MINISTRY OF HEALTH
REPUBLIC OF SOUTH SUDAN

CONSOLIDATED CLINICAL GUIDELINES ON USE OF ANTIRETROVIRAL DRUGS FOR HIV TREATMENT AND PREVENTION

2017

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ACKNOWLEDGEMENTS

ACRONYMS AND ABBREVIATIONS

3TC	Lamivudine
AAFB	Alcohol acid fast bacilli
ABC	Abacavir
AIDS	Acquired Immune deficiency Syndrome
ANC	Antenatal care
ART	Antiretroviral Therapy
ARVs	Antiretroviral Drugs
ATV	Atazanavir
AZT	Zidovudine
BCG	Bacille Calmette Guerin (vaccine for TB)
BF	Breastfeeding
BMI	Body Mass Index
CD4	CD4+ T cell (T lymphocyte bearing CD4 receptor)
CDR	Case Detection Rate (for TB)
CO	Clinical Officer
CPT	Cotrimoxazole Preventive Therapy
CSF	Cerebrospinal fluid
CTX	Cotrimoxazole
CXR	Chest X Ray
D4T	stavudine
DBS	Dried Blood Spot
ddI	Didanosine
dl	decilitre
DNA-PCR	Deoxyribonucleic acid polymerase chain reaction (for EID)
DOTS	Directly Observed Treatment Short Course (for TB)
EHRZ	Anti-TB regimen: Ethambutol, Isoniazid, Rifampicin, Pyrazinamide
EFV	Efavirenz
EIA	Enzyme immune assay
EID	Early Infant Diagnosis (of HIV)
ELISA	Enzyme Linked Immuno Sorbent Assay
eMTCT	elimination of Mother To Child Transmission (of HIV)
EPI	Expanded Program for Immunization
EPTB	Extra-pulmonary tuberculosis
FDC	Fixed Dose Combination
FP	Family Planning
FTC	Emtricitabine
GOSS	Government of South Sudan
HAART	Highly active Antiretroviral Therapy
HB	Hemoglobin
HBC	Home Based Care
HBV	Hepatitis B Virus
HCT	HIV Counseling and Testing
HCV	Hepatitis C Virus
HEI	HIV-Exposed Infants
HIV	Human immunodeficiency virus
HIVDR	HIV Drug Resistance
HSV	Herpes Simplex Virus
HTS	HIV testing and counselling
IC	Infection Control (for TB)
ICF	Intensified Case Finding
IM	Intramuscular
INH	Isoniazid
IPT	Isoniazid Preventive Treatment
IRIS	Immune Reconstitution Inflammatory Syndrome
ITN	Insecticide Treated (mosquito bed) Net
IV	Intravenous
KS	Kaposi sarcoma
LFTs	Liver Function Tests
LPV/r	Lopinavir / ritonavir
LTFU	Lost to Follow Up
M&E	Monitoring and Evaluation
MCH	Maternal and child health
MDR-TB	Multiple Drug Resistant tuberculosis

MTCT	Mother to child transmission (of HIV)
NFV	Nelfinavir
NNRTIs	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NSP	National Strategic Plan (for HIV/AIDS)
NVP	Nevirapine
OI	Opportunistic Infection
ORS	Oral Rehydration Solution
PC	Palliative Care
PCP	Pneumocystis Carinii (jiroveci) Pneumonia
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PGL	Persistent Generalized Lymphadenopathy
PHDP	Positive Health Dignity and Prevention (also PwP)
PI	Protease Inhibitor
PITC	Provider Initiated HIV Testing & Counseling
PLHIV	People Living with HIV/AIDS
PML	Progressive multi focal Leucoencephalopathy
PMTCT	Prevention of Mother to Child Transmission
POC	Point of Care (technology)
PreP	Pre-exposure Prophylaxis
PTB	Pulmonary tuberculosis
PwP	Prevention with Positives (also PHDP)
PNC	Postnatal Care
RH	Reproductive Health
RSS	Republic of South Sudan
RTV	Ritonavir (as PI pharmacoenhancer)
SCM	Supply Chain Management
SGBV	Sexual & Gender Based Violence
sdNVP	single dose nevirapine
SOP	Standard Operating Procedure
SQV	Saquinavir
SRH	Sexual and Reproductive Health
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TEN	Toxic Epidermal Necrolysis
TDF	Tenofovir (Disoproxil Fumarate)
TB	Tuberculosis
TSR	Treatment Success Rate (for TB)
VCT	Voluntary Counseling and Testing
VIA	Visual inspection (of cervix) with acetic acid
VL	Viral Load
VMMC	Voluntary Medical Male Circumcision
WBC	White Blood Cells
WHO	World Health Organization
ZDV	Zidovudine (or AZT)

1 INTRODUCTION

1.1 BACKGROUND AND CONTEXT

South Sudan has a generalized HIV epidemic with a prevalence of 2.6% and 179,00 people estimated to be living with HIV including adults and children (South Sudan 2016 GARPR Report). The country has geographic areas with high HIV concentration in the three Equatorial states: Eastern, Central and Western Equatoria, found along the country's southern region, accounting for 60% of new HIV infections. According to the latest Modes of Transmission study (MoT, 2013), sex workers, their clients, and peri-natal transmission (Mother-to-Child Transmission), account for seven out of every ten new HIV infections. Furthermore, it is reported that peri-urban communities, cross-border areas and those along the transport corridors seem to have higher HIV prevalence than in the general population. The HIV treatment response in S. Sudan needs to be adapted to the country's context which is characterized by civil war, high number of returnees and internally displaced persons (IDPs) facing humanitarian crisis. These guidelines provide context-specific recommendations for the delivery of HIV treatment services using a public health approach in a resource-constraint and conflict setting. A large population including PLHIV face food insecurity and its potential impact on adherence to ARVs and OI medications. Access to life-saving ARVs may be challenging particularly among refugees residing in the neighbouring countries and among the internally displaced communities.

The first national guidelines for the use of antiretroviral drugs in South Sudan were launched in 2008. At that time, the CD4 threshold for antiretroviral therapy (ART) initiation in adults was 200 cells/mm^3, and for pregnant women not eligible for ART, a short course of ARV prophylaxis during pregnancy until shortly after delivery (option A) was recommended. In 2012, an addendum to these guidelines expanded ART eligibility to include all adult People Living with HIV (PLHIV) with CD4 below 350 cells/mm^3. By December 2016, there were 35 accredited ART sites nationally. The number of clients (adults, adolescents, pregnant and breast-feeding women and children) receiving treatment was 20,000 by the end of 2016. Treatment coverage across all populations is approximately 11%. .

In 2015, the World Health Organization (WHO) released Consolidated ARV Guidelines for the Prevention and Treatment of HIV Infections.. The recommendations were aimed at increasing equitable access to quality ART and reducing HIV transmission. The 'consolidated' guidance on clinical HIV care and prevention addresses all the various population groups (adults, adolescents, children and pregnant women), in different clinical care settings including tuberculosis (TB) clinics, Mother & Child Health (MCH) clinics, ART clinics, and HIV testing sites.

These recommendations provide an opportunity for improved quality of life for PLHIV and reduction in new HIV infections and have prompted revision of the South Sudan HIV treatment guidelines.
The following are the major highlights of the revised guidelines:

- All newly diagnosed HIV positive patients should be **re-tested** for HIV to verify their HIV positive status **prior to treatment initiation**. This is being recommended as a measure to minimize 'false positive' test results considering the medical, psychological, social and financial implications of life- long ART treatment to an individual.
- It is recommended that key populations and HIV-negative partners in sero-discordant couples retest at least annually. Depending on client risk behaviours, more frequent voluntary retesting should be offered.

- Diagnosing HIV-exposed infants as early as possible through DNA PCR testing is critical to starting ART as soon as possible and thus preventing early morbidity and mortality. It is recommended that **all HIV-exposed infants** have HIV virological testing at six weeks of age or at the earliest opportunity thereafter
- Health workers should **retest previously HIV-negative women** as follows:
    - first trimester of pregnancy or first ANC visit
    - in 3rd trimester during labor/ or delivery
    - at 6 weeks and at 6 months postnatally

- All HIV positive adults and adolescents irrespective of CD4 counts or WHO stage are eligible to start ART **(Treat All). Patients should be initiated on ART as soon as the patient is ready and preferably within one week**
- In adults and adolescents, **the preferred 1st line regimen is tenofovir + lamivudine (or emtricitabine) + efavirenz (TDF + 3TC + EFV** as a **once daily Fixed Dose Combination (FDC)** and should be prescribed for all population groups including adults, pregnant women, clients co-infected with HIV and TB or HBV
- The country has introduced **Efavirenz 400 mg** which can be used as a **substitute for Efavirenz 600** mg. The 400mg EFV formulation has demonstrated fewer CNS-related side effects compared to the standard dose. It is important to note **that 400mg EFV CANNOT be used among pregnant women, lactating women and TB patients** as currently there is insufficient evidence in support of its use in these groups. Once the 400mg EFV formulation is available in the country; the Ministry of Health will issue guidance on how to transition patients to the newer low dose formulation.
- **Routine viral load (VL) monitoring is recommended** to monitor treatment and facilitate earlier detection of treatment failure. All patients initiating therapy will routinely have a viral load assay done at 6 and 12 months after beginning therapy and every 12 months thereafter. VL assays are also recommended for patients already on treatment who are showing evidence of immunologic and or clinical failure.
- All PLHIV should be screened for TB including asking about TB exposure/contact history at each encounter with a health worker or visit to a health facility.
- Isoniazid Preventive Therapy (IPT) is very effective in preventing TB disease in individuals who have latent TB infection. IPT will be administered for **6 months**. To be eligible for TB-IPT the HIV-positive individual must:
    - Have no symptoms or signs of TB – such as current cough, fever, weight loss and night sweats
    - No current history of alcohol misuse
    - Have no history of active liver disease, liver insufficiency, or jaundice
    - Have no history of hypersensitivity to isoniazid
    - Have no history of exfoliative dermatitis
    - Be motivated for TB-IPT after being educated about the benefits, possible side-effects and risks.
- Xpert MTB/RIF should be used rather than conventional microscopy, culture, and drug susceptibility testing as the initial TB diagnostic test in adults and children suspected of having HIV-associated TB
- A systematic review found no evidence in the use of urine dipsticks for estimating renal toxicity in patients with HIV on TDF in the absence of laboratory capacity. Therefore, urine dipsticks is no longer used for monitoring TDF-associated renal toxicity

