multiplied by BSA/1.73. That would, for example, tell us if child's CrCl is high enough to safely use adult TDF dose (generally > 70 ml/min).

k = 0.45 for infants 1 to 52 weeks old

k = 0.55 for children 1 to 13 years old

Interpretation of Renal Creatinine Clearance

≥ 90 ml/min. = Normal

60-89 mL/min = Mild Renal insufficiency

30-59 ml/min = Moderate Renal insufficiency

≤ 29 mL/min = Severe Renal insufficiency

Note:

For children, If clearance $> 70\,$ mL/min, OK for TDF; if clearance $< 70\,$ mL/min, not give TDF

If decrease in creatinine clearance \geq 15%, consider possible TDF toxicity and switch from TDF

Notice:

-In case of drug toxicity, change only the suspected molecule not all drugs

- It is advised that after stopping EFV or NVP the patient should continue with their 2–NRTI based regimen (e.g. TDF + 3TC) for 7 days after stopping the NNRTIs to avoid likelihood of resistance.

11.5. ART regimen for children younger than 10 years of age

11.5.1. The first line option ART regimen in children

Table 9.First line option ART regimen in children

	Children young than 3	Children 3 to 10 years of
	years of age	age < 35 kg
Preferred	ABC+ 3TC+ LPV/r	ABC+3TC+ EFV
Alternatives	a) ABC + 3TC + NVP	ABC + 3TC + NVP
	b) $AZT + 3TC + LPV/r$	AZT + 3TC + EFV or NVP
	c) $AZT + 3TC + NVP$	HBV co-infection: TDF +
		3TC + EFV or NVP

*Note:

- In Hepatitis B co-infection, TDF may be considered in children older than 2 years
- By 3 years of age, a child should be switched from LPV/r to EFV based regimen if the VL is suppressed

11.5.2. Dosing and administration of and prescription of first-line ART regimen in children

For the dosing, administration and prescription of ART first line-ART regimen for children refer to medical file (Dosing chart for children and Adolescent).

11.6. HIV-TB Co-infection management in children younger than 10 years of age

11.6.1. Screening of TB-HIV Co-infection in Children

All HIV positive children should be screened for active TB disease at enrolment and regularly at each encounter with a health worker or visit to a health facility. Children having the following symptoms should be evaluated for TB disease: any cough, fever, loss of weight and history of contact with an infectious TB case.

11.6.2. Isoniazid Preventive Therapy (IPT) in Children

Children living with HIV who are unlikely to have active TB on symptombased screening and have known contact with a TB case should receive 6months of IPT (10 mg/kg/day).

11.6.3. Diagnosis of TB-HIV co-infection in Children

The following examinations are used to diagnose active TB infection:

- Sputum if child is able to produce sputum sample, induced sputum if available, or gastric aspirate if child unable to provide sputum sample (typically younger than 5-10 years old)
- AFB Microscopy with Ziehl Nelson stain and culture, if available
- GeneXpert (based on availability).
- Tuberculin skin test: A negative TST does not exclude TB disease. It may be negative despite the child having TB, especially in severe disseminated TB, malnutrition and HIV disease
- Chest X-ray

<u>Note</u>:

Children suspected of having extra-pulmonary TB should be managed at a referral centre. Fine needle aspiration (FNA) or a lymph node biopsy may be performed if a lymph node is suspicious for tuberculosis.

Refer to Annex.2.1. Diagnostic algorithm of TB-HIV co-infection

11.6.4. Treatment of TB-HIV co-infection in Children

- As for TB uninfected children, all HIV-positive children with confirmed TB co-infection are eligible for ART regardless of CD4 count and clinical stage.
- ART should be started in any child with active TB disease as soon as possible and within eight weeks following the initiation of anti-TB treatment irrespective of the CD4 count and clinical stage
- The TB treatment in children diagnosed with TB disease should be initiated immediately. The TB treatment lasts for 6 months for newly diagnosed cases and for 8 months for previously treated cases, but lasts 12 months for meningeal and osteo-articular forms of TB disease.

Phases	Months/	Drug	Paediatric tablets		
	dosage		5-7Kg	8-14 kg	15-20 kg
Intensive	2 months	$(R_{60}H_{30}Z_{150})$	1	2	3
	(56 doses)	$(R_{60}H_{60})$	1	2	3
		(E ₁₀₀)	1	2	3
Continuous	4 months	$(R_{60}H_{30})$	1	2	3
	(112 doses)	$(R_{60}H_{60})$	1	1	2

Table 10.TB Treatment for children: 2(RHZ)E/4(RH)

Current ART	ART Adjustment with Anti-TB Therapy		
	Children < 3 Years Old	Children > 3 Years Old	
ABC/AZT+ 3TC + EFV	ABC+AZT+ 3TC EFV currently not recommended under 3 years*	ABC/AZT+ 3TC + EFV	
ABC/AZT+ 3TC + NVP	Increase NVP by 30%* Or switch to EFV if > 3.5kg	Substitute NVP with EFV	
ABC/AZT+ 3TC+LPV/r	Replace Rifampicin	Increase the dose of Ritonavir to achieve 1:1 ratio (LPV/r)	
	Alternative: Substitute LPV/r with NVP increased by 30% for < 3.5kg	<i>Alternative</i> : ABC + 3TC + AZT (not a strong combination)	

Table 11.ART and Anti-TB therapy in Children

Note*:

1) If NVP dosing increased, ALAT should be done at 2 weeks, 1 month, 3 and 6 months

11.7. Management of Opportunistic Infections in Children

Refer to Annex.2.2. Management of common opportunistic infections

11.8. Management of Treatment Failure in Children

11.8.1. Identification of Treatment Failure

Monitoring people living with HIV receiving ART is important to ensure successful treatment, identify adherence problems and determine whether and which ART regimens should be switched in case of treatment failure.

The treatment failure is defined by the virological failure (plasma viral load >1000 copies/ml) based on two consecutive viral load measurements after 3 months with adherence support. Refer to **Annex.2.3.** Early Management of Treatment Failure.

A poor immune reconstitution despite a good virological control is frequent during the first year of HAART. This condition seems mainly driven by the age and the low baseline CD4 count of the patients.

The monitoring of ART response and identification of treatment failure are the same as for adolescent and adults except the following specifics to children:

NB: Clinical follow up and pharmacy refill shall be done every month in children less than 10 years and every 3 months in stable and adherent children more than 10 years old or in boarding school.

Table 12.Second Line ART in Children

First-line Regimen	Preferred Second-line Regimen	Alternative Second-line Regimen
Children < 3 years		
ABC + 3TC + LPV/r	ABC+3TC+RAL	AZT+ 3TC + LPV/r (switch to EFV if the child is > 3 years age)
ABC + 3TC + NVP	AZT+ 3TC + LPV/r	
AZT + 3TC + LPV/r	ABC + 3TC + RAL	ABC + 3TC + EFV
AZT + 3TC + NVP	ABC + 3TC + LPV/r	
Children 3 to 10 years	of ages	
ABC + 3TC + EFV	AZT + 3TC + ATV/r if > 6 YO	AZT+ 3TC + LPV/r if children less than 6 years
AZT + 3TC + EFV/NVP	ABC + 3TC + ATV/r if > 6 YO	ABC+3TC+ LPV/r if children less than 6 years

NB:

- Keep TDF in second line if active HBV infection
- ATV cannot be co-administered with rifampicin,
- *ATV* boosted with *RTV* (*ATV*/*r*) is recommended for children aged at least 6 years (see dosing below)

11.8.3. Dosing of Second-line Drugs in Children

- ABC/TDF/3TC and LPV/r refer to the first line regimen dosing (Paediatric dosing)
- ATV/r capsules: 100 mg, 150 mg, 200 mg, and 300 mg

Table 13. Dosing of Second-line Drugs in Children

Weight (kg)	Once-Daily Dose
15–<20 kg	ATV 150 mg + RTV 100 mg, both once daily with food
20–<32 kg	ATV 200 mg + RTV 100 mg, both once daily with food
32–<40 kg	ATV 250 mg* + RTV 100 mg, both once daily with food
≥40 kg	ATV 300 mg + RTV 100 mg, both once daily with food

<u>Note</u>:

*FDC is preferred *Dose requires two different capsule strengths of ATV

Refer to Annex.2.4. Management of Treatment Failure for patients on second line regimen

11.8.4. Regimens for Third-line ART in Children

Table 14. Regimens for Third-line ART in Children

NNRTIS	PIs	IIs
Etravirine (ETV)	Darunavir (DRV/r)	Raltegravir (RAL)
In some cases, TDF and 3TC should be associated		

Note:

- Third line is given by Expert only
- Genotyping & VL are required before switching to third line.
- In some case, switching to second line may require genotyping (clinical decisions in case of poor adherence suspicion)

Refer to Annex.2.5. Management of Treatment Failure on Second Line Regimen

11.9. Monitoring of children on ART

Clinical assessment and laboratory tests play a key role in assessing individuals on ART is initiated and then monitoring their treatment response and possible toxicity of ARV drugs.

Note that once started, ART is a treatment for life but should be changed in the following cases:

- Drug toxicity or severe side effects
- Drug interaction
- Co-infection
- Treatment failure confirmed by viral load

11.9.1. Recommendations on Monitoring of children

Table 15. Recommendations on Monitoring of children

Period	Clinical	Laboratory	
M0	Psychological support	CD4, HBsAg, HCVAb,	
(Baseline)		CRAG if CD4<200/ml	
M1	Adherence, screen side effects and	Creatinine (Clearance) if	
	encourage to screen for NCDs	TDF	
M2	Adherence, screen side effects and	None	
	encourage to screen for NCDs		
M3	Adherence, screen side effects and	Creatinine (Clearance) if	
	encourage to screen for NCDs	TDF	
M6	Adherence, screen side effects and	VL, Creatinine	
	encourage to screen for NCDs	(Clearance) if TDF	
M12	Adherence, screen side effects and	VL, Creatinine	
	encourage to screen for NCDs	(Clearance) if TDF	
M18	Adherence, screen side effects and	VL, Creatinine	
	encourage to screen for NCDs	(Clearance) if TDF	

Note:

(1) CD4 will be done at Baseline, then continued annually only patients who fail to suppress their VL at 6months (12month, 24 month,) up to when the patient will suppress the VL then we will stop CD4

(2) For children, clinical consultation and adherence support should be done on monthly basis, each consultation should inform treatment dosing adjustment according to the child weight.

(3) FBC, ALAT and amylase will be done if clinically indicated or as per regime of the child

(4) Genotyping is recommended for patients failing second line or some special cases failing first line before ART switching as per provider judgment.

11.9.2. Evaluation of Dermatological Toxicity

Table 16. Grading and evaluation of dermatological toxicity in adult

Grade 1	Grade 2	Grade 3*	Grade 4
Erythema,	Widespread	Appearance of	Appearance of the
pruritus	maculopapular	blisters or humid	following signs:
	eruptions of	desquamation or	affecting the mucosa,
	dry	ulceration or	Stevens Johnson
	desquamation	association with	syndrome, Erythema
		fever or pain	multiform, necrosis, or
			exfoliative dermatitis.

*Note that the suspected drug will be stopped only if the toxicity is \geq Grade 3

11.9.3. Evaluation of Hepatotoxicity

	Normal	Grade1	Grade 2	Grade3*	Grade4
ALAT(SGPT)	< 40	50-100	100-200	200-400	>400
(UI/l)					

Table 17. Grading and evaluation of hepatotoxicity in adult

*Note that the suspected drug will be stopped only if the toxicity is \geq Grade 3

11.10. Management of most common ARVs side effects

Refer to Annex.2.5. Management of most common ARVs side effects

11. HIV CARE AND TREATMENT FOR ADOLESCENTS AGED BETWEEN 10-19 YEARS

11.1. Psychosocial assessment and treatment preparation for adolescent living with HIV aged between 10 -19 years

As was mentioned in the Chapter 10 psychosocial assessment is done for the purpose to identify all psychological and social needs which could affect the adherence. The psychosocial assessment is conducted through individual counselling and is done to every new HIV positive enrolled in care and treatment services and to experienced ART clients at every visit for ensuring a good adherence.

For the adolescents perinatal infected psychosocial assessment is done at every visit in ART services while for adolescents sexually infected the psychosocial assessment have to be conducted ART initiation.

The below table gives details of how to conduct psychosocial assessment among adolescents.

Table 18. Psychosocial assessment and treatment preparation atenrolment and at every visit

At enrolment

During individual counselling health care providers ask open end questions in order to assess the psychological and mental health status of the adolescents. Through the Mental health screening tool(see annex 2.9), health care providers assess the following:

- Depression
- Emotion
- Behaviour
- Cognitive

Health care providers should also assess sexual abuse, drugs and alcohol history.

When mental or psychological problems are identified, health care providers should refer the patient to mental health specialization services

Health care providers should assess also the social health of the adolescent which include family, community, spiritual life and school or job.

Adolescents sexual activity

- Does he/she have sexual partner?
- Does he /she use the condom?
- What does he/she think about disclosure (partner or relative) Is there any fear or concern about disclosure?

Adolescent family history financial and economic status

- Can he/she identify the support from the family?
- Does the caregiver have a job?
 - Is the schedule of his school or job facilitating the time to take the medication?
 - How does the adolescent arrive to health centre? Does she /he have transport fees from home to health facility?
 - How is the spiritual life of adolescent? What is his/her religion?
 - How is his/her accommodation? Do they access to clean water and sanitation? How many members of the family do live in the household?
 - Does the adolescent have the medical insurance?
 - How is his/her school performance?

To prepare ART adherence in advance

- To encourage the adolescents to attend education and preparation session before ART initiation
- To encourage the adolescents to have treatment supporter

As the children aged 12 can be tested for HIV without their parents' consent, in the process of ART initiation this categories of age is not obligated to bring their parents but encouraged to have treatment supporters.

N.B: -Document all information of psychosocial assessment in patient file in psychosocial part

- Give the appointment for education and preparation on treatment in not later than three days

For new HIV positive clients, psychosocial assessment is completed by education and preparation to ART medication.

11.1.1. Preparation of new HIV positive adolescents to ART medication

Preparing new HIV positive clients to ART medication is not a single day event, it is a process. The clients have to attend education sessions not later than three days after diagnosis. The preparation is done in group and also in individual counselling session.