- **Infant prophylaxis** should be given based on **HIV risk stratification**. High risk infants are defined as those with:
    - High maternal viral load >1000 copies/ml during the last 4 weeks before delivery or
    - An infant born to HIV infected woman who has received less than 4 weeks of ART at the time of delivery or
    - An infant born to a newly diagnosed HIV infected woman during labor, delivery and postpartum (Incident HIV infection)

- Health workers should offer high-risk infants **dual ARV prophylaxis of AZT and NVP for 12 weeks** post- delivery.
- The country has now recommended use of a **PI based regimen as the preferred first line ART** for **children below 3 years** of age. However, where LPV/r is not available mainly due to its requirement for cold chain conditions; NVP-based regimens can be used for children under 3 years. However, for **children above 3 years; EFV is the preferred NNRTI backbone**. It is anticipated that the country will introduce the heat stable Kaletra pellets (LPV/r) to replace the use of syrup.
- Inf
- A new chapter on 'Differentiated ART care' has been added. Differentiated care is a **client-centred approach** that simplifies and **adapts HIV services** across the cascade to reflect the healthcare needs, preferences and expectations of various groups of people living with HIV (PLHIV). A **stable client** on ART (first- or second-line) is defined as someone who:
    - **Where viral load is available,** has no current OIs, has a VL <1000 copies/ml and is at least six months on their current ART regimen
    - **Where viral load is not available,** has no current OIs, a CD4 >200cells/mm^3, been at least six months on a current ART regimen.
- Stable patients on ART are given **five ARV refill options** namely: **Fast-track ART Refill model, Club refill model, ART Outreach model, Community ART Refill Groups and Family Member Refill model**
- The **frequency of clinic** visits has been reduced. Stable **adult** clients on ART should be seen for a clinical assessment **once every 6 months and 3-monthly visits for drug pick up.**
- **Oral PrEP** will be provided to individuals who are HIV uninfected and are at substantial risk of HIV infection (HIV incidence of >3%).. These sub-populations include populations such as sex workers and their clients, fishermen, long- distance truck drivers, men who have sex with men (MSM), uniformed forces, adolescents and young women engaged in transactional sex.
- **Recommended medicines for PrEP are Daily oral tenofovir/emtricitabine (TDF/FTC 300mg/200mg) or TDF/3TC preferably as an FDC**

Implementation of these recommendations is supported by the national scale-up plan that is aimed at achieving universal access by 2017. The guidelines support expansion of HIV testing and counselling (HTS) especially through provider-initiated testing and counselling (PITC) and early infant diagnosis (EID), further decentralizing ART to match PMTCT and TB care delivery, adoption of task shifting to alleviate the human resource gaps, and strengthening the supply chain management and M&E systems to support services scale-up.

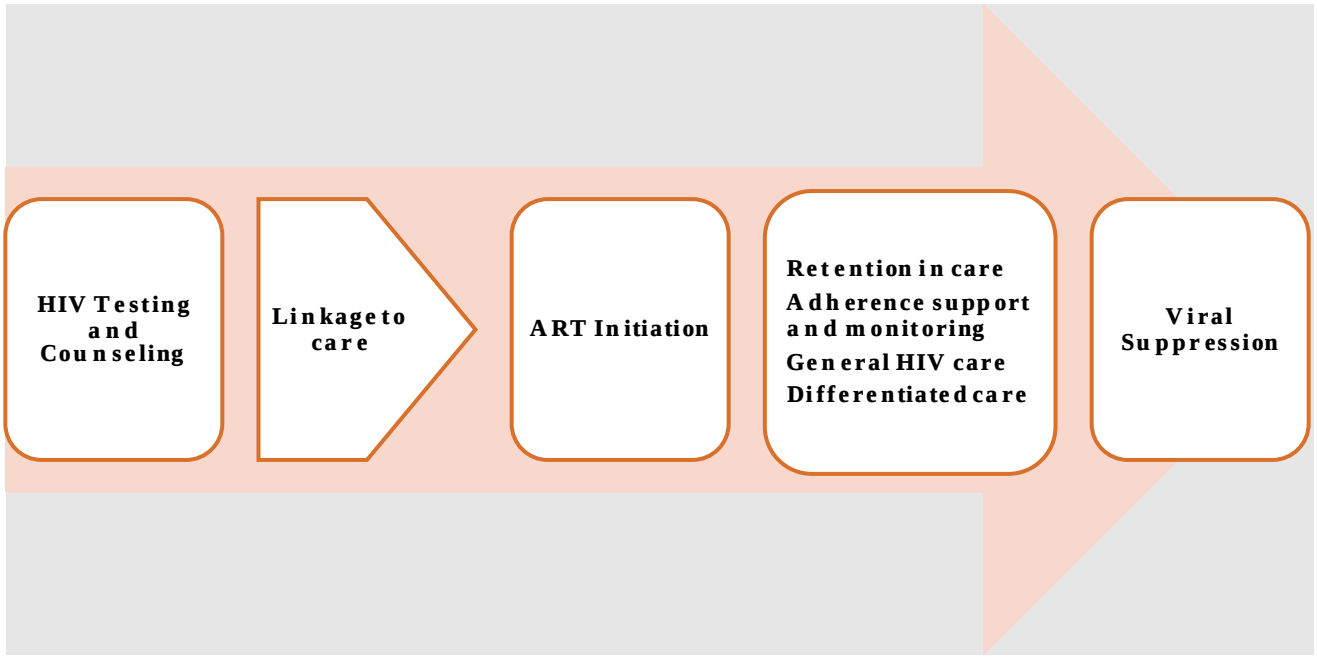
1.2 RATIONALE FOR REVISED AND CONSOLIDATED GUIDELINES

The guidelines have been revised to incorporate advances in HIV treatment and key recommendations from the World Health Organization. The guidelines are aimed at standardizing the management of HIV in different populations and age groups and clinical care settings using an integrated approach, and emphasize the fact that HIV treatment and prevention should be offered in a comprehensive continuum of care setting as shown in Figure 1.1. Previously, there was separate guidance based on population group or HIV intervention.

In addition, the revised guidelines contribute to the National HIV/AIDS Strategic Plan goal of universal access to ART by 2017.

'Continuum of care' refers to a comprehensive package of HIV prevention, diagnostic, treatment and support services provided for PLHIV and their families ranging across initial HIV diagnosis and linkage to care, management of opportunistic infections, initiating, maintaining and monitoring antiretroviral therapy, and palliative care.

Figure 1.1: Continuum of HIV care



1.3 OBJECTIVES OF THE GUIDELINES

The objectives of consolidated guidelines are:

- To provide a standardized and simplified guide for the use of antiretroviral drugs in the comprehensive HIV/AIDS service delivery setting.
- Ensure timely initiation of ARVs for HIV treatment and prevention
- Improve clinical outcomes, promote adherence and improved retention of clients in care
- Strengthen health systems to support service delivery in the continuum of care
- To serve as a training tool and reference material for health service providers, program managers, researchers, and people living with HIV.

Specific national program objectives include:

1. To scale-up HIV Testing Services (including PITC) and especially HTS approaches that promote linkage to care
2. To initiate ART for all HIV positive adults, adolescents and children (for prevention & treatment) including pregnant and breastfeeding women
3. To decentralize and scale –up services with capacity building for ART and accreditation of additional health facilities to initiate ART, manage, monitor and refer clients for further management
4. To introduce and rollout Pre-exposure Prophylaxis (PrEP) among HIV negative individuals with substantial risk of HIV infection (defined as HIV incidence of 3 per 100 person-years)
5. To strengthen the capacity of health care workers for service delivery; develop a national policy to address task shifting; recruit additional staff; and enhance staff retention
6. To strengthen the supply chain management system to support scale-up of all HIV interventions

7. Strengthen program monitoring and evaluation
8. Roll-out early infant diagnosis testing services, and use of viral load for monitoring HIV treatment response and for the diagnosis of treatment failure
9. Strengthen linkages and integrate services for all population groups, and clinical care settings

1.4 TARGET AUDIENCE

These guidelines are targeted to reach the following audiences:

- Clinicians and other health service providers in both public and private sectors
- Program managers of the national and state HIV program, the TB program, laboratory services, MNCH and reproductive health programs, commodity supply chain management for HIV related commodities
- Health facility administrators
- Training Institutions and Researchers
- Development partner agencies that support the national program and those that work with civil society
- Regulatory authorities

1.5 SCOPE AND COMPONENTS OF THE GUIDELINES

The guidelines include several chapters:

- Chapter 1 describes the background, rationale, objectives of the guidelines and the target audience
- Chapter 2 covers *HIV Testing and Counseling (HTS)*, a key strategic entry point to prevention, treatment, care and support services.
- Chapter 3 covers Antiretroviral *Therapy, When to start ART, Preparations prior to ART initiation, standard treatment, monitoring HIV disease, ART Follow up, Treatment Failure and Nutrition Assessment, Counselling and Support.*
- Chapter 4 looks at the needs of adolescents living HIV
- Chapter 5 outlines *Prevention of Mother to Child HIV transmission, a* central component in the continuum of care for women living with HIV to reduce the burden of HIV in the paediatric population.
- Chapter 6 & Chapter 7 look at *HIV infection in children* which tends to follow a more aggressive course than in adults. Children are therefore given a special section highlighting some of the unique features of care in this population. Recommendations on *Infant and Young Child Feeding* are covered in Chapter 8.
- Chapter 8 highlights *Management of Comorbidities, TB and HIV* co-management since TB is a common cause of illness among PLHIV. This chapter will also include some common HIV-associated malignancies such cancer of the cervix among women living with HIV.
- Chapter 9 is a new chapter which describes the Framework of Differentiated Care, models of ARV delivery, decentralization of ART services, service integration and linkages, adherence and retention in care and contingency plans for crisis situations
- Chapter 10 outlines recommendations on *ARV drugs for HIV Prevention* . Prevention remains the cornerstone in HIV control in the absence of a cure.
- Chapter 11 highlights health systems to support HIV services delivery including *Laboratory Services, Monitoring and Evaluation, Supply Chain Management and Human Resource*

Table 1.1: Intergrated Provision and scheduling of clinical HIV services

	2.4	Ascertain current HIV status at each visit offer HCT to eligible clients in all settings	√		√		√		√		√
	3.3	At HIV diagnosis, enrollment in care, at ART initiation	√		√		√		√		√
	Table8.2	When diagnosed, and throughout the course of care	√				√				√
	3.1	At every visit	√		√		√		√		√
	3.3	At baseline and 6 monthly - while on ART	√				√				
	6.2.2	At every scheduled visit as needed	√		√						
	8.9	At every visit	√		√		√				
		At every visit – for women of child- bearing age	√		√						√
	8.8	At every scheduled visit	√				√		√		√
	3.5.1	Dispense one ITN per person living with HIV every 24 months	√						√		
	7	At every visit					√		√		
	3.2	Preferably within the same day of diagnosis or as soon as patient is ready	√				√		√		√
	3.8	At 2/52, monthly for 6/12, thereafter 6-monthly for clinically stable adult and adolescent patients. For PMTCT, see monthly for 3/12 then quarterly. For TB, see monthly.	√								
	6.4	At admission					√				
		Initiate within 3 months, therafter synchronize clinic visits with ART refill and clinical visits	√				√		√		√
	5.4	After delivery					√				
	5.4.2	At birth (may dispense NVP in ANC) and during the first 6 weeks post -partum.					√				
	5.5	Monthly for the 1st 3 months i.e. 6, 10, and14 weeks (as per immunisation schedule). Thereafter, see quarterly for healthy infants. For infants that are Ab seropositive at 9 months and no PCR available, see monthly till HIV is excluded.					√		√		
	10.3.1	As soon as possible after risk exposure					√				

*Use of CD4 testing for monitoring treatment response will be phased out when viral load testing becomes more routinely available

2 HIV TESTING SERVICES (HTS)

HIV testing services (HTS) is a key strategic entry point to prevention, treatment, care and support services. The goal of HTS is to identify as many people as possible with HIV early in their infection and link them successfully to prevention, treatment, care and support services and to link those who test negative to HIV prevention services. This chapter has been updated to align with the recently revised 2016 South Sudan National HTS Guidelines. The global 90-90-90 targets calls for 90% of all people with HIV to be diagnosed, 90% of people with HIV diagnosed receiving antiretroviral therapy (ART) and 90% of those on ART to have a suppressed viral load by 2020. Knowledge of HIV sero-status among people who are HIV infected is therefore a critical step in the HIV care cascade. These guidelines promote early diagnosis of HIV and an acceleration in treatment initiation as this has been proven to have better clinical outcomes.

Special emphasis is placed on testing people who have not previously been tested including those who have a high risk of contracting HIV. These high-risk groups include sex workers, members of the uniformed forces, truck drivers and other migrant workers, people in prisons and other closed settings, and men who have sex with men. Many vulnerable groups exist in the country and need targeting for HTS interventions. These include refugees, internally displaced populations and survivors of sexual assault.

Key messages & recommendations:

- HIV testing services (HTS) is provided through two approaches: client initiated testing and conseling (CITC), provider initiated testing and counselling (PITC), using either the facility-based model (at health facilities, stand-alone sites), or community-based models in different settings such as Home-based door-to-door including index clients, mobile and outreach, work-place, educational institutions, campaigns, and self-testing.

- Regardless of the approach or model, HTS must be voluntary and adhere to the five 'Cs'— Consent, Confidentiality, Counselling, Correct test results and linkage to Care

- Provider Initiated Testing and Counseling (PITC) is recommended for:
- All clients accessing health care services and their partners, regardless of whether they demonstrate signs and symptoms of HIV infection
- Partners and children of people living with HIV (PLHIV)
- Key populations at high risk for HIV infection
- All clients seen during mobile and outreach HTS
- Men seeking Voluntary Medical Male Circumcision (VMMC)

- Components of the PITC protocol include:
- Pre-test information (through group education or one-on-one interaction)
- HIV testing
- Post-test counseling
- Linkages to prevention, treatment, care, and support services

- This guidelines recommend retesting at least annually to key populations and to HIV-negative partners in serodiscordant couples. Depending on client risk behaviours, more frequent voluntary retesting should be offered and available.

- **Re-testing before starting ART**
  Prior to ART initiation; health workers should re-test HIV positive people. This is being recommended as a measure to minimize 'false positive' test results considering the medical, psychological, social and financial implications of life- long ART treatment to an individual. Enrol all adults and children with confirmed HIV infection into care and treatment to ensure they can start ART as soon as possible
- **Lay providers** who are **trained and supervised** can independently conduct safe and effective **HIV**

2.1 PRINCIPLES OF HTS

The MOH in South Sudan is committed to ensure that the 5 principles of counselling are observed.

- Persons receiving HIV testing services (HTS) must give informed **Consent** to be tested and counselled. Clients should freely decide whether to accept the test (opt-in), or decline (opt-out).
- HTS services are **Confidential:** what the HTS provider and the client discuss will not be disclosed to any one else without the expressed consent of the person being tested.
- HTS services must be accompanied by appropriate pre-test information and post-test **Counseling**
- HTS providers should strive to provide high-quality testing services, and ensure the provision of **Correct** test results.
- HTS should provide **Connections** (linkages) to prevention, care, and treatment services.

2.2 HTS APPROACHES AND MODELS

HTS is provided through two major approaches, Client initiated Testing and Counseling (CITC), and Provider initiated testing and Counseling (PITC). To increase access to HIV diagnosis, all HTS approaches should be implemented in South Sudan, with priority given to PITC, targeted outreach HTS, and HIV testing for Early Infant Diagnosis.

2.2.1 Client-Initiated HIV Testing and Counseling (CITC):

- Also referred to as Voluntary Counseling and Testing (VCT), involves individuals actively seeking HTS from a facility that offers the service. This approach was developed before treatment became available where standalone sites were set up for clients who desired to know their HIV status.
  CITC is still an approach that may be used to complement other approaches in order to widen access to HTS services especially in high burden settings so as to reach the first 90.

2.2.2 Provider-Initiated Testing and Counseling (PITC):

- PITC refers to HIV testing and counseling that is recommended by health care providers to persons attending health care facilities as a standard component of medical care.
- PITC involves the provision of pre-test information and obtaining consent with the option of individuals to decline testing. In a generally low prevalence setting such as South Sudan, routine PITC will most likely not be cost-effective and hence the need to prioritize and target persons who request testing, those who exhibit clinical signs and symptoms indicative of HIV, or meet the categories below:
  - Partners, children and family members of HIV infected index clients
  - Pregnant and breast feeding women during ANC visits
  - TB patients and those with presumptive TB
  - STI patients, key populations and vulnerable people including female sex workers, organized forces, men who have sex with men and truck drivers.
  - People presenting with HIV-associated conditions at in-patient and out-patient departments

- Attendees of malnutrition clinics
- Clients accessing reproductive health
- Clients accessing male circumcision services
- All persons reporting sexual assault or rape

- PITC aims to identify unrecognized or unsuspected HIV-infected persons and link them to prevention, treatment, care and support services.
- Partners and children of PLHIV should also be offered testing through index-case testing. Providing HTS to family members of HIV clients (after consent and/or disclosure of the HIV client) improves support for adherence to ART and other care interventions.

Couples' HIV testing and Counseling:

Couple HTS enhances safer sexual behaviour, increases services uptake and treatment adherence, and identifies couples that would benefit from ART for prevention of HIV transmission (the sero-discordant couples) or ART for their own health (sero-concordant positive). Both partners must consent to testing and agree to learn the results together.

- Couple HIV testing and counselling (with support for mutual disclosure) should be offered in all HTS settings (including ANC) to married and co-habiting couples, premarital couples, polygamous unions, and any other partnerships.
- All PLHIV should be supported to encourage partner testing and disclosure of HIV status.
- HIV-positive partners in a sero-discordant relationship should be offered ART.
- Reproductive health counseling should be provided to couples of child bearing age.

- PITC models include:
  - Facility-based HTS (at health facilities, stand-alone sites)
  - Community-based HCT including Home-based door-to-door, mobile and outreach, work-place, educational institutions, campaigns.