In group session: Adolescent clients starting ART should participate in at least two distinct structured group education session. Health provider will use the appropriate material to facilitate the session preparing clients to ART initiation. Existing clients should not be mixed in the same sessions with new clients, who will have different knowledge levels and questions. Clients should be encouraged to bring their treatment supporters to the group education sessions. Before the group education session, health care workers consider the member of the groups and adapt the education session to particularity of the group for example if the group is for the pregnant women the focus will be transmission

mother to child, alimentation of the baby, etc. If the group is for adolescents, the focus will be prevention of risk behaviours, peer pressure, sexual and reproductive health etc.

The table below presents key topics to be discussed during group education

Phase	Topics during group education
	• The client's understanding of his own diagnosis
	• Knowledge of how HIV is transmitted and prevented
Basic	• How HIV affects the immune system
Information	• The meaning of the CD4 count
About HIV	• What is ART and who needs ARVs and ART; beliefs and
Care and	attitudes about ART
Treatment	• Benefits and challenges of ART and drug resistance
	• Importance of ongoing care and regular clinic visits and
	keeping appointments
	Positive living
	Importance of disclosure
	• Family testing and enrolment
	Nutrition
	• Safer sex, dual protection, and prevention and treatment of STIs
	 Pregnancy intentions and preventing new infections in
	• Fregnancy mentions and preventing new meetions in babies
	• OI prophylaxis and treatment of OIs (especially CTX)
	• TB prevention and treatment
	• Identification of sources of social support (family,
	treatment supporter, counsellor, support groups,
	community groups)
	• Summary, question-and-answer period, reminder to participants about the next session (time, date, location)
	 Offer to provide follow-up on any of these topics in
	individual counselling
	individual counsering
	• ART = lifetime commitment.
	• Importance of adherence to care plan and to treatment
Adherence	• What can happen if you don't adhere to care and

Table 19. Phases and topics to be discussed during group education

tractment		
treatment		
Previous adherence experiences (CTX, TB, etc.)		
 Common adherence barriers and challenges. 		
Adherence strategies and tips.		
• Special adherence issues for pregnant women and		
adolescents		
• Understanding the treatment plan (explanation of each		
ARV, dosing schedule, what to do about missed or late		
doses)		
Preventing and managing side effects.		
• Problem-solving around adherence barriers, including the		
use of tools such as medicine diaries, pill boxes, watches,		
cell phones, etc.		
How to make the care and treatment plan part of everyday		
life		
What to do if there is a problem or question		
Reminders on positive living, safer sex, and pregnancy		
planning		
Linkages and referral to support groups and community		
support services		
Summary, time for questions and answers		
• Offer to provide follow-up on any of these topics in		
individual counselling.		

In individual sessions: Although group education sessions are efficient for giving key information to many people simultaneously, clients initiating care and treatment also need to speak privately with a health care worker but adolescents (10-19years) will be accompanied by their parents/caregivers or treatment supporter. So, before any client begins ART, provide at least one individual counselling session. In this session, the health care worker answers any questions of clients and assesses the readiness of clients to start ART medication.

To assess the readiness, health care workers consider the following key elements

- Does the client understand HIV, AIDS, ARVs, Viral load, CD4 count/percentage, and their relationship with health status?
- Does he/she understand the importance of keeping appointments?
- Successful adherence to OI treatment (If any)
- Does he/she have treatment supporter to assist treatment adherence and medication reminder?
- Does she/he know the specific regime drugs (names of drugs, colour/shape, how and when to take) and common side effects and their management?
- Discussion of adherence strategy, including medication schedule and methods for remembering. What to do when planning to be away from home. Remembering to keep appointment.
- Patient's desire and commitment to taking lifelong therapy
- Household conditions of drug storage met
- Health care team has to ensure that the clients allow home visits in the context of adherence assessment or support.

Note that all information captured during this session are documented in patient file in psychosocial part.

11.1.2. ART Adherence among HIV positive adolescents

The ability to execute treatment adherence implies treatment literacy of the patient/caregiver. This means that the patient must understand both the disease process and necessary medications.

Poor adherence may encompass any of the following:

- Missing one or more doses of a given drug.
- Missing entire days of treatment.
- Missing appointments.
- Not taking medications on time.
- Not following dietary instructions.

Like for children, assessing adolescent adherence is done in multidisciplinary team approach. Adherence monitoring should be the duty of every health care provider participating in the care of HIV-infected adults.

What could be the barriers of adherence among adolescents?

For addressing adherence, health care workers have to know what could be the causes of bad adherence among the target group of adolescents. Some factors highlighted bellows are specifically to adolescents:

- Stigma
- Forgetting
- Disclosure issues
- Worrying about disclosure
- Falling away from home and busy and varied schedules including school attendance
- Feeling well is leading to passivity and neglecting to take ART
- Denial and fear their HIV infection
- Sexual development
- Depression and mental disorders
- Active alcohol/substance abuse
- Pill burden and dosing
- Palatability
- Treatment fatigue
- Peer pressure
- Low self-esteem
- Misinformation
- Distrust of the medical establishment
- Fear and lack of belief in the effectiveness of medications
- Unstructured and chaotic lifestyles
- Lack of familial and social support
- Co morbidities
- Adverse effects of medication
- Negative attitude of health care team
- Illiteracy
- Poor understanding of the relationship between non-adherence and resistance

Adherence assessment among adolescents

Like for children, adolescents who are taking ART treatment have to be assessed their adherence in order to overcome any issues which could affect negatively the goal of ART treatment. The adherence assessment is task of multidisciplinary team involved in ART services.

Below are methods to adhere adherence:

Pill identification test (in pharmacy service)

- 1. Could you share with me the name or show me your medication?
- 2. Explain more how and when these medication are taken.

Pharmacy record form review (in pharmacy service)

Health care providers check if the client respects the appointment for picking the medication, if he/she does not experience any medication stock out.

Pill count methods in pharmacy

At every visit, clients are encouraged to bring the remaining pills for the next appointment. With this health care providers in collaboration with client, to calculate the proportion of adherence by using the bellow formula:

% Adherence = Dispensed – Returned x 100/ Expected to be taken

Self-report (consultation, counselling and pharmacy room)

- 1. What is your perception on the potential consequences of not taking the medication every day?
- 2. How difficult is it to integrate your medication with your school/home schedule?
- 3. How much support or stigma do you experience at your school / home in regards to your medication administration constraints?
- 4. How hard is it to stick to your daily medication schedule? How often do you take drug holiday?

- 5. What support or reminds do you have to help take your medicine at the same time?
- 6. Some young people find it hard to always remember to take their pills, thinking back over the past four days, have you missed any of your doses? What about the last two weeks? What about the last four month
- 7. With your twice daily medication, is it the morning or evening dose that seems to be difficult to take? How do you handle it?
- 8. How suitable is it to take your evening medication on time?
- 9. Sometimes medicine makes people not feel well, does this happen to you? Does this make you stop your medicine?
- 10. When you travel or leave home, how do you take your medicine?
- 11. Taking medicine every day is real inconvenience for some people; do you ever have difficulties about sticking to your ART treatment plan?

Strategies for promoting and supporting adherence among adolescents

Interventions for promoting and supporting ART adherence need to be focused to the individual adolescent's need and done in multidisciplinary approach. Health care workers help clients to adhere by working to make services clientfriendly, practicing good communication skills, maintaining confidentiality, offering peer support, and developing outreach and follow-up systems. Working in clients friendly services, good communication, ongoing education and peer support group, and strong outreach and follow up.

Table 20. Strategies for promoting and supporting adherence among adolescents

Strategies	Strategies What to do	
Clients friendly services	 Arrange appointments for adolescents who have to see more than one health care provider at one visit Arrange appointments for adolescent at a time when they don't go to school (in the weekends) Arrange a good environment(where clients could sit with shade Good counsellor attitude with: 	
Good communication	 Good counsellor attitude with: Active listening Respect and dignity to the patients Never judge someone that you are counselling. Ask open-ended questions about adherence to help the client share. Encourage and praise the clients who have a good adherence 	
Confidentiality	 Remind clients that their information may be shared among the multidisciplinary team but will not be disclosed outside that group. Make sure all clients understand that what is said at the health facility is confidential. Assure clients that HIV status of their children will not be disclosed without their consent. Remind clients that they might see other community members at the health centre and help them prepare for this. 	
Ongoing education, counselling and peer support	 During the ongoing education session, health care workers ensure that the adolescents know his/her HIV status especially when the diagnosis was disclosed to their parents when the adolescent was young. If the disclosure is not yet done, plan it in collaboration with adolescents/ caregivers At every visit, health care providers have to ensure IEC session on different topics such as the importance of taking the drugs every day, drugs resistance, safe sexual activity, how to handle medications adverse effects. Discussing about traditional medicine and religious beliefs Remind clients how to take medication properly 	

	(their names, dosing and	
	• Encourage adolescents and adults to attend in peer	
	support groups	
	• Encourage adolescents to use phones, watches or	
	any other new technologies for reminding them to	
	take the medication and to respect the appointment	
	• Connect the clients to peers support group and	
	monitor it.	
	• Encourage clients to have treatment supporters. For	
	adolescent who are in boding school, encourage	
	them to identify a teacher or any adults persons who	
	can play a role of treatment supports at school	
	- At every 6 months, health care workers arrange the	
	education session with adolescent and their parents. This help to increase the literacy of adolescents as	
	1 2	
	well as their parents/caregivers about the HIV, its	
	treatment and the importance of a good adherence.	
Outreach and	Managing severe and non-severe adverse effects	
follow up	- Assess mental health status and refer to appropriate	
-	services if any problem related identified	
	- Use an appointment system to track which patients	
	are supposed to come to the clinic each day, and for	
	which services.	
	- Give clients reminder cards (carte de rendez vous)	
	so they know when to come back to the clinic.	
	Develop tracing systems to follow up with clients	
	who miss appointments.	
	- Keep contact information updated and organized for	
	each client	
	- Link HIV clients with PLHIV associations and	
	nongovernmental organizations (NGOs) in the	
	community that can help support adherence.	
	For clients who have missed appointments: Conduct	
	home visits and counselling for assessing caused related	
	to appointment missed	
	to uppointment inissed	

11.1.3 Psychosocial support group for adolescents

11-14 years old

The objectives are to understand: how the virus affects the body (i.e. how HIV affects cells)' identify the three modes of transmission of HIV, what does NOT transmit HIV (the myths/misconceptions); confidentiality (age appropriate discussions; and challenges to taking medicine at school

Topics

- The multiplication of the virus and the role of ARV;
- Life experience with HIV, secret;
- Taking drugs;
- Life hygiene;
- Hard times in the life of the child and the future;
- HIV transmission and prevention;
- Positive behavior;

15-21 years old

The aim is to enable the adolescent to plan for his/her positive future life

Topics

- Identifying their own emotions
- Sharing these emotions with the class (optional)
- Talking about ways of dealing with these feelings
- Understanding that HIV is not something to be ashamed of and to talk about ways of combating stigma
- Define self esteem
 - Share some problems they are facing at home or in school because of stigma
 - o Define school, home, and self-stigma
 - \circ Talk about reproductive health and positive prevention

11.2. Nutrition assessment for adolescents living with HIV aged between 10 -19 years

Adolescents living with HIV could have acquired HIV infection prenatally or become infected during adolescence. Opportunistic infections and other symptoms result in faltering growth and reduced length and height in almost all HIV-positive children. For adolescents, nutrition assessment using anthropometry should be usually conducted as an initial approach, along with physical examination. BMI-for-age by gender is the best indicator of malnutrition.

11.2.1. General recommendations

HIV-infected adolescent should be routinely assessed for nutritional status, including weight, height and BMI/Age at scheduled visits.

✓ HIV-infected adolescent who are moderately or severely malnourished should be managed as per the national guidelines for uninfected person.

Assessment	Diagnosis	Action
Measure the height and weight, know the age Calculate BMI: weight / height in m ² Observe the signs of malnutrition and record	Refer on WHO growth tables or charts in the medical file. Severe malnutrition if BMI / Age <= -3Zs or oedema	Ifmedicalcomplications(e.g.,infection, severe anaemia,dehydration)Refer or admit the child tothehospitalTreaturgentlycomplicationsGive F75, F100orRUTFIf no medical complications:Treated as an outpatientwith RUTF and continuecounselling
	Mild and moderate Malnutrition if the BMI/Age=-2ZS- 1Zs/>-3ZS-2Zs Good nutritional status if BMI/Age > - 1ZS	If medical complications, treat these complications Give CSB + If no complications give CSB + and continue counselling Praise the mother and encourage him.

Table 21. Nutritional management for adolescents living with HIV

11.3. Initial clinical and laboratory evaluation of adolescents living with HIV aged between 10 -19 years

11.3.1. Clinical evaluation

- o History, review of systems, and past medical history
 - General health status
 - Drug history
 - Sexual History (if applicable)
 - Past medical history: STI; past or present HIV-related illness; Risks for opportunistic infections
 - Screening for opportunistic infections and HIV staging
- Comprehensive physical examination

11.3.2. Laboratory evaluation

• Baseline:

0

- CD4 Cell Count,
- Hepatitis B surface antigen (Ag HBs),
- Hepatitis C antibody (HCV Ab),
- Liver Function (ALAT, ASAT)
- Renal Function (Creatinine and calculation of creatinine clearance)
- Cryptococcus antigen (if CD4 count < 200cells/mm³)
- LFTs (for patients starting NVP based regimen)
- Additional studies as clinically indicated

Creatinine clearance calculation for adolescents

If Creatinine machine reports in mg/dL: (140-age) X weight (kg) (weight at present)

— X 0.85 for a woman

72 X creatinine (mg/dL) Or

If Creatinine machine reports in µmol/L:

(140-age) X weight (kg)

X 0.85 for a woman

0.81 X creatinine (µmol/L)

Interpretation of Renal Creatinine Clearance

≥ 90 ml/min. = Normal
60-89 mL/min = Mild renal insufficiency
30-59 ml/min = Moderate renal insufficiency
≤ 29 mL/min = Severe renal insufficiency

Note:

- If clearance > 50 mL/min, OK for TDF; if clearance < 50 mL/min, give ABC
- If decrease in creatinine clearance ≥ 15%, consider possible TDF toxicity and switch to ABC.

Important Notice

In Case of Drug Toxicity, change only the suspected molecule, not all of the drugs in the regimen
It is advised that after stopping EFV or NVP the patient should continue with their 2–NRTI based regimen (e.g. TDF + 3TC) for 7 days after stopping the NNRTIs to avoid likelihood of resistance.

11.4. ART Regimen for adolescents living with HIV aged between 10 -19 years

11.4.1. The first line ART regimen in adolescents

Table 22.Options recommended in first line regimen in adolescents

	NRTI	NNRTI
1st	Tenofovir(TDF)+Lamivudine(3TC)*Efavirenz(EFV)	
2nd	Abacavir(ABC)+ Lamivudine(3TC)*Efavirenz(EFV)	
3rd	Tenofovir(TDF)+Lamivudine(3TC)*	Nevirapine(NVP)
4th	Abacavir(ABC)+ Lamivudine(3TC)*	Nevirapine(NVP)
5th	Zidovidine (AZT))+Lamivudine(3TC)*	Efavirenz(EFV)
6th	Zidovidine (AZT))+Lamivudine(3TC)*	Nevirapine(NVP)

*Lamivudine can be substituted by FTC

- If contra indication to Efavirenz then give, Niverapine
- If contra indication to TDF then give Abacavir

11.4.2. Dosing and administration of first-line ART regimen in adolescents

Table 23. Dosing and administration of first-line regimen in adolescents

Molecule	Dosage	
Tenofovir(TDF)	300 mg once a day	
Abacavir(ABC)	300 mg twice a day or 600 mg once a day	
Lamivudine(3TC)	150 mg twice a day or 300 mg once a day	
Emtricitabine(FTC)	200 mg once a day	
Efavirenz(EFV)	600 mg once evening	
Nevirapine(NVP)	200 mg once a day for 14 days and then 200 mg	
	twice a day	
Zidovidine (AZT)	300 mg twice a day	

Available FDC in Rwanda:

- (1) TDF + 3TC + EFV
- (2) TDF + 3TC
- (3) ABC+3TC
- (4) AZT+3TC+NVP
- (5) AZT+3TC

	Adolescents <35 kg	Adolescents > 35 kg		
Preferred	ABC* 600mg+ 3TC300mg+	TDF 300mg + 3TC 300mg +		
	EFV 600mg (Evening**)	EFV 600mg (Evening**)		
Alternatives	ABC*600mg + 3TC 300mg +	TDF 300mg + 3TC 300mg +		
	NVP (200 mg OD)	NVP (200 mg OD)		
	[Initial Phase (15 Days)]	[Initial Phase (15 Days)]		
	then continue with	then continue with		
	ABC*600mg+ 3TC 300mg +	TDF 300mg + 3TC 300mg +		
	NVP (200 mg BID)	NVP (200 mg BID)		
	[Maintenance phase]	[Maintenance phase]		
	$A7T 200mg \pm 2TC 150mg \pm NWD 200mg (twice a day)$			
	-AZT $300\text{mg} + 3\text{TC}$ 150mg + NVP 200mg (twice a day)			
	-(AZT 300mg +3TC 150mg twice a day + EFV400 mg OD			
	evening (25-34.9kg)/EFV 600mg OD evening (>35kg)			
HBV co-	TDF 300mg + 3TC 300mg + EFV 600mg /NVP 200mg (BID).			
infection				
Madas				

Table 24. Prescription of ART first line regimen in adolescents

Note:

(*)Give the formulation of ABC 600mg to facilitate once daily dosage.

 $^{(**)}\mbox{Encourage taking drugs in the evening before 8:00pm due to daytime side effects of EFV$

Adolescents >35kg who are already taking ABC-containing regimens can safely substitute ABC for TDF.

Adolescents >35kg should be given once-daily dosing when possible to maximize adherence (e.g. ABC 600mg + 3TC 300mg).

The association of 3 NRTIs (ABC+3TC+AZT) is possible but because of the reduced potency should not be considered except in cases of extreme necessity or after expert opinion/review.

11.5. HIV-TB Co-infection Management in adolescents living with HIV aged between 10 -19 years

11.5.1. Screening of TB-HIV co-infection in adolescents

All adolescents living with HIV should be screened for active TB infection at enrolment and regularly at each clinical encounter with a clinical algorithm using the following symptoms or signs:

- Cough
- Fever or night sweats
- Weight loss
- Contact with someone known to have TB

Refer to Annex.2.0Screening's algorithm of TB-HIV co-infection in adolescents

11.5.2. Diagnosis of TB-HIV Co-infection in adolescents

- Systematic Xpert test prior to ART initiation regardless of clinical symptoms.
- X-ray for patients with persistent of clinical symptoms after negative Xpert test or if patient is enable to provide sputum
- FNA for extra pulmonary TB where it is possible.

Refer to Annex.2.1 Diagnostic's algorithm of TB-HIV co-infection in adolescents

The following are national recommendations on TB-HIV Management:

- 1. The standard first-line anti-tuberculosis regimen in Rwanda is 2RHZE₇/4RH₇ (see Rwanda National TB Guidelines for detailed instructions regarding management of TB)
- 2. The TB treatment lasts for 6 months for newly diagnosed cases and for 8 months for previously treated cases, but lasts 12 months for meningeal and osteo-articular forms of TB disease
- 3. For the treatment of tuberculosis in HIV-infected patients in combination with the ritonavir boosted protease inhibitors Lopinavir

(LPV/r), Atazanavir (ATZ/r), and Darunavir (DRV/r): Rifampicin will be replaced by Rifabutin <u>150 mg per day. The TB treatment will be</u> <u>individual tablet as rifabutin in combination with other anti-TB</u> <u>drugs is not available</u>.Patients with MDR TB should be referred to appropriate treatment centres

- 4. Co-infected patients (TB-HIV) should receivePyridoxine25mg daily (100mg daily for MDR-TB/HIV).
- 5. If a patient has contra-indication to EFV, it can be substituted by LPV/r (with doubled dose of LPV/r) or Atazanavir
- 6. If a patient has contra-indications to both EFV and LPV/r, triple NRTI regimen of AZT/3TC/ABC is acceptable during the TB treatment period.
 - 7. In co-infected patients, the priority is to first treat TB basing on patient's clinical status and CD4 count. Time for ART initiation varies between 2 and 8 weeks as follows:

Category 1	Months/ Number of	Drug	Dosage a (in kilos)	according	to weigh
	doses		29-37 kg	38-54 kg	>54 kg
Intensive Phase	2 months	$(R_{150}H_{75} Z_{400}E_{275})$	2 tab	3 tab	4 tab
(1)	56 doses	S (*)	0.5 g	0.75 g	lg
Intensive Phase	1 month 28 doses	(R ₁₅₀ H ₇₅ Z ₄₀₀ E ₂₇₅)	2 tab	3 tab	4 tab
Continuation phase	5monthss 140 doses	$(R_{150}H_{75} Z_{400}E_{275})$	2 tab	3 tab	4 tab

11.5.3. Treatment of TB-HIV Co-infection in adolescents

Recommendations on TB-HIV Management

People on different ART regimens	ART regimens adjustment
TDF/ABC/AZT + 3TC + EFV	No adjustment (EFV remains 600mg daily)
TDF/ABC/AZT + 3TC + NVP	Substitute NVP with EFV
TDF/ABC/AZT + 3TC + LPV/r	Double dosing of LPV/r during anti- tuberculosis therapy or substitute Rifampin with Rifabutin
TDF/ABC/AZT + 3TC + ATV/r	Substitute ATV/r with double-dosing of LPV/r or substitute Rifampin with Rifabutin

Table 26.Recommendations on TB-HIV Management

The dosage will be based on medical judgment of the patient's response to therapy, and not exceed 600mg/day in some older children.

- Avoid combination of Fluconazole with NVP: use EFV
- Do not use Fluconazole in the first trimester of pregnancy

Rifampicin decreases Fluconazole concentration: increase Fluconazole from 800 to maxim dose (1200mg) and double dosing if maintenance

11.6. Management of Opportunistic Infections in adolescents 10-19 years of ages

Refer to Annex.2.2. The table summarizing the management of Opportunists Infections

11.7. Management of Treatment Failure in adolescents

11.7.1. Identification of treatment failure

Monitoring people living with HIV receiving ART is important to ensure successful treatment, identify adherence problems and determine whether and which ART regimens should be switched in case of treatment failure. The treatment failure is defined by the virological failure (plasma viral load >1000
copies/ml) based on 2 consecutive viral load measurements after 3 months with adherence support. A poor immune reconstitution despite a good virological control is frequent during the first year of HAART. This condition seems mainly driven by the age and the low baseline CD4 count of the patients.

Refer to Annex.2.3. Early Management of Therapeutic Failure

11.7.2. Second-line ART in Adolescents

Table 27.Second Line Regiment ART in adolescents

First-line	Preferred Second-line			
Regimen	Regimen	line Regimen		
Adolescents 10 to	19 years of age <35 kg			
	AZT + 3TC + ATV/r	AZT+ $3TC + LPV/r$ if		
EFV/NVP	if>6 YO	children less than 6 years		
	ABC + 3TC + ATV/r	ABC+3TC+ LPV/r if		
EFV/NVP	if>6 YO	children less than 6 years		
Adolescents 10 to 19 years of age >35 kg				
TDF/ABC+ 3TC	AZT + 3TC + ATV/r	AZT + 3TC + LPV/r		
+ EFV/NVP				
AZT + 3TC +	TDF + 3TC + ATV/r	ABC + 3TC + ATV/r		
EFV/NVP		or LPV/r		

NB:

1) Keep TDF in second line if HBV infection

2) ATV cannot be co-administered with rifampicin, use Rifabutin

3) ATV boosted with RTV (ATV/r) is preferred for adolescents (see dosing below)

11.7.3. Dosing of Second-line Drugs in Adolescents

For dosing of second line drugs in adolescent refer to the children and adolescent dosing chart in appendices or the patient file.

11.7.4. Regimens and dosage for Third-line ART in Adolescents

NNRTIs	PIs	IIs
Etravirine (ETV)	Darunavir (DRV/r)	Raltegravir (RAL)
In some cases, TDF and 3TC should be associated		

In Rwanda, the 3rd line regimen combination is: RAL/ETV/DRV/r*

Note:

- Third line doses: Refer to Section below (Dose tables)
- Patients on 3rd line should receive extensive adherence support and counselling.
- Patients on 3rd line should receive nutrition supplement (at least 400 kcal e.g. 500 ml of porridge per dose)
- Consider the VL >2,000 copies/ml as Genotyping Threshold and >1,000 copies as Treatment Failure Threshold
- The 3rd line regimen must only be given upon expert consultation and usually with the assistance of genotyping test.
- Before prescribing third-line therapy, the patient MUST undergo extensive additional adherence counselling and should have a treatment partner involved with assisting in adherence.
- Third line combination can be adjusted based on Genotyping results and upon HIV Expert view.
- NRTI backbone may be necessary based on genotyping test or in case of Hepatitis B co-infection.

Molecule	Dosage
Raltegravir	400 mg twice a day
Ritonavir	100 mg twice a day
Darunavir	600 mg twice a day
Etravirine	200 mg twice a day

Table 31. Dosing of Third Line Drugs in Adolescent

Note:

- *1) Third line is given by Expert only*
- 2) Genotyping & VL are required before switching to third line.
- *3)* In some case, switching to second line may require genotyping (clinical decisions in case of poor adherence suspicion)

11.8. Monitoring of adolescent on ART

Clinical assessment and laboratory tests play a key role in assessing adolescent on ART is initiated and then monitoring their treatment response and possible toxicity of ARV drugs.

Note that once started, ART is a treatment for life but should be changed in the following cases:

- Drug toxicity or severe side effect
- Drug interaction
- Co-infection
- Treatment failure confirmed by viral load

11.8.1. Recommendations on Monitoring of Adolescent

Period	Laboratory	Clinical	Psychosocial
Mo (Baseline)	CD4, HBsAg, HCV Ab, CRAG if CD4<200/ml	TB and STI Screening	+
M1	Creatinine (Clearance) if TDF	+	+
M2	None	+	+
M3	Creatinine (Clearance) if TDF	TB and STI Screening	+
M6	VL, Creatinine (Clearance) if TDF	TB and STI Screening	+
M12	VL, Creatinine (Clearance) if TDF	TB and STI Screening	+

Table 32. Recommendations on Monitoring of Adolescent

<u>Note:</u>

(1) VL shall be done at M6 after ART initiation thereafter every 12 months

(2) In case of treatment failure, VL will be done 3 months after adherence intervention

(3) After the first year adherence shall be assessed every 3 months in patients demonstrating excellent adherence for the first year

(4) After the first year, pharmacy refill shall be done every 3 months (not monthly) for patients demonstrating excellent adherence for the first year with VL suppression; this will depend on the available stock of ARVs.

(5) FBC, ALAT and amylase will be done if clinically indicated or based on the regimen

(6) Genotyping is recommended for patients failing second line or some special cases failing first line before ART switching as per the provider judgment.

(7) Clinical exam should be done on monthly basis for the 1st quarter then after it will be on quarterly basis

11.8.2. Evaluation of Dermatological Toxicity

	8	8	v
Grade 1	Grade 2	Grade 3*	Grade 4
Erythema,	Widespread	Appearance of	Appearance of the
pruritus	maculopapular	blisters or humid	following signs:
	eruptions of	desquamation or	affecting the mucosa,
	dry	ulceration or	Stevens Johnson
	desquamation	association with	syndrome, Erythema
		fever or pain	multiform, necrosis, or
			exfoliative dermatitis.

 Table 33. Grading and evaluation of dermatological toxicity in adult

*Note that the suspected molecule will be stopped only if the toxicity is \geq Grade 3

11.8.3. Evaluation of Hepatotoxicity

Table 34. Grading and evaluation of hepatotoxicity in adult

	Normal	Grade1	Grade 2	Grade3*	Grade4
ALAT(SGPT)	< 40	50-100	100-200	200-400	>400
(UI/l)					

*Note that the suspected molecule will be stopped only if the toxicity is \geq Grade 3

11.9. Management of most common ARVs side effects

Refer to Annex.2.6 Management of most common ARVs side effects

12. HIV CARE AND TREATMENT FOR ADULTS OVER 19 YEARS OF AGE

12.1. *Psychosocial assessment and treatment preparation for HIV* positive adults

As mentioned in the previous sections, the psychosocial assessment is done for the purpose to identify psychological and social a needs which could affect the adherence. For adults, the psychosocial assessment is done through individual counselling in enrolment to new HIV positive clients. For more details refer to psychosocial assessment for adolescents in chapter 11.