2.2.2.1 Facility Based HTS Models

Health care facility-based HTS services: (also see **Table 2.2**)

- HTS services should be provided with other services being offered in health care facilities in the public, private and non-governmental sectors.
- HTS with diagnostic HTS**,** the health care providers offer HTS to individuals who show signs or symptoms consistent with HIV-related disease or AIDS.
- Mandatory and compulsory HIV testing can be performed for specific reasons such as tissue donation and medico legal circumstances such as rape and defilement. However, individuals should be informed of test results, and testing should be accompanied by appropriate counseling. Mandatory screening for HIV of blood and blood products destined for transfusion, may also present an opportunity for persons to know their HIV status.

Stand-alone HTS services:

- May be provided at sites that are situated outside health care facilities. Additional HIV prevention, treatment, care and support services can also be provided from these sites.

Table 2.1: Advantages and key considerations for facility-based HTS

Model	HTS Approach	Target group	Advantages	Key Considerations
Health care facility-based	**PITC**	People seeking health services	• HTS is integrated into existing services • Reduces missed opportunities to identify HIV positive persons • Links HIV positive persons to prevention, treatment, care and support services • Cost effective, efficient and less expensive • Low stigmatization as people could be attending the facility for other services • Close links with other existing medical services • Can provide outreach services	• Counselling space could be a challenge • Work overload for existing staff • Not ideal for people who do not frequent health services e.g. men, adolescents, and youths • Clinic operating hours may limit or affect access to HTS services
Stand-alone HTS site	**CITC**	General population including those that do not frequent health care facilities	• Convenient to those who do not want to be seen visiting public health care facilities • Accessible to key populations • Can be located in busy, easily accessible locations • Staff are dedicated to full time HTS service provision • Anonymous and confidential HIV testing is offered • Flexible operating hours • Can provide outreach services	• Attracts the more motivated clients • Poor referral mechanisms for follow up care and support • High likelihood of staff burnout • Possibility of stigmatization of the site • Expensive to maintain and sustain services as they are usually donor-funded • Could be underutilized if services are not advertised

2.2.2.2 Community Based HTS models:

Community-based HTS (CBHTS) contributes to reduction in stigma and discrimination by removing social barriers to HTS. Through increased knowledge of HIV status, more people can access prevention, treatment, care and support services. CBHTS is more likely to reach first-time testers, PLHIV with higher CD4 cell counts, men, adolescents, discordant couples, and key populations. Different settings can be used to provide CBHTS as follows: Home-based, including index client; Mobile and Outreach; Workplace; HTS in Educational institutions; and Campaigns.

Home based HTS including index clients :

- Should be provided using the door-to-door approach. It facilitates access to hard-to-reach, rural and underserved populations. Known HIV-positive or TB clients can act as index clients and consent to provision of HTS services in their homes.

Workplace HTS services:

- Usually provided as part of comprehensive workplace HIV programs. Reaches both men and women in formal and informal employment through their workplaces. Services can be provided either as a static service or as an outreach from facilities providing HTS services. Men who do not want or do not have time to access public health facilities for HTS can benefit from this model.

Outreach & Mobile HTS:

- Should be provided from health facilities and stand-alone sites. Mobile teams can provide outreach HTS services in such premises as community halls, school halls, and youth facilities. They target the general population, people living in remote rural areas, and key populations who include those at high risk of acquiring HIV (e.g. sex workers) and vulnerable groups (e.g. prisoners and highly mobile populations such as long distance truck drivers). It is essential to establish strong support systems and referral mechanisms at community level before initiating outreach HTS.

Educational institutions:

- Improves access to HTS for students in educational institutions. Issues concerning informed and parental consent, confidentiality, peer pressure, linkages and follow-up need to be addressed before setting up services. This model contributes to normalization of HTS and early access to knowledge of one's HIV status.

Campaigns:

- HTS campaigns can take different forms including service provision through mobile or outreach services, creating awareness and directing clients to service provision sites, and as part of disease prevention campaigns e.g. malaria Campaigns can vary in duration and can target specific populations such as couples or youths. It is important to ensure clients who have an HIV test are linked to appropriate post-test services

HIV self-testing (HIVST):

- This option refers to a process in which a person collects his/her own specimen (oral fluid) and then performs a test and interpretes the result, often in private or with someone he or she trusts. .

2.2.2.2.1 HIV Self-Testing (HIVST)

- **HIV self-testing (HIVST)** refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts.
- HIVST does not provide a definitive HIV positive diagnosis, and therefore, a **positive self-test result** always requires further testing and confirmation from a trained tester using the national testing algorithm at a health facility.
- Individuals at high ongoing risk, or who test within six weeks of possible HIV exposure, should be encouraged to retest. HIVST is not recommended for users with a known HIV status who are taking antiretroviral drugs, as this may lead to an incorrect self-test result (false non-reactive).
- HIVST **can be delivered through various approaches** in the public and private sectors, including community-based and facility-based channels

Table 3.2-2 gives a summary of the advantages of community-based HTS services.

Table 2.2: Advantages of Community-based HTS

Model	HTS Approach	Target group	Advantages
Home based including index	**PITC and CITC**	• Hard to reach • Underserved • Rural • Index	• Families test together • Early identification of infected children • Cost-effective • Increases HTS uptake • Reduces inequities • Increases number of first-time testers • Early identification of HIV-infected people • Early identification of sero-discordant couples
Mobile and Outreach	**PITC**	• Rural populations • Marginalised populations • Populations underserved by formal health system • Key populations	• Can be offered in different settings e.g. churches, educational institutions, • Normalises HIV testing • Reduces financial costs to the client • Moonlighting services can be provided at times and locations that are co key populations e.g.at night for sex workers and their clients
Workplace	**PITC and CITC**	• Employees and their families	• Able to reach men who find it difficult to get time to go to health facilities • Able to provide HTS to employees' families • Convenient for both employers and employees • Employers can have HTS services in the company clinic
Educational institutions	**PITC and CITC**	• Students and teachers	• Normalizes HIV testing thus reducing stigma • Early identification of HIV-infected children, adolescents and young adul • Early linkages to prevention, treatment, care and support services • Access to information on HIV prevention
Campaigns	**PITC and CITC**	• General population • Selected, targeted populations	• Mobilises communities to support HTS thus normalizing HIV testing • Increases HTS uptake • Can target specific groups • Can be linked to specific events
Self-testing	**CITC**	• General population • Health workers • Key populations	• Autonomy and empowerment • Confidentiality • Convenient • Increased knowledge of HIV status • Less stigma around HIV testing • Fewer resource requirements from the health system

2.3 HTS IN SPECIFIC POPULATIONS

2.3.1 HTS in infants and children below 18 months

- PITC should be implemented in all infant care settings to identify HIV-exposed infants (HEI) and ensure prompt linkage of HIV-infected infants to ART.
- All infants with unknown HIV status or uncertain HIV exposure should have their HIV exposure status ascertained using maternal serological antibody (Ab) test. If the mother is not available, perform serologic test on the infant.
- Routinely ascertain the mother's HIV status regardless of whether the child is healthy or sick by reviewing the mother's health passport or ante-natal care (ANC) card for the latest HIV test result.
- HIV-exposed infants should have serological Ab testing, regular clinical monitoring, and CPT.
- Perform rapid HIV test*:*
    - <u>For the mother: If</u> she was not tested at least <u>twice</u> during pregnancy and delivery, tested HIV negative more than 3 months prior, or if mother's HIV status is unknown or unclear.

- For the child, if the mother is unavailable/has died /doesn't consent to maternal HTS.
- If the child is sick, even if the mother tested negative during pregnancy or delivery. This is to evaluate for new HIV infection in the child.

o A negative antibody test in the infant means the infant or child < 4 months of age is not exposed to HIV.
o If the infant is HIV-exposed (i.e. infant and/or mother is Ab positive), then diagnose HIV infection using virological testing such as DNA PCR if available.
o Samples for PCR testing can be whole blood or dried blood spots (DBS) on filter paper cards that must be transported to reference laboratories. However, DBS is preferred for ease of storage and transportation to distant laboratories. Capacity for PCR testing in South Sudan is yet to be fully established.

Where virologic testing is readily available;

o All HIV- exposed infants should be tested within 6 weeks of birth or at the earliest opportunity thereafter.
o If the DNA PCR test is positive, the infant is likely to be infected and should be initiated on ART immediately while a second blood specimen is collected for confirmatory testing.
o If the DNA PCR test is negative and the child is still breastfeeding or has breastfed in the 3 months before testing, the test result is not definitive and the child should be re-tested.
  - A rapid diagnostic test for HIV serology may be used at 9months to rule out HIV infection in asymptomatic HIV-exposed infants. If serology is positive, PCR should be done to diagnose HIV infection.
  - A final test should be done 3 monthsfter breastfeeding has ended. If rapid test is positive and infant is <18months of age, PCR is needed to diagnose HIV.

*Where **virologic testing is not readily available**;*

o Infants with a presumptive diagnosis of HIV (**Table 2.3**) should be managed as follows; treat the acute illness; initiate ART; repeat Ab test after 18 months of age; continue ART if Ab positive.. An infant started early on ART may have a negative rapid antibody test at 18 months (even when infant is HIV infected because they may fail to mount sufficient immune response). Therefore, in such instances, do not stop ART but closely monitor the infant (obtain a DBS sample for DNA PCR test at 18 months to confirm HIV status or 3 months after cessation of breast feeding).
o

HIV-exposed infants who are 'well' (asymptomatic) should have an Ab test at 9 months of age. If positive and infant is well, continue close clinical follow-up and repeat test at 18 months of age or 3 months after breastfeeding cessation, whichever is later. If the antibody test is negative and the infant has not breast fed in the prior three months infant is uninfected.