For new HIV positive clients, psychosocial assessment is completed by other sessions of education and counselling preparing them to ART medication while for experienced HIV positive clients it is in complement with adherence counselling conducted at every visit.

12.1.1. Preparation of new HIV positive adults for initiation of ART

Preparing new HIV positive clients to initiate ART medications is not a single event, it is a process. The clients have to attend education sessions 1-2 ideally. These guidelines recommend to minimize unnecessary education sessions except for special cases. Initiation of ARVs same day is preferable however it should be within 1 week for majority of patients.

The preparation is done in groups and also in individual counselling sessions.

In group sessions: adult clients starting ART should participate in at least two distinct structured group education session. Health provider will use the appropriate material to facilitate the session preparing clients to ART initiation. Existing clients should not be mixed in the same sessions with new clients, who will have different knowledge levels and questions. Clients should be encouraged to bring their treatment supporters to the group education sessions. Before the group education session, health care workers consider the member of the groups and adapt the education session to particularity of the group for example if the group is for the pregnant women the focus will be transmission mother to child, alimentation of the baby, etc. If the group is for adolescents, the

focus will be prevention of risk behaviours, peer pressure, sexual and reproductive health etc.

Table 35 presents key topics to be discussed during group education

Table 35.Key topics to be discussed during group for the preparation of
new HIV positive adults to ART medication

	T	
•	• Importance of adherence to care plan and to treatment	
Adherence	• What can happen if you don't adhere to care and	
to HIV	treatment	
Care and	• Previous adherence experiences (CTX, TB, etc.)	
Treatment	• Common adherence barriers and challenges.	
	• Adherence strategies and tips.	
	• Special adherence issues for pregnant women and	
	adolescents	
	• Understanding the treatment plan (explanation of each	
	ARV, dosing schedule, what to do about missed or late	
	doses)	
	 Preventing and managing side effects. 	
	use of tools such as medicine diaries, pill boxes, watches,	
	cell phones, etc.	
	• How to make the care and treatment plan part of	
	everyday life	
	• What to do if there is a problem or question	
	• Reminders on positive living, safer sex, and pregnancy	
	planning	
•	• Linkages and referral to support groups and community	
	support services	
	• Summary, time for questions and answers	
•	chief to provide tonow up on any of these topies in	
	individual counselling.	

In individual sessions: Although group education sessions are efficient for giving key information to many people simultaneously, clients initiating care and treatment also need to speak privately with a health care worker. Therefore, before any client begins ART, at least one individual counselling session should be provided. In this session, the health care worker answers any questions of clients and assesses the readiness of clients to start ART medication.

To assess the readiness, health care workers consider the following key elements

- Does the client understand HIV, AIDS, ARVs, Viral load, CD4 count/percentage, and their relationship with health status?
- Does he/she understand the importance of keeping appointments?
- Successful adherence to OI treatment (If any)
- Does he/she have treatment supporter to assist treatment adherence and medication reminder?
- Does she/he know the specific regime drugs (names of drugs, colour/shape, how and when to take) and common side effects and their management?
- Discussion of adherence strategy, including medication schedule and methods for remembering. What to do when planning to be away from home. Remembering to keep appointment.
- Patient's desire and commitment to taking lifelong therapy
- Household conditions of drug storage met
- Health care team has to ensure that the clients allow home visits in the context of adherence assessment or support.

Note that all information captured during this session are documented in patient file in psychosocial part.

12.1.2. ART Adherence among HIV positive and adults

Adherence is the process of taking medications in the correct amount, at the correct time, and in the way they are prescribed (with or without food). Proper storage of medications is another component of successful adherence. The ability to execute treatment adherence implies treatment literacy of the patient/caregiver. This means that the patient must understand both the disease process and necessary medications.

Poor adherence may encompass any of the following:

- Missing one or more doses of a given drug.
- Missing entire days of treatment.
- Missing appointments.
- Not taking medications on time.
- Not following dietary instructions.

Like for children, assessing the patient's adherence should be done in multidisciplinary team approach. Adherence monitoring should be the duty of every health care provider participating in the care of HIV-infected adults.

What could be the barriers of adherence among adults?

Barriers for adherence among adults are not far for those identified among adolescents. For more details refer to the chapter 11.1.2

Adherence assessment among adults

Like for children, adolescents and adults who are taking ART treatment have to be assessed their adherence in order to overcome any issues which could affect negatively the goal of ART treatment. The adherence assessment is task of multidisciplinary team involved in ART services.

Below are methods to adhere adherence:

Pill identification test (in pharmacy service)

- 1. Could you share with me the name or show me your medication?
- 2. Explain more how and when these medication are taken

Pharmacy record form review (in pharmacy service)

Health care providers check if the client respects the appointment for picking the medication, if he/she does not experience any medication stock out

Pill count methods in pharmacy

At every visit, clients are encouraged to bring the remaining pills for the next appointment. With this health care providers in collaboration with client, to calculate the proportion of adherence by using the bellow formula:

% Adherence = Dispensed – Returned x 100/Expected to be taken

Self-report (consultation, counselling and pharmacy room)

- 1. What is your perception on the potential consequences of not taking the medication every day?
- 2. How difficult is it to integrate your medication with your school/home schedule?

- 3. How much support or stigma do you experience at your school / home in regards to your medication administration constraints?
- 4. How hard is it to stick to your daily medication schedule? How often do you take drug holiday?
- 5. What support or reminds do you have to help take your medicine at the same time?
- 6. Some people find it hard to always remember to take their pills, thinking back over the past four days, have you missed any of your doses? What about the last two weeks? What about the last four month
- 7. With your twice daily medication, is it the morning or evening dose that seems to be difficult to take? How do you handle it?
- 8. How suitable is it to take your evening medication on time?
- 9. Sometimes medicine makes people not feel well, does this happen to you? Does this make you stop your medicine?
- 10. When you travel or leave home, how do you take your medicine?
- 11. Taking medicine every day is real inconvenience for some people; do you ever have difficulties about sticking to your ART treatment plan?

12.1.3. Strategies for promoting and supporting adherence among adults

Strategies for promoting and supporting adherence are done at every visit and by multidisciplinary team. The interventions are same as those done for children and adolescents: services client-friendly, practicing good communication skills, maintaining confidentiality, offering peer support, and developing outreach and follow-up systems.

Table 36. Strategies for promoting and supporting adherence among adults

Strategies	What to do
Clients	
friendly	- Arranging a good environment
services	
Good	- Good counsellor attitude with :
communication	• Active listening
	• Respect and dignity to the patients
	• Never judge someone that you are counselling.
	 Ask open-ended questions about adherence to help the client share.
	- Encourage and praise the clients who have a good
	adherence
Confidentiality	 Remind clients that their information may be shared among the multidisciplinary team but will not be disclosed outside that group. Make sure all clients understand that what is said at the
	health facility is confidential.
	- Remind clients that they might see other community members at the health centre and help them prepare for this.
Ongoing	- At every visit, health care providers have to ensure
education, counselling and peer support	• IEC session on different topics like Importance of taking the drugs every day, drugs resistance, safe sexual activity, how to handle medications adverse effects. Discussing about traditional medicine and religious beliefs
	• Remind clients how to take medication properly (their names and dosing
	• Encourage adults to attend in peer support groups
	• Encourage adults to use phones, watches or any other new technologies for reminding them to take the medication and to respect the appointment

	 Connect the clients to peers support group and monitor it. Encourage clients to have treatment supporters .For adolescent who are in boding school, encourage them to identify a teacher or any adults persons who can play a role of treatment supports at school
Outreach and follow up	 Managing severe and non-severe adverse effects Assess the Mental health status and refer to appropriate services if any problem related identified Use an appointment system to track which patients are supposed to come to the clinic each day, and for which services. Give clients reminder cards (carte de rendez-vous) so they know when to come back to the clinic. Develop tracing systems to follow up with clients who miss appointments. Keep contact information updated and organized for each client Link HIV clients with PLHIV associations and nongovernmental organizations (NGOs) in the community that can help support adherence. For clients who have missed appointments: Conduct home visits and counselling for assessing caused related to appointments missed

12.1.4. Psychosocial support group for Adults (19 years old and above)

The aim is to <u>help patients to adopt positive behaviors and attitudes with respect</u> to <u>HIV/AIDS</u>.

Topics

-Sharing life experience of HIV positive status and treatment

-Providing information and knowledge on HIV/AIDS and prophylactic; and antiretroviral treatment and correct prejudices and false beliefs,

-Promoting emotional support and exchange of experience;

-Strengthening compliance to prophylactic and antiretroviral treatment,

- Association, Income Generating Activities....

Home visit

The medico-psychosocial team have to work with patients to develop and provide a personalized plan of care and home support that helps them live with dignity and independence that align individual needs.

Objectives of home visits:

- To identify the residence of the patient: to verify and complete the information that was recorded earlier in the patient's dossier.
- Ensure a more intensive counseling (for example: failure to disclose HIV serostatus, refusal of testing by the partner).
- Assess the economic and social situation of the patients.
- Find patients who have missed an appointment or are lost to follow up.
- Catalyze participation of the family in the treatment process.
- Break the isolation of the patient.

Organization of home visits:

- Identify cases that need home visits from consultation information, follow up registers, appointment diaries or databases.
- Plan the visits.
- Determine the personal objectives of each patient.
- Prepare the materials to be utilized: (vehicle, kits to be distributed, reporting forms, etc.)

- Carry out home visits.
- Reporting: complete the home visit form and summarize the report in the patient's dossier. Give a verbal report during the staff meeting.

12.2. Nutrition assessment for adults

HIV-infected persons should be routinely assessed for nutritional status, including weight, height and BMI/Age at scheduled visits.

✓ HIV-infected adults who are moderately or severely malnourished should be managed as per the national guidelines for uninfected person.

12.2.1. Nutritional management for Adults living with HIV

Among adults, weight loss and wasting are strongly associated with poor health outcomes for PLHIV. Maintaining weight is a key component of any health care plan for PLHIV. Many anthropometric indices can be used for adults but the most commonly used are: BMI and MUAC. PLHIV should be weighed every month, and keep a record of weight to detect changes as quickly as possible. Weight should be assessed using the same scales.

Table 37.Nutritiona	onal management of adults living with HIV	
Assessment	Diagnosis	Action
	IfBMI18.5- 24.9orMUAC≥23:Goodn utrition If BMI between 16-	Encourage the client and ensure regular monitoring Treat with CSB+(8Kg) and identifying
	18.49orMUACbetween1 9-23 cm:	possible causes, and provide appropriate nutritional counselling
Measure the weight and height and calculate the BMI=weight (kg)/Height (m) ² Measure the	If BMI<16 or MUAC<19 cm Severe malnutrition.	Treat with RUTForF75, F100accordingto the national protocol Admit or Refer to the Hospital if medical complications.

MUAC if Pregnant	1. If BMI between 25	1. Identify the possible causes
or Lactating	and29.9: Overweight	and provide appropriate
women		dietary counselling to prevent
	2 If DMI> 20: Obasity	obesity
	2. If BMI \geq 30: Obesity	2. Identify the possible causes
		and provide appropriate
		dietary counselling to prevent
		complications

12.3. Initial clinical and laboratory evaluation of adults (> 19 years of ages)

12.3.1. Clinical evaluation

- History, review of systems, and past medical history
 - General health status
 - Drug history
 - Sexual History (if applicable)
 - Past medical history: STI; past or present HIV-related illness; Risks for opportunistic infections
 - Screening for opportunistic infections and HIV staging (WHO stage)
- Comprehensive physical examination

12.3.2. Laboratory evaluation

- Baseline:
 - CD4 Cell Count,
 - Hepatitis B surface antigen (Ag HBs),
 - Hepatitis C antibody (HCV Ab),
 - Liver Function (ALAT*, ASAT*)
 - Renal Function (Creatinine and calculation of creatinine clearance)
 - Cryptococcus antigen (if CD4 count < 200cells/mm³)
 - LFTs (for patients starting NVP based regimen)
- Additional studies as clinically indicated

Creatinine clearance calculation for adults.

If Creatinine machine reports in mg/dL: (140-age) X weight (kg) (weight at present)

- X 0.85 for a woman

72 X creatinine (mg/dL) Or

If Creatinine machine reports in µmol/L:

(140-age) X weight (kg)

X 0.85 for a woman

0.81 X creatinine (µmol/L)

Interpretation of Renal Creatinine Clearance

≥ 90 ml/min. = Normal 60-89 mL/min = Mild renal insufficiency 30-59 ml/min = Moderate renal insufficiency ≤ 29 mL/min = Severe renal insufficiency

Note:

- If clearance > 50 mL/min, OK for TDF; if clearance < 50 mL/min, give ABC
- If decrease in creatinine clearance \geq 15%, consider possible TDF toxicity and switch to ABC.

Important Notice

- In Case of Drug Toxicity, change only the suspected molecule not all drugs in the regimen

- It is advised that after stopping EFV or NVP the patient should continue with their 2–NRTI based regimen (e.g. TDF + 3TC) for 7 days after stopping the NNRTI to avoid likelihood of resistance.