Table 2.3: Criteria for Presumptive diagnosis of severe HIV disease in infants below 18

A presumptive diagnosis of severe HIV disease should be made if:	
The child is confirmed as being HIV antibody positive AND	The infant is symptomatic with two or more of the following: o Oral thrush o Severe pneumonia o Severe sepsis

	o Failure to thrive OR A diagnosis of any AIDS-indicator conditions(s) can be made

Other findings that support the diagnosis of severe HIV disease in an HIV seropositive infant include:

- Recent HIV-related maternal death or advanced HIV in mother
- Child's %CD4 is <20%

Confirm the diagnosis of HIV infection as soon as possible.

AIDS indicator conditions include some but not all HIV pediatric clinical stage 4 conditions such as *pnemocystis carinii(jiroveci)* pneumonia, cryptococcal meningitis, severe wasting, or severe malnutrition, Kaposi' sarcoma, extra-pulmonary TB

As per IMCI definition:

- Oral thrush: creamy white –to –yellow soft small plaques on red or normally colored mucosa which can be scraped off (pseudomembranous) or red patches on the tongue, palate or lining of mouth, usually painful or tender.
- Severe pneumonia: cough or difficult breathing in a child with chest pain with chest in-drawing, stridor, or any of the IMCI general danger signs i.e. lethargic or unconscious, not able to drink or breastfeed, vomiting and presence or history of convulsions during current illness; responding to antibiotics
- Severe sepsis: Fever or low body temperature in young infant with any sever sign, e.g. fast breathing, chest in-drawing, bulging fontanelle, lethargy, reduced movement, not feeding or sucking breast milk, convulsions.

Table 2.4: Recommended Testing Approaches for Infants and Children below 18

Category	Test required	Purpose	Action
A. Infant with unknown exposure status	Maternal serological Ab test If the mother is unavailable then infant Ab test	To identify /confirm exposure	If HIV-exposed, do virological test (where available). Enrol all HIV-exposed infants in monthly care and provide CPT
B. HIV-exposed infant who is well.	Virologic testing (EID test) at 6 weeks of age *or earliest opportunity thereafter.*	To diagnose HIV	If test is positive, send confirmatory test and start ART. If test is negative, perform Ab test at 18 month or 3 months post breastfeeding cessation, which ever is later..
	If virologic test is not available, perform Ab test at 9months of age.	To To confirm HIV exposure	• • *If HIV Ab positive at 9 months of age, continue CPTwith close clinical follow up. If infant remains well, repeat Ab test at 18 months of age or 3 months post breast feeding cessation.* • *If infant becomes sick, symptoms develop during follow-up, see category C below.* • *If HIV Ab negative, assume uninfected. If still breastfeeding, continue follow-up and CPT, and repeat testing 3 months after cessation of breastfeeding or at 18 months of age. If negative stop CPT. If positive start ART.*
C. HIV-exposed infant who is unwell/ sick	HIV serological test.	To confirm HIV exposure	If Ab positive, send sample for virologic testing to confirm HIV (where available). If symptomatic with two or more of the following; oral candidiasis/thrush, severe pneumonia, severe sepsis , failure to thrive or has a diagnosis of any AIDS-indicator condition(s), presume infant is HIV-infected, treat acute illness, start ART, confirm HIV with DNA PCR virologic test (if available) or Ab test after 18 months. Stop ART if confirmed negative.
D. Infant or child who has completely discontinued breastfeeding	If 3 months or more after breast feeding, do Ab test for HIV exposed child < 18months and virologic testing if serologic test is positive	To exclude HIV infection after exposure	If Ab test is negative infant is not HIV –infected. If ab test is positive infant is < 18 months of age perform virologic test infant is > 18 months of age, infant is HIV –infected start HIV care and ART

2.3.2 Counseling children and youth:

Children and youth have unique vulnerability to HIV infection, and as their ability to comprehend HIV/AIDS issues differs from that of adults, this population deserves special consideration. The welfare

of the child should be the paramount guiding principle when considering testing; the counselor should determine reasons for testing with the parent or guardian.

- Anyone 18 years of age and above requesting HTS should be considered able to give full, informed consent.
- Young people under age 18 years of age who are married, pregnant, parents, engaged in behaviour which puts them at risk, or are child sex workers are considered capable of giving their own consent for HTS (emancipated minors), and do not need a parent or guardian's consent.
- HTS of those who are under 18 years and are not emancipated minors, should be done with knowledge and consent of a parent or guardian. Verbal consent is sufficient.
- For those under 18 years of age who have no parents or guardians, parental/guardian consent will not be required before testing is done but the young person will be asked to sign a declaration that they have no parents or guardians. HTS services will be provided in consultation with social services' providers or institutional heads.
- Providing information about the HIV status of a child should be done only if necessary in the interest of the child with his parents'/guardian's consent; and only to trustworthy teachers who have received training in HIV counseling.
- Adolescents should be disclosed to at the time of HIV testing as their understanding of the HIV test results is critical for successful linkage and retention in care and treatment services
- HTS counselors should be trained on a child developmental approach to gradual disclosure of HIV status for younger children. Young children should be told their status incrementally to accommodate their cognitive skills and emotional maturity, in preparation for full disclosure.
- For additional detail on psychosocial support needs of adolescents, refer to **Chapter 4**. Further guidance on HIV disclosure counseling for children younger than 10 years can be found at: *http://www.who.int/hiv/pub/hiv_disclosure/en/*.

2.3.3 HTS for male circumcision:

- HTS is part of the minimum service package for Voluntary Medical Male Circumcision (VMMC), thus providing an opportunity to reach men with HIV prevention and care services.
- VMMC may be implemented using a mixed-service delivery model including fixed-facility sites, outreach, mobile services and campaign events.
- The Ministry of Health will provide guidance on the introduction and rollout of the VMMC programme

2.3.4 HTS for Key Populations

- Key populations are at increased risk of being infected or affected by HIV. Key populations include sex workers, injecting drug users, transgender people and men who have sex with men (MSM), people in prisons or in closed settings.
- Priority populations are made up of people who are at an increased risk of HIV transmission because of their circumstances. In the context of South Sudan, these include clients of sex workers, fishermen, long- distance truck drivers, uniformed forces, adolescents and young women engaged in transactional sex.
- It is important to design strategies for HIV testing services targeting the different key populations. Examples of these include:
    - Moonlight testing for female sex workers)
    - Testing at border points or trucking stops for distance truck drivers
    - Use of peers both for mobilization and performing of HIV testing services
    - Each group should also have specific additional services incorporated into an integrated screening approach.

- Other considerations include:
  - Linking HIV-negative key populations to prevention services, including PrEP, should be a priority
  - Like all HTS, programmes for key populations need to emphasize WHO's "5 Cs" - particularly consent, confidentiality and connection to comprehensive prevention, treatment and care.
  - HIV Self Testing may prove to be another important way to increase access to HIV testing among key populations and, hence, to prevention, treatment and care services
  - Intensified TB case finding, along with HTS, also is particularly beneficial among key populations. These populations are highly vulnerable to TB, particularly in countries with high burdens of both TB and HIV
  - Retesting at least annually is recommended for all people from key populations

2.4 THE PITC PROTOCOL

Recommendation:

PITC should be offered to everyone (adults, adolescents, and children) attending all health facilities; including partners, children and family members of HIV infected index clients, adult and periatric medical and surgical out patient and inpatient services; STI, TB clinics, reproductive health service(ANC, maternity, family planning), services for infants and children public and private facilities, mobile and outreach, services for key populations..

A. Pre-test information:

- Can be provided as group education (an interactive health education session to groups of waiting clients and facilitated by peer educator, nurse or counsellor) or as a one-on-one session between provider and client.
- Gives information on benefits of HTS; confidentiality and interpretation of test results; HIV transmission, prevention, and treatment; partner HIV testing and disclosure
- Information, Education, and Communication (IEC) materials such as posters and brochures may supplement group education
- Routinely ascertain HIV status of clients, initiate new test if status is unknown or unclear.
- Reinforce education messages, encourage testing, and seek consent for HIV testing (verbal consent is sufficient). Always remind clients that they have a right to decline testing.

B. ***HIV testing:*** - See testing algorithms for adults and children in **Figure 2.1** and **Figure 2.2** .

C. Post-test counseling:

Clearly communicate the meaning of the HIV test results to the client. Couples should be encouraged to receive results together.