12.4. ART Regimen for Adults

12.4.1. First line ART regimen options in Adults

There are 4options recommended in first line regimen for adults > 19 years old:

Table 38.Options recommended in first line regimen for adults

	NRTI	NNRTI
1	Tenofovir(TDF)+Lamivudine(3TC)*	Efavirenz(EFV)
2	Tenofovir(TDF)+Lamivudine(3TC)*	Nevirapine(NVP)
3	Abacavir(ABC)+ Lamivudine(3TC)*	Efavirenz(EFV)
4	Abacavir(ABC)+ Lamivudine(3TC)*	Nevirapine(NVP)

*Lamivudine can be substituted by FTC

- If contra indication to Efavirenz prefer ATZ/r or Lop/r instead of Nevirapine when CD4 > 350.
- If contra indication to TDF then give Abacavir

12.4.2. Dosing and administration of first-line regimen in adults

Molecule	Dosage
Tenofovir(TDF)	300 mg once a day
Abacavir(ABC)	300 mg twice a day or 600 mg once a day
Lamivudine(3TC)	150 mg twice a day or 300 mg once a day
Emtricitabine(FTC)	200 mg once a day
Efavirenz(EFV)	600 mg once evening
Nevirapine(NVP)	200 mg once a day for 14 days and then 200 mg
	twice a day

12.4.3. Prescription of ART first line regimen in adults

- 1) TDF + 3TC + EFV (FDC): TDF 300mg + 3TC 300mg + EFV 600mg
- 2) ABC + 3TC + EFV: ABC 600mg+ 3TC300mg+ EFV 600mg (Evening*)
- 3) ABC**+3TC+NVP:

- Initial Phase (15 Days): ABC600mg + 3TC 300mg + NVP (200 mg OD)
- Maintenance phase: <u>ABC600mg+ 3TC300mg(OD)</u> + NVP (200 mg BID)

 $^{(\ast)}$ Encourage taking drugs in the evening before 8:00pm due to daytime side effects of EFV

(**) Give the formulation of ABC 600mg to facilitate once daily dosage

4) TDF + 3TC + NVP: TDF 300mg + 3TC 300mg (OD) + NVP 200mg (Twice a day).

<u>Note:</u> The association of 3 NRTIs (ABC+3TC+AZT) is possible but because of the reduced potency should not be considered except in cases of extreme necessity or after expert opinion.

Available fixed dose combination (FDC) in Rwanda:

(1) TDF + 3TC + EFV (FDC)

- (2) **TDF** + **3TC**
- (3) AZT+3TC+NVP
- (4) AZT+3TC
- (5) ABC+3TC

12.5. HIV-TB co-infection in Adults

12.5.1. Screening of TB-HIV co-infection in Adults

All HIV-positive adults should be screened for active TB infection at enrolment and regularly at each clinical encounter with a clinical algorithm using the following symptoms or signs:

- 1) Cough
- 2) Fever or night sweats
- 3) Weight-loss
- 4) Contact with someone known to have TB

Refer to Annex.2.0. Screening's algorithm of TB-HIV co-infection

12.5.2. Diagnosis of TB-HIV Co-infection

Refer to Annex.2.1. Diagnostic algorithm of TB-HIV co-infection

12.5.3. Treatment of TB-HIV Co-infection

The following are national recommendations on TB-HIV Management:

- 1) The standard first-line anti-tuberculosis regimen in Rwanda is 2RHZE₇/4RH₇ (see Rwanda National TB Guidelines for detailed instructions regarding management of TB).
- 2) Co-infected patients(TB-HIV) should receive anti TB treatment based on Rifabutin to replace Rifampicin
- 3) Patients with MDR TB should be referred to appropriate treatment centres
- 4) Co-infected patients (TB-HIV) should receivePyridoxine25mg daily (100mg daily for MDR-TB/HIV).
- 5) If a patient has contra-indication to EFV, it can be substituted by LPV/r (with doubled dose of LPV/r) or Atazanavir
- 6) If a patient has contra-indications to both EFV and LPV/r, triple NRTI regimen of AZT/3TC/ABC is acceptable during the TB treatment period.
- 7) In co-infected patients, the priority is to first treat TB basing on patient's clinical status and CD4 count. Time for ART initiation varies between 2 and 8 weeks as follows:

Recommendations on TB-HIV Management

Table 40. Recommendations on TB-HIV Management in Adults

People on different ART regimens	ART regimens adjustment
TDF/ABC/AZT + 3TC + EFV	No adjustment (EFV remains 600mg daily)
TDF/ABC/AZT + 3TC + NVP	Substitute NVP with EFV
TDF/ABC/AZT + 3TC + LPV/r	Double dosing of LPV/r during anti-tuberculosis therapy or substitute Rifampin with Rifabutin
TDF/ABC/AZT + 3TC + ATV/r	Substitute ATV/r with double- dosing of LPV/r or substitute Rifampin with Rifabutin

*The dosage will be based on medical judgment of the patient's response to therapy, and not exceed 600mg/day in some older children.

- Avoid combination of Fluconazole with NVP: use EFV
- Do not use Fluconazole in the first trimester of pregnancy
- Rifampicin decreases Fluconazole concentration: increase Fluconazole from 800 to maxim dose (1200mg) and double dosing if maintenance.

12.6. Management of Opportunistic Infections

Refer to Annex.2.2. Management of opportunistic infections

12.7. Management of Treatment failure in adults

12.7.1. Identification of Treatment Failure

Monitoring people living with HIV receiving ART is important to ensure successful treatment, identify adherence problems and determine whether and which ART regimens should be switched in case of treatment failure.

The treatment failure is defined by the virological failure (plasma viral load >1000 copies/ ml) based on 2consecutive viral load measurements after 3 months with adherence support. A poor immune reconstitution despite a good virological control is frequent during the first year of HAART. This condition seems mainly driven by the age and the low baseline CD4 count of the patients.

Refer to Annex.2.3. EarlyManagement of Treatment Failure

12.7.2. Recommended Regimens for First and Second-line ART

 Table 41. Recommended Regimens for Second-line ART in adults after

 Failure of Specific First Line Regimens

First-line Regimens	Second-line Regimens
TDF+3TC + EFV/NVP	AZT+3TC+ATV/r or LPV/r *
ABC+ 3TC+EFV/NVP	AZT+3TC+ATV/r or LPV/r *
AZT+ 3TC+EFV/NVP	TDF+ 3TC+ATV/r or LPV/r *

* In case of Hepatitis B co-infection, maintain TDF: AZT + TDF + 3TC + ATV/r or LPV/r

12.7.3. Dosing of Second Line ART

Table 42.Dosing of Second Line ART in adults

Molecule	Dosage
ATV/r 300 mg /100 mg (FDC)	300/100 mg orally once a day
LPV/r 200mg/50 mg (FDC)	400/100 mg twice a day

For TDF, ABC, AZT refers to the dosing table for the first line regimen NB: The pill burden for LPB/r regimen is 2 pills twice a day compared to ATV which is one pill once per day (Both in combination with NRTIs.

Refer to Annex.2.4. Management of Treatment Failure for patients on Second Line ART

12.7.4. Recommended Regimens for Third-line ART

In Rwanda, the 3rd line regimen combination is: RAL/ETV/DRV/r*

- The 3rd line regimen must only be given upon expert consultation and usually with the assistance of genotyping test.

- Before prescribing third-line therapy, the patient MUST undergo extensive additional adherence counselling and should have a treatment partner involved with assisting in adherence. Adherence counselling is critical to the success of this regimen.

- Third-line regimens will only be prescribed at specialized centres with trained providers.

- Third line combination can be adjusted based on genotyping results and upon HIV Expert review

-NRTI backbone may be necessary based on genotyping test or in case of Hepatitis B co-infection

Any patient on the second-line with VL > 2,000 copies/ml based on 2consecutive viral load measurements after 3 months with adherence support is eligible for third-line ART.

Refer to Annex.2.5. Algorithm of genotyping and third line initiation

12.7.5. Dosing of Third Line Drugs

Molecules	Dosage
Raltegravir	400 mg twice a day
Ritonavir	100 mg twice a day
Darunavir	600 mg twice a day
Etravirine	200 mg twice a day

Table 43. Dosing of Third Line ART in adults

12.8. Monitoring of adults on ART

Clinical assessment and laboratory tests play a key role in assessing adults on ART is initiated and then monitoring their treatment response and possible toxicity of ARV drugs.

Note that once started, ART is a treatment for life but should be changed in the following cases:

- Drug toxicity or severe side effect
- Drug interaction
- Co-infection
- Treatment failure confirmed by viral load

12.8.1. Recommendations on Monitoring of Adult

Table 44. Recommendations on Monitoring of Adult

Period	Laboratory	Clinical	Psychosocial
Мо	CD4, HBsAg, HCV Ab, CRAG	TB and STI	+
(Baseline)	if CD4<200/ml	Screening	
M1	Creatinine (Clearance) if TDF	+	+
M2	None	+	+
M3	Creatinine (Clearance) if TDF	TB and STI	+
		Screening	
M6	VL, Creatinine (Clearance) if	TB and STI	+
	TDF	Screening	
M12	VL, Creatinine (Clearance) if	TB and STI	+
	TDF	Screening	

Note:

- (1) Follow up CD4 should be done for only for clients that have not suppressed their VL; the schedule is M6 after ART initiation thereafter every 12 months
- (2) In case of treatment failure, VL will be done 3 months after an intensified adherence intervention
- (3) After the first year adherence shall be assessed every 3 months in patients demonstrating excellent adherence for the first year
- (4) After the first year, pharmacy refill shall be done every 3 months (not monthly) coinciding with clinical and adherence assessment FBC, ALAT and amylase will be done if clinically indicated
- (5) Genotyping is recommended for patients failing second line or some special cases failing first line before ART switching.
- (6) If baseline CD4 is more than 350 avoid Nevirapine based regimen
- **12.9.** Management of most common ARVs side effects

Refer to Annex.2.6 Management of most common ARV side effects in appendices.

PART III. SEXUAL TRANSIMITTED INFECTIONS

13. GENERALITIES ON SEXUALLY TRANSMITTED INFECTIONS

Sexually transmitted Infections (STIs) are a major public health concern and constitute a high risk of HIV transmission.

Therefore, they should be timely and efficiently prevented, diagnosed and treated.

13.1. Principles Guiding STI Prevention and Treatment

The policy in the area of the care of STIs is based on the following principles:

- The integration of STI control activities in the minimum activity package of health services;
- Advocacy and mobilization of resources;
- Implementation of multi-sector participation;
- Mobilization of the community and specific groups;
- To avoid stigmatization.

13.2. Strategies

The prevention and the control of STIs are based especially on five major strategies:

- a. Education and counselling of high risk persons on changing their sexual behaviour;
- b. The identification of infected persons with clinical signs (symptomatic) or without clinical signs (asymptomatic) that should consult services in charge of diagnosing and the treatment of STI;
- c. Efficient and early diagnosis and treatment of persons infected by STIs;
- d. Evaluation, treatment, and counselling of partners of persons infected by STIs;
- e. Vaccination of persons with high risk to STI for example systematic vaccination of adolescent girls against HPV before they start sex.

13.3. Major Components of STI Comprehensive Care

Complete care of STIs includes:

- 1) IEC/BCC (focus on risk factors, STIs and HIV relationship)
- 2) Systematic screening of syphilis in pregnant women
- 3) Systematic screening of STIs for new-born, adolescents and adults
- 4) Screening and systematic treatment of FSW and MSM
- 5) Carry out the correct diagnosis;
- 6) Provide correct antimicrobial treatment corresponding to the syndrome of STI, corresponding to the clinical diagnostic of STI or corresponding to the micro-organism of the STI;
- 7) Explain the adherence of the treatment;
- 8) Demonstrate the correct condom use and to make them available and accessible;
- Provide counselling on the treatment of partners and to give the patient an orientation form for the sexual partner so that he/she can send it to his/her partner (s);
- 10) Systematic HTC.

14. PREVENTION OF SEXUALLY TRANSMITTED INFECTIONS

14.1. Primary Prevention: Reduction of the Risk of Infection

- \cancel{P} Reduction of the number of partners
- $\hat{\not{P}}$ Consistent and correct use of condoms
- ℰ Counseling for MC

14.2. Secondary Prevention of STIs

This is the prevention of STIs complications and constitutes primary prevention of HIV infection

- \Rightarrow Promotion of the attitude to seek treatment
- \Rightarrow Provision of quality care services
- \Rightarrow Offer of support and counseling services

15. MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS

In Rwanda, the management of STIs uses 2 approaches implemented at different levels:

- Syndromic approach (recommended at all Health Centres and District Hospitals)
- Etiologic approach (recommended at Referral and provincial hospitals and some district hospitals which have higher lab capability)

15.1. Syndromic Management of STIs

15.1.1. Definition

The syndrome approach is based on the identification and treatment of a set of symptoms and signs called "syndrome", which is easy to recognize basing on the information and symptoms observed during the history and physical examination.

15.1.2. Different STI Syndromes

These syndromes, which may be caused by one or several STI germs, are the following:

- 1. Urethral discharge in men;
- 2. Vaginal discharge;
- 3. Genital ulceration;
- 4. Inguinal bubo;
- 5. Painful swelling of the scrotum;
- 6. Pelvic pain in women;
- 7. Venereal vegetation or growth (Condylomas);
- 8. Purulent conjunctivitis of the new born baby.

The syndrome approach enables one to carry out rapid presumptive diagnosis and to administer immediate treatment beginning with the first consultation. It enables the client to receive treatment without delay and increases the chances of healing.

Below is the summary of syndromic management of STIs and we recommend you refer to STIs Provider manual and specific algorithms (see

on annexes different STI algorithms) for more detailed information on STIs management approach.

15.2. Etiologic Diagnosis and Management of STIs

15.2.1. Definition

The etiological approach uses laboratory tests with the support of information obtained from the interview and physical examination. It constitutes an ideal strategy in the care of STI but it requires adequate laboratory and highly qualified personnel. Refer to Annex 2.7 STI syndromes, signs and Management & Annex 2.8 STIs Etiologies and Management

15.3. Special Cases

15.3.1. Female Sexual Workers (FSW)

Sex workers are vulnerable groups and core groups for the transmission of STI and HIV. Their care and treatment is a process that is both classic and specific. It is specific, given the profession of sex workers and the prevalence of STI/HIV in women. Consequently, active diagnosis of STI is highly recommended.

In practice, presumptive treatment of the commonest and the most morbid STI (risk of the Pelvic Inflammatory Syndrome, infertility) is recommended during the first visit in the absence of obvious clinical signs of STI. (See specific algorithm).

15.3.2. Men Who Have Sex with Men (MSM)

MSM, including those with HIV infection, should routinely undergo nonjudgmental STI/HIV risk assessment and client-centered prevention counseling to reduce the likelihood of acquiring or transmitting HIV or other STIs.

Healthcare providers should be informed about the local community resources available to assist MSM (Condom, lubricants, drugs, etc.).

Clinicians also should routinely ask MSM about symptoms consistent with common STIs, including urethral discharge, dysuria, genital and perianal ulcers, regional lymphadenopathy, skin rash, and anorectal symptoms consistent with proctitis, including discharge and pain on defecation or during anal intercourse. Care providers should perform appropriate diagnostic testing on all symptomatic patients.

Routine laboratory screening for common STIs (HIV serology, syphilis serology, a test for urethral infection with *N. gonorrhoeae* and *C. trachomatis* in men who have had insertive anal intercourse, a test for rectal infections with *N. gonorrhoeae* and *C. trachomatis* in men who have had receptive anal intercourse, a test for pharyngeal infection with *N. gonorrhoeae* in men who have had receptive oral intercourse is indicated for all sexually active MSM. It is also recommended to do HCV tests for all MSM.

15.3.3. Persons in Correctional Facilities

Screening for symptomatic and asymptomatic STIs in detention facilities and jails facilitates the identification and treatment of persons with infections. This will eliminate complications for the individual and will reduce the prevalence of STIs among detainees who are released back into the local community.

15.3.4. Management of Sexual Abuse and Aggression of Children

Definition

Sexual abuse occurs when a child is engaged in sexual activities that it may not understand for which its psychomotor development is not prepared and therefore the child cannot give its consent and/or these activities violate the law or the taboos of the society. These sexual activities include any forms of sexual contacts: Sexual intercourse (oral, genital, ano-genital, and genito-genital).

Initial Examination

- To collect data and information on the circumstances in which the sexual abuse occurred;
- To determine if possible, the time separating the aggression and the date of consultation ;
- To carry out meticulous physical examination in search of the signs of STI (genital discharges, ulcerations and genital vesicles, condylomas);

- To collect anal samples in the two sexes, vaginal swab in case of a young girl, and urethral samples in case of a boy in the view to search for gonococcus, Trichomonas vaginalis;
- To carry out serological tests for HIV, hepatitis B and syphilis;
- To carry out the pregnancy test in case of a young girl who has already started having menstruations.
- -To search for clinical signs of STI and carry out serological tests for HIV, hepatitis B and syphilis of the aggressor or the suspected perpetrator of the aggression if he/she has been identified.

Suggestive Clinical Signs of Sexual Abuse

Major genital signs are: genital discharges, tear or the absence of the hymen, fissure or anal gaping, trauma of the perineum, recto vaginal fistula or vesico-vaginal fistula, and pelvic pain. There are also signs linked to physical trauma and behavioral disorders.

Signs	Girls	Boys
Genitals	- Absence or tear of the hymen ;	- Anal gaping
	- Fissure or anal openness;	- Anal fissure
	- Trauma of the perineum;	- Recto anal fistula
	- Vesico-vaginal fistula;	Presence of STI.
	- Recto vaginal fistula;	
	- Pelvic pain ;	
	- Presence of STI.	
Other Sig	ns :	
- C	utaneous trauma;	
- N	larked docility on examination;	

- Exaggerated fear by the patient of a parent or close relative.

Management of Sexual Abuse in a Child

Treatment

- If the pregnancy test is negative, prescribe within 72 hours (following the aggression or sexual abuse) urgent contraception;
- If HIV serology is positive in the aggressor, treat the child and start the ARV treatment (PEP). The results are the best when treatment is started

as soon as possible following exposure and ideally no later than 72 hours;

- If a germ is isolated, it is necessary to treat the child by taking into account its sensitivity to antibiotics (or treatment according to the STI syndrome identified);

If no germ is isolated and if there exists other risk factors that have been identified in the aggressor or if the aggressor presents STI or has recent precedents of STI, in this case there is need to provide presumptive treatment. This treatment must take into account the syndrome of the suspected STI in the aggressor.

ANNEXES.

Annex. 1.0: HIV Testing and Counselling Procedures



Powered by RBC/HIV Div.

Services Provided Act	Activities
Prenuptial consultation and related services;	IEC/BCC including HIV, PMTCT, reproductive health and family planning
Couple counselling and Testing	HIV Testing and Counselling (HTS)
•	Family planning
•	Condom distribution
•	Referral for HIV positive cases
•	Referral to other services as needed
•	STI and TB screening
PMTCT Prong II: Prevention of unintended pregnancies among women living with HIV	ncies among women living with HIV
Services Provided Act	Activities
Prenuptial consultation and related services;	IEC/BCC including HIV, PMTCT, reproductive health and family planning
Couple counselling and Testing	Family planning
•	Condom distribution
•	Referral to other services as needed
•	STI and TB screening
PMTCT Prong III: Preventing HIV transmission from women living with HIV to their infants	om women living with HIV to their infants
Services Provided Act	Activities
ANC	IEC/BCC including HIV, PMTCT, reproductive health and family planning
•	HTS with her partner (if available)
•	STI Screening and Treatment
If t	If the woman is tested positive for HIV:
•	Open a follow up file for people living with HIV (Green File)
•	Blood collection for CD4 Count, Full Blood Count (FBC), Liver Function Tests (LFTs)
	and Renal Function Tests (GFR)
•	TB Screening
•	Counselling on nutrition and nutritional support for mothers with moderate or severe
	malnutrition
	Lifelong ART initiation (Option B+)

	Cotrimoxazole prophylaxis
	If the woman is tested negative and the partner is positive => Serodiscordant Couples:
	 Couple counselling on how to remain negative for the woman and positive attitudes for
	the partner
	 Provision of prophylaxis to the pregnant woman according to the protocol
	 Referral to care and treatment for the positive partner and initiate ART per test and treat
	guidelines
	 HIV test every 3 months for the HIV-negative woman
Maternity	Labour and Delivery
	 HIV test for previously HIV-negative mothers
	If mother tests positive in labour and delivery:
	Lifelong ART initiation as soon as possible for HIV positive mothers identified in
	delivery room
	 Delivery procedures for minimal risk of MTCT
	Referral to care and treatment after opening the green file if tested positive in the
	delivery room.
	Immediate post-natal care for all infants:
	 Disinfection of the new-born child
	 Vaccination
	 Counselling on the feeding and diet for the mother-child pair.
	 Counselling on family planning and offer the appropriate method
	Additional immediate post-natal care if mother is HIV-positive:
	 ART Prophylaxis to the new-born from HIV positive mothers
	 Opening a file for exposed infants (Pink file).
Post-natal care/	Services for the Child from HIV-positive Mother
Mother-Child Follow Up	 Vaccination
	 HIV testing of the child according to the national protocol
	 TB screening
	 Anthropometric measurement
	 Search for signs of HIV infection
	 Cotrimoxazole prophylaxis at 6 weeks
	Nutritional care of the child
---	--
	 Psychomotor evaluation
	 Referral of HIV+ children to paediatric care and treatment
	Services for the HIV + Mother', HIV- Mother in Serodiscordant couple (SDC) and
	Mother with unknown HIV status
	 HTS of mothers whose HIV status is unknown
	 HIV testing of HIV-negative mothers whose partners are HIV-positive every 3 months
	during the period of breastfeeding.
	CD4 controls
	 Viral load measurements every 6 months during PMTCT period (pre& postpartum
	periods)
	 ARV initiation for newly identified cases
	 Continue ARV for known HIV positive mothers
	 Regular biological controls (FBC, LFTs and RFTs)
	 Verification of CTX prophylaxis
	 Nutritional counselling and support
	 Family planning (IEC and offer of contraceptive methods)
PMTCT Prong IV: Providing appropriate trea	PMTCT Prong IV: Providing appropriate treatment, care and support to mothers living with HIV, their children and families.
Services Provided	Activities
Facility and Community	 HIV testing for all other children of known HIV-positive mothers
	 Care and follow up of HIV-positive children of HIV-positive mothers
	 Follow up of the male partner in case of sero-discordant couple where the male partner
	is negative
	 Nutritional counselling and support for infants and young children born to HIV-
	positive mothers
	 Support groups
	-



Annex. 1.2: HIV Testing Among HIV Exposed Infants

Annex. 2.0: Screening algorithm of TB-HIV co-infection





Annex. 2.1: Diagnostic algorithm of TB-HIV co-infection

Annex. 2.2: Management of Common Opportunistic Infections

Pneumococcal and other bacterial pneumonia			
Symptoms & Signs	Diagnostic Test(s)		
 Symptoms: Fever and Productive cough of acute onset, Pleuritic chest pain, Malaise, Chills and dyspnoea Clinical findings: Fever, signs of consolidation on the diseased side or simply crackles, low blood pressure, tachypnea, sometimes leading to confusion or decreased level of consciousness in advances cases. 	 CXR Sputum M, GeneXpert, C &S Blood Culture The assessment of severity is important to decide about the right treatment. If the patient presents with 3 of severity signs, transfer to a facility with ventilation should be considered. 		
Treatment O2 and rehydration Analgesics and antipyretics Antibiotics - First choice: Amoxicillin 500 mg tds po X 7days - Second choice: Amoxy-clavulinic acid po or IV or cefuroxime IV X 7 days. - If staphylococcus suspected : Cloxacillin 500mg quid po or IV X 7 days If general condition is not good, consider IV drugs in first 2-3 days and then change to oral therapy.			
Oral Hairy Leucoplakia			
Symptoms & Signs	Diagnostic Test(s)		
 Signs: White asymptomatic lesion with corrugated surface, Very often on lateral surface of the tongue. 	Clinical but sometimes biopsy		
Treatment			
Indicated if pain: Acyclovir 800mg po 5x/day for 2 to 3 weeks ARV			

Pulmonary TB			
Symptoms & Signs	Diagnostic Test(s)		
Symptoms	Imaging:		
- Cough for more than 2 weeks	CXR		
- Fever	Lab:		
- Night sweating	- Sputum ZN stain		
- Loss of weight	- Hemogram (Anaemia)		
- Poor appetite	- Low Na, High ESR)		
- Other Risk factors (HIV+,			
Smoker, Health worker, Diabetic,			
Malnourished)			
- Bacterial pneumonia not			
responding to ATB			
~			
Signs:			
- Fever			
- LOW			
- Adenopathies			
- Signs of pneumonia,			
bronchopneumonia			
Treatment			
2RHZE(7)4RH(7)			

Kaposi's sarcoma			
Symptoms & Signs	Diagnostic Test(s)		
Signs:	Clinical diagnosis, may need		
- Hyper pigmented nodules,	histology by biopsies		
- Purpuric or erythematous plaques			
sometimes progressing to			
ulcerative lesions on the face,			
trunk, limbs, or oral cavity.			
- They are usually asymptomatic-			
neither painful nor pruritic.			
- Lymphadenopathy,			
- Respiratory,GIT,pericardial or			
ocular symptoms			
Treatment			
- ARV			
- Bleomycin alone or associated with Vincristine			

Herpes Zoster (Zona)			
Symptoms & Signs	Diagnostic Test(s)		
 Lesions are vesicles, painful and involve several dermatomes, Lesions can take a long time to heal when they become necrotic. They can show secondary infection and deep scarring. Zoster Ophthalmic is when the ophthalmic branch of the trigeminal nerve is often involved and cause corneal scarring with loss of vision in that eye. 	 Diagnosis: Based on clinical symptoms and signs. A Tzanck test show multinucleated giant cells with inclusion bodies which are pathognomonic. 		
Treatment			
Acyclovir 10mg /kg IV every 8 hours; for7-14 days (For encephalitis: 21d) <u>Or</u> Acyclovir 800mg PO 5 times daily for 7 days +Systemic antibiotics + Analgesics for pain and fever			
+NSAID			
<u>Or</u> Carbamazepine 200-600mg daily or Amitriptyline 25-75 mg (effective in controlling post –zoster neuralgias)			

Miliary TB	
Symptoms & Signs	Diagnostic Test(s)
Fever, night sweats, weakness, weight	CXR: Miliary pattern.
loss, cough sometimes and dyspnoea,	Lab: Sputum ZN staining is
hepatomegaly, splenomegaly,	negative in 80%
lymphadenopathy, choroidal	Anaemia, leukopenia, DIC.
tubercules on eye examination.	
Treatment	
2 RHZE7 4RH7.	

Pneumocystis Jirovecii Pneumonia	\mathbf{N}^{\prime}		
Symptoms & Signs Symptoms:	Diagnostic Test(s)- Hypoxia(Low saturation on		
 Sub-acute onset of shortness of breath. Dry cough Fever, fatigue, chest pain HIV + not on Cotrimoxazole 	 walking Elevated LDH: Sensitive but not specific. CXR: Usually a diffuse, bilateral interstitial pattern, 		
prophylaxis yet with low CD4 Count	pneumothorax		
Clinical Findings:	- CXR normal in early disease in		
- Fever,	up to 10 to 20%.		
- Tachypnea,	- Sputum induction and staining		
- Tachycardia,			
- Normal chest exam in 50%, rales/			
rhonchi,			
- Cyanosis.			
Treatment			
- Oxygenation			
- Rehydration			
For Moderate to Severe PCP—Total D	uration = 21 Days (AII):		
<u>Preferred Therapy:</u>			
• TMP-SMX: (TMP 15–20 mg and SMX 75–100 mg)/kg/day IV given q6h			
or q8h (AI), may switch to PO after clinical improvement (AI).			
Alternative Therapy:			
 Pentamidine 4 mg/kg IV once daily infused over at least 60 minutes (AI); may reduce the dose to 3 mg/kg IV once daily because of toxicities (BI) or Primaquineb 30 mg (base) PO once daily + (Clindamycin [IV 600 q6h or 900 mg q8h] or [PO 450 mg q6h or 600 mg q8h]) (AI). **Adjunctive corticosteroid may be indicated in some moderate to severe cases 			
(see indications and dosage recommendations below)			
For Mild to Moderate PCP—Total Duration = 21 days (AII):			
Preferred Therapy:			
• TMP-SMX: (TMP 15–20 mg/kg/day and SMX 75–100 mg/kg/day), given			
PO in 3 divided doses (AI) or			
• TMP-SMX DS (960Mg) - 2 tablets TID) (AI).		