For the HIV-negative client:

- Focus on risk reduction interventions
- Persons who require re-testing include those whose initial test results were indeterminate, those who tested negative but are at an on-going risk for acquiring HIV (uninfected partners in sero-discordant relationships, pregnant women, 'key' populations, sero-negative individuals taking Pre- or Post-exposure Prophylaxis), and those who may be in the early stages of infection and have not yet developed a sufficient level of antibodies that can be detected by serological testing +--
- If male and HIV negative, counsel and refer for male circumcision (VMMC) services

For the HIV positive client:

- Focus on encouraging acceptance of HIV diagnosis; partner and family testing including children and disclosure; assessing and resolving barriers to accessing care.
- Refer to HIV care site for enrollment into ART and additional counseling; provide information on local HIV services' providers and support networks.
- Counsel on HIV re-infection, prevention & transmission
- If HIV diagnosis is not accepted (i.e. the client is in denial) – refer for additional counseling

2.5 HIV TESTING ALGORITHM

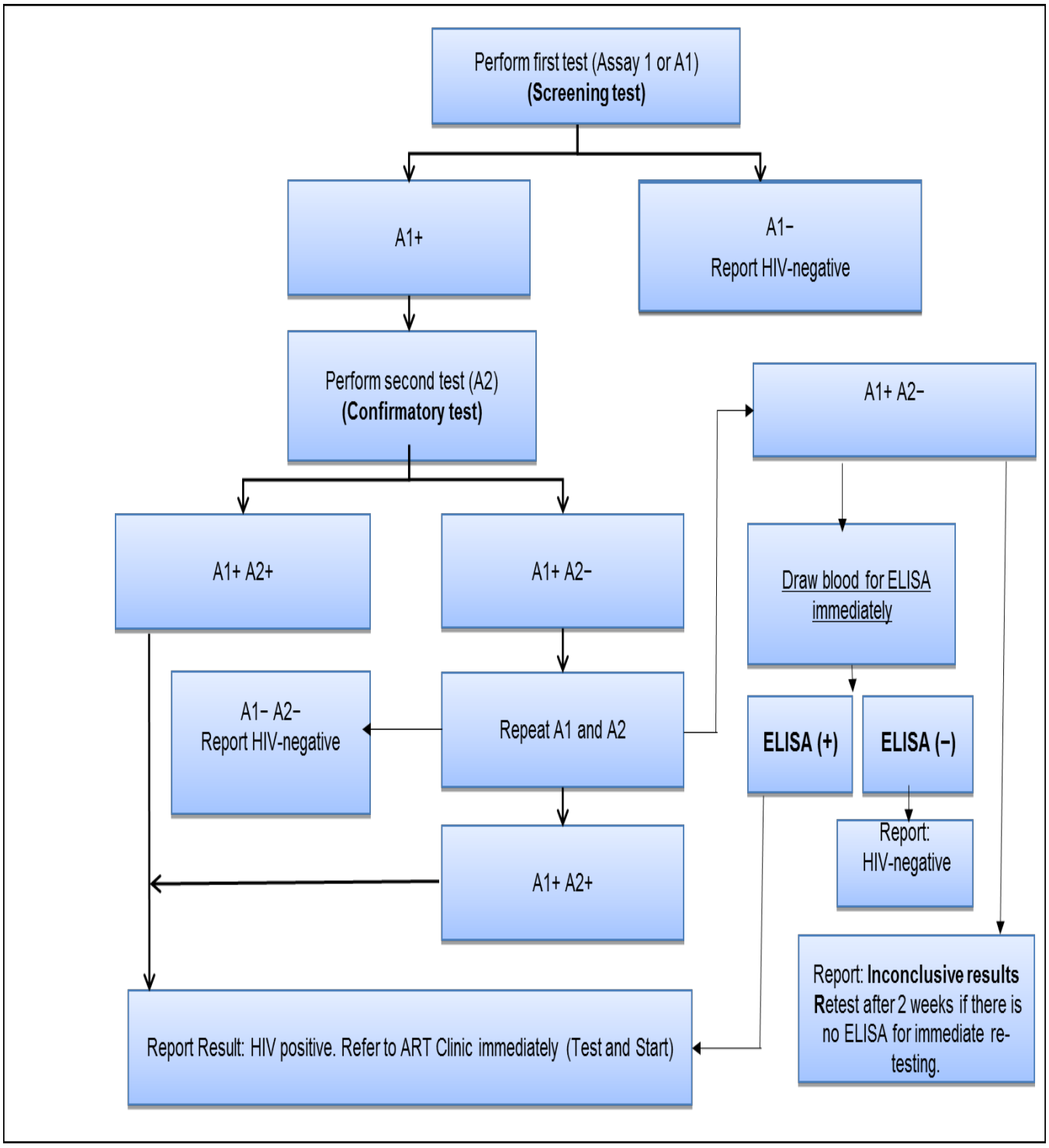
2.5.1 In adults and children above 18 months of age:

Diagnosis of HIV infection in adults and children older than 18 months is usually done by detection of Ab to HIV using rapid tests or Enzyme Immunoassays (EIA). The approved HIV rapid test kits for use in South Sudan in the HIV testing algorithm are Determine (used as the screening or first test), Unigold (used as the confirmatory test.The rapid tests can be performed using whole blood, serum or plasma samples. Whenever possible, rapid testing should be done with a finger prick sample. HIV rapid testing can be performed in the laboratory, in non-laboratory hospital setting, clinic or community settings by health care providers trained to perform HIV rapid tests. However, all testing done outside a laboratory setting must be supervised by qualified laboratory personnel to ensure accurate and quality results.

These guidelines recommend a two- test strategy for HIV diagnosis in all settings providing HTS being health facilities, clinics or community based settings. All qualified laboratory personnel or other trained health workers involve in specimen collection, testing and reporting results must adhere to this testing strategy. The two test strategy in the flowchart below which is intended for use with serology assays, describes the sequence of assays and number of tests to be performed. The following section provides a description of the flowchart.

- All specimens are first tested with one assay (A1), and specimens that are non-reactive (A1–) should be reported HIV-negative. A1 should be the most sensitive assay available, taking into account diagnostic sensitivity, seroconversion sensitivity and, if a fourth generation assay, analytical sensitivity.
- Any specimens that are reactive on the first-line assay (A1+) should be tested with a separate and distinct second assay (A2) comprised of a different antigen preparation to avoid false cross-reactivity with A1.
- For specimens that are reactive on the first-line assay but non-reactive on the second-line assay (A1+; A2–), testing should be repeated using the same specimen with the same two assays. When the two assays use finger-prick whole blood, a new specimen should be taken for the repeat testing.
- Any specimens that remain reactive on the first assay but non-reactive on the second assay (A1+; A2–) **should be reported HIV-inconclusive and the patient or client should be asked to return for retesting in 14 days. However, in facilities where the hospital has ELISA machine, draw blood immediately for retesting and report results as in the chart above.**

Figure 2.1: HIV diagnosis in adults and children aged 18 months or more



HIV testing algorithm for infants and children younger than 18 months

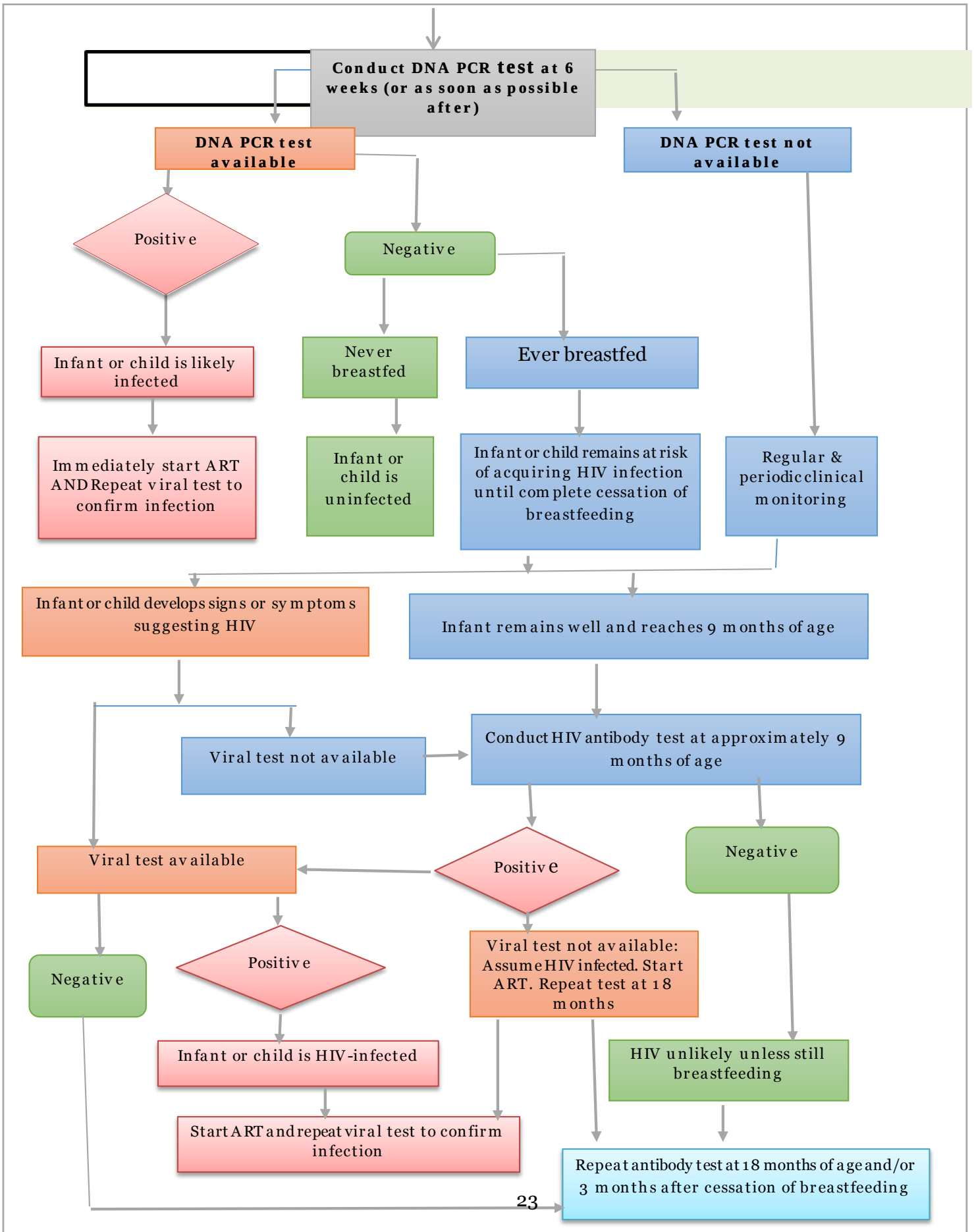
HIV infection in exposed infants and children below 18 months old is diagnosed by virological test because maternal HIV antibodies may remain in their bloodstream until 18 months of age, making

test results from antibodies tests unreliable. Therefore, these guidelines recommend the following HIV testing strategy.

- Firstly, the health worker should determine whether the infant or child is HIV exposed. This should be done by checking the mother's ANC card or Child's Health card for HIV status.
- If the mother is infected with HIV, this means the infant is HIV exposed but not necessarily infected. In this situation, the health worker should collect a dried blood spot (DBS) specimen for a Polymerase Chain Reaction (PCR) test. The first DBS specimen for PCR test should be collected at 6 weeks of age or the earliest time thereafter.

- Secondly, if there is no documentation of the mother's status, rapid HIV testing of the mother to know HIV exposure status of the infant or child should be done.
- If the health worker is unable to test the mother or the infant or child is brought by a caretaker, the health worker should perform a rapid test on the infant or child. If the results are positive, this means the infant has been exposed but this does not confirm HIV infection. In this case, the health worker should collect DBS for a PCR test.
- A **POSITIVE DNA PCR test** result indicates that the child is HIV-**infected.** All infants with a positive DNA/PCR test results should be initiated on ART, and another blood sample is collected on the day of ART initiation to confirm the positive DNA/PCR HIV test result. ART initiation should not be delayed to wait for the confirmatory test result.
- A **NEGATIVE** 1st DNA – PCR test result means that child is **not infected**, but could become infected if they are still breastfeeding. Infants testing HIV negative on DNA/PCR should be re-tested at 9 months of age and again 3 months upon cessation of breastfeeding. Test done at 9 months and after breastfeeding can be serologic tests; if serologic test is positive and infant is <18mo, PCR should be sent to diagnose HIV.

Figure 2.2: HIV testing algorithm for HIV-exposed infants



2.6 LINKAGE FROM HTS TO HIV PREVENTION, TREATMENT AND CARE

- Patient attrition after an HIV diagnosis is one of the major factors that contributes to delayed ART initiation, sub-optimal treatment outcomes and preventable HIV transmission
- Linkage to care is the process of assisting HIV-diagnosed persons to enter medical care. Linkage is described as successful when following receipt of HIV diagnosis, a client has attended an initial visit at the HIV medical care facility, has been registered, initiated on cotrimoxazole, and assessed for ART.
- Linkage to care enables early assessment of patient and preparation for timely initiation of treatment, as well as access to interventions to prevent HIV transmission, other infections and co-morbidities, and interventions to reduce the risk of loss-to-follow-up (LFTU).
- HTS services are required to be linked to local HIV treatment, care and support services and to other units of the respective health facilities. Linkage may be within the same facility (intra-facility), from one facility to another (inter-facility), or between community and facility.

Key barriers to linkage include:

- Psycho-social factors: related to knowledge, beliefs and motivation within a given social context
  - Lack of understanding of why it is important to enroll in care
  - Stigma and fear of disclosure of HIV status
  - Use of herbal and other medicine
- Structural factors, such as related to underlying economic conditions of daily life
  - Accessibility of care
  - Lack of transportation
  - Work responsibilities
  - Food insecurity
- Health care delivery factors:
  - Quality of care at the point of contact with the client (long waiting time, commodity stock-outs, conflict with staff, coordination of care, stigma)
  - Service inaccessibility (distance from home)

Recommended strategies for improving linkage in South Sudan include:

- *Integration of HTS with other services and use of rapid HIV testing kits at Point-of Care:* such as provision of PITC in the ANC, the TB clinic or OPD enhances linkage
- *Decentralization of ART services to peripheral health facilities*
- *Use of triplicate referral forms*; one form is given to the client, one remains at the referring site and the third form is sent to the client receiving site. At regular intervals, monitoring is carried out and clients that are lost-to-follow-up (LTFU) are actively tracked by providers
- *Use of linkage facilitators and other community support groups / workers*; immediately an individual is identified as HIV-infected, s(he) is physically escorted to the referral site from HTS site
- Client reminder and follow-up through *use of mobile phone short message service (SMS) reminders* or telephone calls
- *Immediate CD4 testing at the point of careHTS can be used to prioritize patients for urgent linkage to care and ART initiation*
- *Promoting partner testing may improve the uptake of HIV testing and linkage to care*

3 ANTIRETROVIRAL THERAPY FOR ADULTS & ADOLESCENTS

Antiretroviral Therapy (ART) is associated with clinical and HIV prevention benefits, improving survival and reducing the incidence of HIV infection at the community level. ART helps preserve the immune system of PLHIV, reduces the risk of Opportunistic Infections, restores growth (especially in children), and improves mental functioning and overall quality of life.

- ART may be initiated in the ART clinic, in MNCH settings (ANC, maternity, PNC), in the TB clinic, or while a client is hospitalized (in-patient). However, all patients on treatment should be actively linked to the ART clinic for chronic care. TB clients may be transitioned to ART clinic after completing anti-TB treatment, and women may be transitioned from PMTCT to ART clinic 18 months after delivery, when the HIV status of the baby is known. *However, given the limited HR capacity, facilities may provide HIV care and treatment at a single location to serve all PLHIV including adults, children, pregnant women, HIV exposed infants and TB clients.*
- ART initiation should be done at ART accredited health facilities by medical officers, clinical officers, midwives and nurses trained in ART service provision. Follow-up of ART clients may be done at primary facilities and at community level. Refer to 6.3.5 for ART in pregnant and breast feeding women, and 7.3 for paediatric ART.

At enrolment, clients should have:

1. Clinical evaluation
   - WHO clinical staging 3.3
   - Baseline CD4 cell count - if available
   - Clinical evaluation (History, Physical exam, Lab assessment) 3.7
   - TB screening (refer to Chapter 8)
   - Screening for other comorbidities such as (Cryptococcal disease, Diabetes Mellitus, Hypertension, HBV and HCV)
   - Mental Health, Neurological Diseases and Substance Use assessment (Refer to Chapter 9)
2. Management of HIV related disease 8.8
3. Starting antiretroviral therapy 4.2
4. Provision of basic HIV care
   - Cotrimoxazole Preventive Therapy 3.6
   - Insecticide treated bed net (ITNs) 3.5.1
   - Provider initiated Family Planning 5.2.2.1
   - Prevention with Positives 8.9

3.1 WHEN TO START ART FOR ADULTS AND ADOLESCENTS

All HIV positive adults and adolescents irrespective of CD4 counts or WHO stage are eligible to start ART (Treat All). Patients should be initiated on ART as soon as the patient is ready and preferably within one week.

In circumstances where prioritisation is required, ART should be initiated in all individuals with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and or individuals with CD4 count <350 cells/mm^3

3.2 PREPARATION FOR ART

Client preparation prior to starting ART should include baseline clinical and laboratory assessments as well as a psychosocial assessment to ensure the client can achieve optimal adherence once on treatment. **Treatment should be initiated preferably within 7 days following HIV diagnosis**. Clinical Assessment: Treat any pre-existing infections as a matter of priority. Remember clients *with TB should be initiated on anti-TB treatment first, then ART within 2-8 weeks*

Laboratory Assessment: *Lack of access to laboratory tests should not be a barrier to treatment initiation in settings where resources are limited.* Where tests are not available on-site, arrangements should be made to transport specimens to a facility that is able to carry out the tests if possible. Laboratory tests are useful in pre-treatment assessment as well as in monitoring clients on treatment. The need for Point of Care (POC) technologies is key for ensuring rapid diagnostic results in settings with limited access to laboratory services. In the event that laboratory resources do not permit the full range of 'desirable' tests, minimum 'recommended' tests can be done.

Table 3.1: Baseline Laboratory Tests at ART

Lab test		
Confirming HIV serostatus	Ensure that national testing algorithm has been followed	o Retesting to confirm HIVstatus is required to to ensure correct diagnosis
CD4 testing	As baseline	o If on-site CD4 testing is not available, blood samples should be sent for CD4 cell count testing. o CD4 baseline test result is not required for ART initiation o CD4 count at baseline is useful for determining individual patient's level of immune-suppression and related HIV services
Pregnancy screening (+/-test)	To identify women who need referral for ANC	All pregnant women should be referred for ANC care while taking ART
* Screen for TB symptoms (+/- test)	To identify TB/HIV co-infected	In persons with at least one positive symptom out of the four screening symptoms (Any cough, Fever, Weight lost and Night sweat); Send sample for GeneXpert immediately where possible. In case the GeneXpert is not available do Sputum smear or CXR based on national algorithm). See Figure 13.1
Renal function (if clinically indicated): o Serum creatinine	To detect renal insufficiency at baseline - particularly for clients starting on TDF containing regimen.	TDF induced renal injury is more common in clients with underlying kidney disease such as cases with long standing hypertension, long standing diabetes, people on concomitant nephrotoxic drugs, and older persons. Urinalysis is also recommended a part of ANC care
Blood Pressure measurement	As baseline	Blood pressure measurement is also recommended as part of ANC care.
Random Blood Sugar	For early diagnosis of diabetes mellitius as an important comorbidity in HIV	A random blood sugar of more than 200 mg/dl with symptons and signs of diabetes mellitus (DM) is diagnostic for DM
HBV and HBC testing	To identify TB/HIV co-infected	PLHIV diagnosed with HBV (requiring treatment for HBV) should receive ART as per guidelines (using TDF-3TC of FTC containing regimen)
Do HB or FBC if requires AZT	To detect anaemia or neutropenia,	For clients initiating AZT HB testing is also recommended as part of ANC care
Alanine aminotransferase (ALT)	To exclude liver disease For clients initiating NVP-based regimen	If ALT is high, do not give NVP but use EFV. If ALT is elevated, do Hepatitis B and C surface antigen test, if available or refer.