Alternative Therapy:

• Dapsone 100 mg PO daily + TMP 15 mg/kg/day PO (3 divided doses) (BI) or

• Primaquine 30 mg (base) PO daily + Clindamycin PO (450 mg q6h or 600 mg q8h) (**BI**) *or*

• Atovaquone 750 mg PO BID with food (BI)

Adjunctive Corticosteroids:

For Moderate to Severe PCP Based on the Following Criteria:

• PaO2 <70 mmHg at room air *or*

• Alveolar-arterial O2 gradient ≥35 mmHg

Dosing Schedule:

Prednisone doses (beginning as early as possible and within 72 hours of PCP therapy) **(AI)**:

IV methylprednisolone can be given as 75% of prednisone dose

Days 1-5: 40 mg PO BID

Days 6–10: 40 mg PO daily

Days 11–21: 20 mg PO daily

- Any patient with hypoxia (pa O2 <70mm Hg or a A-a gradient >35 mmHg) should receive prednisone p o as per following regimen:
- D1-5 40mg BD p o; D6-10 40 mg OD p o; D11-21 20 mg OD p o .
- In case of allergy to cotrimoxazole, the other options are either
- Trimethoprim 15mg /kg /day P.O + Dapsone 100 mg/day for 21 days or
- Clindamycin 600-900mg qid X 21 days P.O + Primaquine 15-30mg OD P.O.

Then secondary prophylaxis

Progressive Multifocal Leukoencephalopathy (PML)		
Symptoms & Signs	Diagnostic Test(s)	
- Cognitive disorder ranges	Initial recognition of PML relies on a	
from mild impairment of	combination of clinical and neuroimaging	
concentration to dementia.	findings. The first step is	
Insidious onset.	usually identifying the clinical picture of	
- Focal neurological deficit	steady progression of focal neurological	
seizures, loss of sensation.	deficits. CT scan but MRI is the best imaging	
- Fever and headache are	modality to exclude other pathologies	
rare.	CSF: elevated protein	

Treatment

No specific therapy exists for JCV infection or PML. The main approach to treatment involves ART to reverse the immunosuppression that interferes with the normal host response to this virus.

No prophylaxis or curative Rx available

ARV Therapy remains the only hope for patients.

Lymphomas (NHL)				
Symptoms & Signs Diagnostic Test(s)				
NHL B Cell Types, Stage 4 disease	Biopsy			
with B symptoms, Weight				
loss,Fever,hepatic dysfunction,				
marrow failure, lung disease and				
effusion, CNS signs.				
Treatment				
Chemotherapy: CHOP				
Cyclophosphamide, Doxorubicin, Vinc	ristine, Prednisone			
Cryptococcosis				
Symptoms & Signs	Diagnostic Test(s)			
Symptoms:	CT Scan Brain			
- Insidious onset of fever, Malaise,	Lumber puncture and India Ink			
Headache with / without vomiting	staining, Cryptococcal Ag testing			
Clinical Findings:				
- Features of AIDS, Neck stiffness,				
Behavioural changes, Confusion				
and sometime seizures				
Treatment				
- Amphotericin B 0.7-1 mg/ kg/day, slow IV infusion x 2 weeks followed by				
- Fluconazole (Consolidation and Maintenance Phases).				
- Repetitive lumbar punctures to decrease ICP.				
- Antiepileptic if seizures.				
- Management of coma if comatose.				
Treatment for cryptococcosis consists of 3 phases: induction, consolidation,				
51				

Induction Therapy (For At Least 2 Weeks, Followed by Consolidation

Therapy)

Preferred Regimens:

• Liposomal amphotericin B 3–4 mg/kg IV daily plus flucytosine 25 mg/kg PO QID (AI); *or*

• Amphotericin B deoxycholate 0.7–1.0 mg/kg IV daily plus flucytosine 25 mg/kg PO QID (AI)—if cost is an issue and the risk of renal dysfunction is low.

Consolidation Therapy (For At Least 8 Weeks, Followed by Maintenance Therapy)

• To begin after at least 2 weeks of successful induction therapy (defined as substantial clinical improvement and a negative CSF

culture after repeat LP)

Preferred Regimen:

• Fluconazole 400 mg PO or IV once daily.

Maintenance Therapy

Preferred Regimen:

• Fluconazole 200 mg PO for at least 1 year

Stopping Maintenance Therapy

If the Following Criteria are Fulfilled (BII):

• Completed initial (induction, consolidation) therapy, and at least 1 year on maintenance therapy, *and*

• Remains asymptomatic from cryptococcal infection, and

- CD4 count ${\geq}100$ cells/µL for ${\geq}3$ months and suppressed HIV RNA in response to effective ART.

NOTE: Corticosteroids and mannitol are ineffective in reducing ICP and are NOT recommended

Cerebral Toxoplasmosis/ Toxoplasma Gondi Infection		
Symptoms & Signs	Diagnostic Test(s)	
-Focal neurological signs	LP:	
(hemiparesis/hemiplegia)	- CSF may be normal or	
- Cognitive dysfunction	nonspecific (Mild mononuclear	
- Seizures	pleocytosis and mild to	
- Headache and Fever	moderately elevated protein).	
- Symptoms of diffuse encephalopathy	- Toxoplasma antibody absence	
- Meningeal irritation is less frequent	has a high negative predictive	
-Sometimes signs of raised ICP	value of 94-97%.	
(papilledema/ vomiting).	- CT Scan Brain	

Treatment

- Preferred Regimen (AI):

• Pyrimethamine 200 mg PO once, followed by dose based on body weight:

• Body weight <60 kg: Pyrimethamine 50 mg PO daily + sulfadiazine 1000 mg PO q6h + leucovorin (Folinic acid)10–25 mg PO daily (can

increase to 50 mg daily or BID)

• Body weight $\Box 60$ kg: Pyrimethamine 75 mg PO daily + sulfadiazine 1500 mg PO q6h + leucovorin 10–25 mg PO daily (can

increase to 50 mg daily or BID)

Alternative Regimens:

• Pyrimethamine (leucovorin)c plus clindamycin 600 mg IV or PO q6h (AI); *Total Duration for Treating Acute Infection:*

At least 6 weeks, longer duration if clinical or radiologic disease is extensive or response is incomplete at 6 weeks

Pyrimethamine 200mg loading dose, then 50mg OD po+ Sulfadiazine 1-1.5g qid PO.+ Folinic acid 10mg OD.X 6-8 weeks

- Cotrimoxazole 2 tabs(480mg) PO 3x/day or 5 tabs 2x/day PO for 6 weeks
- Clindamycin 600mg qid PO +Pyrimethamine 200 mg loading then 50mg OD PO +Folinic acid 10mg OD (in case of allergy to sulfa).
 - Prednisone 40mg qid or Dexamethasone IV 4 mg qid in case of raised intracranial pressure.
 - Antiepileptic in case of seizure: Phenytoin 300 mg OD
 - Secondary prophylaxis with cotrimoxazole.

Chronic Maintenance Therapy for Toxoplasma gondii Encephalitis Preferred Regimen:

• Pyrimethamine 25–50 mg PO daily + sulfadiazine 2000–4000 mg PO daily (in 2 to 4 divided doses) + leucovorin 10–25 mg PO daily (A D

daily (AI)

Alternative Regimen:

• Clindamycin 600 mg PO q8h + (Pyrimethamine 25–50 mg + leucovorin 10– 25 mg) PO daily (**BI**); must add additional agent to

prevent PCP, or

• TMP-SMX DS 1 tablet BID or

• Atovaquone 750–1500 mg PO BID + (Pyrimethamine 25 mg + leucovorin 10 mg) PO daily, *or*

- Atovaquone 750–1500 mg PO BID + sulfadiazine 2000–4000 mg PO daily (in 2 to 4 divided doses), or

• Atovaquone 750–1500 mg PO BID

Discontinuing Chronic MaintenanceTherapy:

- Successfully completed initial therapy, remain asymptomatic of signs and symptoms of TE, and CD4 count >200 cells/mm3 for >6

- months in response to ART

Other Considerations:

• Adjunctive corticosteroids (e.g., dexamethasone) should only be administered when clinically indicated to treat a mass effect associated with focal lesions or associated edema; discontinue as soon as clinically feasible.

• Anticonvulsants should be administered to patients with a history of seizures and continued through at least through the period of acute treatment; anticonvulsants **should not be used** as seizure prophylaxis.

Candida Esophagitis/Mucosal candidiasis				
Sympton	ns & Signs			Diagnostic Test(s)
Diffuse	retrosternal	pain,	dysphagia,	Clinical:
odynopha	agia, thrush.			Oral thrush and retrosternal
				chest pain.
Treatma	nt			

Treatment

Fluconazole 200 mg OD PO for 2-3 weeks.

Fluconazole 100 mg PO once daily

Uncomplicated Vulvovaginal Candidiasis

Preferred Therapy:

- Oral fluconazole 150 mg for 1 dose; or
- Topical azoles (clotrimazole, butoconazole, miconazole, tioconazole, or terconazole) for 3–7 days

Disseminated CMV			
Symptoms & Signs	Diagnostic Test(s)		
- Retinitis/esophagitis,	Fundoscopy/biopsy/CSF/		
Colitis/encephalitis, Polyradiculo	BAL fluid		
myelopathy, Dementia/pneumonitis.			
Treatment			
Ganciclovir 5mg/kg IV BD for 3-4 weeks			

Disseminated M. Avium Complex	
Symptoms & Signs	Diagnostic Test(s)
Fever,Night sweats,	- Culture from non-pulmonary sterile site,
- Weight loss,	- AFB blood culture
- Diarrhoea,	- Biopsy from liver, bone
- Abdominal pain	marrow or lymph node
Treatment	
- Clarithromycin 500mg bid po + Ethambu	utol 15 mg/kg/day
- ARV simultaneously or in 1-2 weeks	

Herpes Simplex infection	
Symptoms & Signs	Diagnostic Test(s)
Orolabial herpes (e.g., cold sores, fever blisters) is	Clinical examination or
the most common manifestation of HSV-1 infection.	HSV DNA polymerase
Classic manifestations include a sensory prodrome in	chain reaction (PCR),
the affected area, rapidly followed by the evolution	and viral culture are
oflesions from papule to vesicle, ulcer, and crust	preferred methods for
stages on the lip. The course of illness in untreated	diagnosis of
patients is 5 to 10 days. Lesions recur 1 to 12 times	mucocutaneous HSV
per year and can be triggered by sunlight or	lesions caused by HSV.
physiologic stress.	
Genital herpes is the most common manifestation of	
HSV-2 infection. Typical genital mucosal or skin	
lesions evolve through stages of papule, vesicle,	
ulcer, and crust.	
Treatment	
Treating Orolabial Lesions (Duration: 5–10 days)	
• Valacyclovir 1 g PO BID (AIII), or	
• Famciclovir 500 mg PO BID (AIII), or • Acyclovir	400 mg PO TID (AIII)
Treating Initial or Recurrent Genital Lesions (Dura	tion: 5–10 Days)
• Valacyclovir 1 g PO BID (AI), or • Famciclovir 50	00 mg PO BID (AI), or •
Acyclovir 400 mg PO TID (AI)	
Treating Severe Mucocutaneous HSV Infections (A	III)
 Initial therapy acyclovir 5 mg/kg IV q8h 	
• After lesions begin to regress, change to oral therapy	as above.
• Continue treatment until lesions have completely hea	led

Annex. 2.3: Early Management of Therapeutic Failure



Note:

VL is the gold standard for defining the treatment failure but when not available, the CD4 and clinical status may be used to decide.





<u>NB:</u>

Dosage: Adult Raltegravir 400mgx2/ tab +Darunavir 600mgx2/ tab+ Ritonavir 100mgx2/ tab +Etravirine 200mgx2/ tab; dosage for other molecules which can be used refer to national guideline

Taking ART 3rd line has to be accompanied by meal of at least 400kcal (E.g 500 ml of porridge per dose/one cup).

Annex. 2.5: Genotyping and 3rdLine ART Regimen Initiation



NB:

- Third line doses: Refer to Section below (Dose tables)

- Patients on 3rd line should receive nutrition supplement (at least 400 kcal e.g. 500 ml of porridge per dose)

- Consider 2,000 Copies/ml as Genotyping Threshold and 1,000 Copies as Treatment Failure Threshold

AIIIIA	AITHEX. 2.0. Management of most common ANVS side cheers	IIOII AIN VS SIUE EITECIS
Molecule	Major Type of Toxicity	Suggested Management
TDF	-Tubular renal dysfunction	- If TDF is being used in first-line ART, substitute with AZT or ABC
	- Fanconi syndrome	-If TDF is being used in second-line ART (after d4T + AZT use in first
	-Decreases in bone mineral Density	line
	-Lactic acidosis or severe	-ART), substitute with ABC or DDI
	hepatomegaly with steatosis	-Use alternative drug for hepatitis B treatment (such as entecavir) to
		avoid Hepatic flares if TDF is replaced due to toxicity
ABC	-Hypersensitivity reaction	-If ABC is being used in first-line ART, substitute with TDF or AZT
	-Gastrointestinal intolerance	-If ABC is being used in second line ART, substitute with TDF
AZT	- Anaemia, neutropenia, Myopathy,	-If AZT is being used in first-line ART, substitute with TDF or ABC
	- Lipoatrophy or lipodystrophy	-If AZT is being used in second-line ART, discuss another alternative
	-Lactic acidosis	
	- Severe hepatomegaly with steatosis	
NVP	-Hepatotoxicity	Substitute with EFV. If the person cannot tolerate
	-Severe skin rash and	either NNRTI, use boosted PIs
	hypersensitivity reaction (Stevens-	
	Johnson syndrome)	

Annex. 2.6: Management of most common ARVs side effect

EFV- Persistent central r(such as abnormal mental confusion, C- Hepatotoxicity- Hepatotoxicity- Hypersensitivity resistential syndrome- Potential risk of no (very low risk in hu (very low risk in hu - Male gynecomastiaETV- Severe skin and hypRALRALRALATV/rjaundice, although cosmetic)	ral nervous system toxicity rmal dreams, depression or on, Convulsions) y reaction, Stevens-Johnson of neural tube birth defects	Substitute with NVP (Be careful if high CD4). If the person cannot tolerate either NNRTI, use boosted PIs
ц. Ц. Ч. Г.		the person cannot tolerate either NNRTI, use boosted PIs
, r , r , r , r , r , r , r , r , r , r	nfusion, Convulsions) icity itivity reaction, Stevens-Johnson itivity of neural tube birth defects	
	icity itivity reaction, Stevens-Johnson risk of neural tube birth defects	
T	itivity reaction, Stevens-Johnson risk of neural tube birth defects	
, r R	risk of neural tube birth defects	
, r R - r -	risk of neural tube birth defects	
	(very low risk in humans)	
T R -	comastia	
	- Severe skin and hypersensitivity reactions	Limited options are available
τ - R	01	Seek consult with expert advice
	Rhabdomyolysis, myopathy, myalgia	Limited options are available
1		Seek consult with expert advice
jaundice, cosmetic)	hyperbilirubinemia (clinical I	(clinical LPV/r or DRV/r. If boosted PIs are contraindicated and NNRTIs have
cosmetic)	although not pathologic just f	jaundice, although not pathologic just failed in first-line ART, consider integrase inhibitors
- Nephrolithi	-Nephrolithiasis and risk of prematurity	
DRV/r - Hepatotoxicity	toxicity -	If DRV/r is being used in second line ART, substituting with
- Severe	skin and hypersensitivity	ATV/r or LPV/r can be considered. When it is used in third-line
reactions	IS	ART, limited options are available
	-	Seek consult with expert advice

LPV/r - Electrocardiographi QT interval prolonga - Hepatotoxicity - Pancreatitis, lipo syndrome, dyslipida - Risk of prematurity	-Electrocardiographic abnormalities (PR and QT interval prolongation, torsades de pointes) -Hepatotoxicity -Pancreatitis, lipoatrophy or metabolic syndrome, dvslipidaemia or severe diarrhoea	-If LPV/r is used in first-line ART for children, use an age-appropriate NNRTI (NVP for children younger than 3 years and EFV for children 3 years and older). -ATV can be used for children older than 6 years
OT interval - Hepatotoxi - Pancreatiti syndrome, - Risk of pre	 Prolongation, torsades de pointes) vicity iipoatrophy or metabolic dvslipidaemia or severe diarrhoea 	age-appropriate NNRTI (NVP for children younger than 3 years and EFV for children 3 years and older)ATV can be used for children older than 6 years
- Hepatotoxi - Pancreatiti syndrome, - Risk of pre	 kicity kis, lipoatrophy or metabolic c dvslipidaemia or severe diarrhoea 	3 years and EFV for children 3 years and older). -ATV can be used for children older than 6 years
- Pancreatiti syndrome, - Risk of pre	tis, lipoatrophy or metabolic dyslipidaemia or severe diarrhoea	-ATV can be used for children older than 6 years
syndrome, - Risk of pre	, dyslipidaemia or severe diarrhoea	
-Risk of pre		-If LPV/r is used in second-line ART for adults, use
	ematurity	ATV/r or DRV/r.
		-If boosted PIs are contraindicated and the person has
		failed
		on treatment with NNRTI in first-line ART, consider
		integrase inhibitors
		Seek consult with expert advice
CMX - Anaemia		Dapsone
-GI Intolera	-GI Intolerance (Nausea, vomiting, etc.)	
-Hepatotoxicity	kicity	
-Skin Rash		

ARV	Side effect most common	Drug interaction
Darunavir	Skin rash (10%) and Stevens Johnson	Do not combine with:
(DRV)	syndrome have been reported in some	Rifampicin, Astemizole,
	cases.	alfuzosin and in case of
	Hepatotoxicity, Diarrhoea, nausea,	severe liver failure do
	headache, Hyperlipidaemia,	not adjust
	Hyperglycaemia, fat distribution	Do not use with
	inappropriate, probability of worsening	pregnant women
	bleeding with haemophilia.	
Ritonavir	Gastro-intestinal discomfort (Diarrhoea,	
(RTV)	nausea, vomiting), Paraesthesia,	
	Hyperlipidaemia (Especially	
	Hypertriglycidemia), Hepatitis, Asthenia,	
	sweetness disturbance; Hyperglycaemia,	
	fat distribution inappropriate; probability of	
	worsening bleeding with haemophilia.	
		D (1' '4
Raltergravir	Diarrhoea, nausea, headache, Pyrexia	Do not combine with:
(RAL)		Rifampicin, Phenytoin,
		and Phenobarbital. Do
		not use with pregnant
		women
Etravirine	Nausea, skin Rash, hypersensitivity	Do not combine with
(ETV)	, , , , , , , , , , , , , , , , , , ,	NVP, EFV,
		Atazanavir/rit

Notice:

It requires expert advice in case of suspecting clinical sign which jeopardize the patient's life.

Syndrome	Symptom	Signs	Frequent Causes	Treatment
Urethral	 Urethral 	 Urethral 	 Gonococcus 	1 st Choice:
discharge in	discharge	discharge (if	 Chlamydia 	 Ciprofloxacine, tab, 1g SD
men	 Dysuria 	necessary, ask the		 Doxycycline, tab 100mg *2/d/7d
	 Frequent 	patient to empty		2 nd Choice:
	urination	his/her glans)		 Ceftriaxone, 250 mg in IM single dose
				with 1g of azithromycin oral if
				available.
				 Erythromycin, 1g x2/ d /7 days
Genital	 Genital 	 Genital 	 Syphilis 	1 st Choice:
ulcerations	wound	ulceration	 Wet Chancre 	 Benzedrine penicillin 2.4 Million IU
		 Inguinal 	 Genital herpes 	IM single dose unique.
		lymphadenopathy		 Ciprofloxacin 500 mg x2/day /3 days
				 Acyclovir 400 mg x2/ day/5 days
				2 nd Choice:
				 Erythromycin 1 g x 2/ day/14 days in
				case of allergy to penicillin.
				 Ceftriaxone, 250 mg in IM single
				dose.
				 Acyclovir 400 mg x2/ day/5 days

Syndrome	Symptom	Signs	Frequent Causes	Treatment
Vaginal	 Vaginal 	 Vaginal discharge 	Vaginitis :	 Metronidazole or Tinidazole, 2 g
discharge	discharge	(leukorrhea)	Trichomonas	in a SD
	 Itching 		 Candida 	 Clotrimazole 200 mg vaginal
	vulva		 Bacterial 	tablet in a single dose in the evening
	 Dysuria 		vaginosis	before going to bed for 3 days.
	 Dyspareu 		Cervicitis:	
	nia		 Gonococcus 	
			 Chlamydia 	Ciprotloxaine,tab,500mg SD
			 Trichomonas 	 Doxycycline ,tab 100mg *2/d/7d
			 Candidosis 	 Metronidazole or Tinidazole, 2 g
				in a SD
				 Clotrimazole 200 mg vaginal
				tablet in a single dose in the evening
				before going to bed for 3 days.
				2 nd Choice:
				 Ceftriaxone. 250 mg in IM single
				dose and if available azithromycin,
				l g single dose.
				 Erythromycin, 1g x2/ d /7 days
				 Fluconazole gynae tab 150 mg in
				single dose.

Pelvic pain in women	 Abdomin al pain during sexual relations Dyspareun ia 	 Vaginal discharge Sensitivity of the lower abdomen to palpation Temperature > 38° (inconstant) 	te - Chlamydia 10 - Mixed Anaerobes 3°	 1st Choice: Ciprofloxacin,tab,1gr SD Doxycycline, tab 100mg *2/d/21d Metronidazole, tab 1g*2/d/14days Metroidazole, tab 1g*2/d/14days 2nd Choice: Ceftriaxone, 250 mg in IM single dose and if available azithromycin, 1g single dose. Erythromycin, 1g x2/ d /21 days Tinidazole, 1g x2/d/14days
Syndrome Painful swelling of the scrotum	Symptom Pain and swelling of the scrotum	Signs Scrotum	Frequent Causes Gonococcus Chlamydia	Treatment1* Choice:• Ciprofloxacin,tab,500mg SD• Doxycycline ,tab 100mg *2/d/7d2nd Choice:• Ceftriaxone, 250 mg in IM single dose.• Erythromycin, 1g x2/ d/7 days and if available azithromycin 1g single dose.

Inguinal	 Inguinal 	 Ganglion 	 Wet chancre 	1 st Choice:
bubo	Adenopathy	Tumefaction	 Venereal 	 Ciprofloxacin,tab,500mg SD
	4	 Fluctuation 	Lympho-	 Doxycycline ,tab 100mg *2/d/7d
		 Abscess or 	granulomatosis	2 nd Choice:
		fistulas	•	 Ceftriaxone, 250 mg in IM SD
				 Erythromycin, 1g x2/ d /7 days
Purulent	 Swollen 	 Eyelids 	 Gonococcus 	 Ceftriaxone, 50 mg per kg in IM single
conjunctivitis	eyelids	oedema	 Chlamydia 	dose.
of the	 Baby 	 Purulent 		 Erythromycin, 50mg per kgx2/ d /7
newborn	cannot open	discharge		days
	its eyes			
	 Ocular 			
	discharge			
Syndrome	Symptom	Signs	Frequent Causes	ises Treatment
Venereal	 Genital/anal 	 Genito-anal 	l - Papilloma	Destruction of the
vegetations	external growths	/ths external growths	wths virus	condylomatous tissue by physical
(Condyloma)				and clinical method (Use of
				imiquimod 3.75% or 5% cream
				or podophylline cream, liquid
				nitrogen, silver nitrate crayon,
				curettage followed by the
				application of iodine dye).

Symptoms and Signs	Etiologies	Laboratory Tests	Disease	Treatment
- Urethral discharge;	Chlamydia	Direct cytological examination Infection due	Infection due	1 st Choice:
- Cervicitis and lower trachomatis	trachomatis	to look for intracytoplasmic to Chlamydia	to Chlamydia	 Doxycycline, 100 mg x
abdominal pain in		inclusions, culture, antigen		2 day 7 days during meals
women;		detection and PCR		2 nd Choice:
- Conjunctivitis of the				• Erythromycin, 1g x2
new born may be				day /7 days
asymptomatic				
- Ano-genital ulcers Treponema	Treponema	Microscopic examination on a	Syphilis	1 st Choice:
(chancre);	pallidum	dark background is used in		 Benzedrine penicillin
- Inguinal tumefaction;		primary and secondary		2.4 Million IU IM single
- Generalized itching.		syphilis. At later stages,		dose unique.
		nontreponemal VDRL and		2 nd Choice:
		RPR are the commonly used		• Erythromycin 1 g x 2/
		tests, but they require		day/14 days in case of
		confirmation with more		allergy to penicillin.
		specific treponemal tests such		
		as FTA-ABS and TPHA		

Annex. 2.8: STIs Aetiologies and Management

Symptoms and Signs	Etiologies	Laboratory Tests	Disease	Treatment
Genital ulcers with Haemophilis		Haemophilus ducreyi can be	Wet Chancre	1 st Choice:
inguinal	ducreyi	isolated by direct examination		 Ciprofloxacin 500 mg
tumefaction(bubo) in		after gam stain or Toluidine or		x2/day/3 days
most of the cases		culture		2 nd Choice:
				 Ceftriaxone,250 mg in
				IM single dose
				 Erythromycin, 1g
				x2/day /14 days in case
				of pregnancy
Viral Infections				
Vesicular lesions and	Herpes virus	Vesicular lesions and Herpes virus The most common diagnostic Genital	Genital	 Acyclovir 400 mg x3/
ano-genital ulcerations	of the	the tests are: Direct Fluorescence, Herpes	Herpes	day/5 days
	simplex type	simplex type Tzanck test to search for		
	2 (HSV-2)	Herpes cytopathogenic effect,		
		culture in cellular media and		
		Western blot		

	Etiologies	Laboratory Tests	Disease	Treatment
Swollen ano-genital Condylomas; Cervical	Human papilloma	Clinical examination	Genital Condylomas	Consists in the destruction of the condylomatous tissue by physical and
condylomas; cervix	Virus			clinical method (Use of imiquimod
cancer in women.	(HPV)			3.75% or 5% cream or podophylline cream. liquid nitrogen. silver nitrate
				crayon, curettage followed by the
				application of iodine dye).
Others				
Asymptomatic;	Trichomona	Trichomonas is	Trichomonas	Metronidazole or Tinidazole, 2 g in a
abundant mucous	s vaginalis	diagnosed through		single dose
vaginal discharge		direct specimen		If persistence of signs despite good
		examination		observance, give: Metronidazole 500
				mg x 2/ day /7 days or Tinidazole
				500 mg x 2 day / 5 days
Thick vaginal	Candida	Direct examination and	Candida	Clotrimazole 200 mg vaginal tablet in
discharge; itching and	albicans	culture are the most		a single dose in the evening before
vulvar burning		common methods for		going to bed for 3 days.
		the diagnosis of		Or Fluconazole gynae tab 150 mg in
		Candida infection		single dose

Annex 2.9: Mental health screening questionnaire

The Mental health screening questionnaire is used in Care and treatment services for identifying HIV positive clients who have also mental health problems. It has to be completed at baseline in enrollment and every six month.

TRAC NET Birth date.....

- In the past year, was there ever a time when you felt sad, blue, or 1. 1. depressed for more than 2 weeks in a row? Yes \Box No \Box
- In the past year, was there ever a time lasting more than 2 weeks when you 2. lost interest in most things like hobbies, work, or activities that usually give you pleasure? Yes 🗆 No 🗆
- 3. In the past year, when not high or intoxicated, did you ever feel extremely energetic or irritable and more talkative than usual? Yes \Box No \Box
- In the past year, were you ever on medication or antidepressants for 4. depression or nerve problems? Yes \Box No \Box
- In the past year, did you ever have a period lasting more than 1 month when 5. most of the time you felt worried and anxious? Yes \Box No \Box
- 6. In the past year, did you have a spell or an attack when all of a sudden you felt frightened, anxious, or very uneasy when most people would not be afraid or anxious? Yes \Box No \Box
- In the past year, did you ever have a spell or an attack when for no reason 7. your heart suddenly started to race, you felt faint, or you couldn't catch your breath? Yes \square No \square
- During your lifetime, as a child or adult, have you experienced or witnessed 8. traumatic event(s) that involved harm to yourself or to others? Yes \Box No \Box if yes: In the past year, have you been troubled by flashbacks, nightmares, or thoughts of the trauma? Yes \square No \square
- 9. In the past 3 months, have you experienced any event(s) or received information that was so upsetting it affected how you cope with everyday life? Yes □ No □

IF THE ANSWER TO ANY QUESTION FROM 3 TO 9 IS POSITIVE, REFER TO MENTAL HEALTH SPECIALIST FOR MORE DIAGNOSIS, CARE AND TREATMENT

Date....

Name of counselor and signature.....