Serum cryptococcus antigen if CD4 count is ≤100 cells/ml	To detect asymptomatic infection with *cryptococcus neoformans* infection	o Cryptococcal meningitis is a major cause of death even after ART has been initiated. o Prevalence of cryptococcaemia is higher at low CD4 counts. o Clients with positive serum CrAg should receive pre-emptive anti-fungal treatment for latent cryptococcal infection o Diagnosis and treatment is available at tertiary sites- referral hospitals
Symptom directed lab tests to diagnose pre-existing illnesses:	See management of HIV related diseases 3.5	

*NB : This is a clinical symptom screen, but lab evaluation is recommended if symptomatic

Formula for calculating creatinine clearance in adults and adolescents ≥18 years old

The formula to calculate the creatinine clearance in men is as follows:
(140-age in years) x weight in kg x 1.22
Serum creatinine in micromoles/L
Multiply the answer above by 0.85 for creatinine clearance in women

3.2.1 Psychosocial assessment and adherence counseling

The goal of the psychosocial assessment is to identify problems which may impact negatively on the client's health or treatment outcomes and correct them. The preparation of the client for ART should start with baseline counseling to address the following issues:

- *Expected benefits of ART and limitations of ART*
- Importance of adherence to ART, potential barriers and how to improve adherence.
- *Potential side effects of ART and what to do*
- *Possible drug interactions*
- *Follow-up on ART*
- *The importance of food hygiene and proper nutrition.*
- *Sexual and Reproductive Health (RH) issues*
- For older children and adolescents, disclosure of HIV status
- Clients ' willingness and readiness to start ART

ART adherence counseling:

The goal of ART is to achieve sustained and optimal viral suppression. It is essential for a patient to take medication correctly every day. Very high levels of adherence, taking at least 95% of prescribed doses, are required to achieve sustained suppression of HIV replication over time. Poor adherence can lead to development of drug resistance, and subsequent immunologic and clinical failure. Potential or actual barriers to adherence should be identified and discussed with the client during treatment preparation. These may be related to the client, the provider, the regimen, or the health system. The table below highlights some of these factors.

Table 3.2: Client Preparation to Start ART and Mantain Adherence

Potential Adherence Barrier	
o Poor understanding, misconceptions o Stigma and Lack of disclosure of HIV status, lack of social support o Depression or other psychiatric diseases o Active alcohol abuse o Poverty, transport challenges	• Client education, counseling and support • Assisted disclosure • Linkage to Peer & community support groups • Treatment of underlying psychiatric condition (s) • Referral for social support e.g. nutritional support • Co-management of alcohol abuse/substance use disorder • Co-management of mental health disorders • Nutritional support in food insecure settings
o Regimen complexity o Frequency of dosing o High pill burden o Food requirements or restrictions o Frequency and severity of side-effects	• Use Fixed Dose Combination (FDC) ARVs / Use regimens requiring less frequent dosing i.e. od of bid • Utilise pill boxes especially where client needs multiple drugs • Give clear instructions to clients • Consider client's routine • Use of reminders – IEC can be employed • Do not give unessential medicines • Inform client about possible side effects and what to do in case they occur.

The choice to accept or decline ART ultimately lies with the individual or his or her care giver, and if they choose to defer initiation, ART can be offered again at subsequent visits. If there are mental health, substance use or other problems that are major barriers to adherence, appropriate support should be provided, and readiness to initiate ART should be reassessed at regular intervals. Health workers should ask about other medications they are taking, including herbal remedies and nutritional supplements. Herbal remedies and other nutritional supplements should be discouraged as they are likely to interfere with the way ARV medicines work.

3.3 WHO CLINICAL STAGING

Clinical staging should be performed at HIV diagnosis, at enrolment into ART care, and at every clinical visit during ART follow up.

- HIV-related diseases are grouped into four (4) WHO clinical stages that correlate with disease progression and prognosis of survival: *Stage 1*: Asymptomatic; *Stage 2*: Mild; *Stage 3*: Advanced; *Stage 4*: Severe. See Table 1.1 for staging in adults and adolescents and Table3.4 for staging among children.

- WHO clinical staging requires confirmed HIV infection.
  - An infant aged under 18 months with only a positive HIV rapid antibody test can NOT be given a WHO clinical stage because in infants, HIV antibodies do not confirm HIV infection.
  - However, an infant with HIV antibodies and specific clinical conditions is very likely to have AIDS and needs to start ART without delay (see Table 2.3 for Presumptive diagnosis of severe HIV disease)
- Ongoing clinical assessment of patients on ART is important to determine presence of opportunistic infections, signs of immune reconstitution syndrome, and medication side effects.

3.4 MANAGEMENT OF PATIENTS WITH LOW CD4 COUNT

If CD4 is available at first visit, clients with a CD4 < 100 need special attention. Such patients should be fast-tracked for treatment initiation. They should be screened for symptomatic TB, examined for Kaposi sarcoma and should have blood sent to the laboratorty to be screened for Cryptococcal antigen using CrAG test. They should receive cotrimoxazole and isoniazid (INH) prophylaxis like all other patients and should be closely monitored for 3 months as this is their highest risk period for bacterial infections and TB or cryptococcal IRIS. Health workers should educate them and their families to report immediately to a health facility if they are unwell whilst their CD4 cell count is < 100 copies per ml.

Table3.3: WHO clinical staging for HIV infections: Adults and adolescents

Clinical Stage I:
- Asymptomatic
- Persistent generalized lymphadenopathy

Clinical Stage II:
- Moderate unexplained weight loss (less than 10% of presumed or measured body weight)
- Recurrent respiratory tract infections, e.g., bacterial sinusitis, tonsillitis, otitis media and pharyngitis
- Herpes zoster
- Minor mucocutaneous manifestations (seborrhoeic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular stomatitis)

Clinical Stage III:
- Unexplained severe weight loss (more than 10% of presumed or measured body weight)
- Unexplained chronic diarrhea for longer than 1 month
- Unexplained persistent fever (intermittent or constant for longer than 1 month
- Persistent oral candidiasis
- Oral hairy leukoplakia
- Pulmonary tuberculosis (current)
- Severe bacterial infections such as pneumonias, pyomyositis, empyema, bone or joint infection, bacteremia or meningitis
- Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
- Unexplained anemia (<8gm/dl), neutropenia (<0.5× 10^9 per litre), or chronic thrombocytopenia (<50× 10^9 per litre)

Clinical Stage IV:
- HIV wasting syndrome –
- *Pneumocystis carinii (jiroveci)pneumonia* (PCP)
- Recurrent severe bacterial pneumonia
- Chronic herpes simplex (HSV) infection (orolabial, genital, or anorectal of more than 1 month or visceral at any site
- Oesophageal candidiasis (or candidiasis of the trachea, bronchi or lungs)
- Extrapulmonary tuberculosis
- Kaposi's sarcoma
- Cytomegalovirus infection (retinitis or infection of other organs)
- Central Nervous system toxoplasmosis
- HIV encephalopathy
- Extrapulmonary cryptococcosis induding meningitis
- Disseminated non-tuberculous mycobacterial infection
- Progressive multifocal leukoencephalopathy (PML)
- Chronic cryptosporidiosis
- Chronic isosporiasis
- Disseminated mycosis such as histoplasmosis, coccidioidomycosis

- Lymphoma (cerebral or B-cell non-Hodgkin)
- Symptomatic HIV-associated nephropathy or cardiomyopathy
- Recurrent septicaemia (including non-typhoidal Salmonella)
- Invasive cancer of the cervix
- Atypical disseminated leishmaniasis

Table3.4: WHO clinical staging of HIV in children

Clinical Stage I:
- Asymptomatic
- Persistent generalised lymphadenopathy

Clinical Stage II:
- Unexplained persistent hepatosplenomegaly
- Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
- Herpes zoster
- Lineal gingival erythema
- Recurrent oral ulceration
- Papular pruritic eruption
- Fungal nail infections
- Extensive wart virus infection
- Extensive molluscum contagiosum
- Unexplained persistent parotid enlargement

Clinical Stage III:
- Unexplained moderate malnutrition not adequately responding to standard therapy
- Unexplained persistent diarrhoea (14 days or more)
- Unexplained persistent fever (above 37.5 °C, intermittent or constant, for longer than one month)
- Persistent oral candidiasis (after first 6 weeks of life)
- Oral hairy leukoplakia
- Acute necrotizing ulcerative gingivitis/periodontitis
- Lymph node TB
- Pulmonary TB
- Severe recurrent bacterial pneumonia
- Acute necrotizing ulcerative gingivitis or periodontitis
- Unexplained anaemia (<8.0 g/dl), neutropenia (<0.5 x 10^9/L) or chronic thrombocytopenia (<50 x 10^9/ L)
- Symptomatic lymphoid interstitial pneumonitis
- Chronic HIV-associated lung disease including bronchiectasis

Clinical Stage IV:
- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia (PCP)
- Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration, or visceral at any site)
- Oesophageal candidiasis (or Candida of trachea, bronchi or lungs)
- Extra pulmonary TB
- Kaposi sarcoma
- Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age over 1 month
- Central nervous system toxoplasmosis (after the neonatal period)
- HIV encephalopathy
- Extra pulmonary cryptococcosis (including meningitis)
- Disseminated non-tuberculous mycobacteria infection
- Progressive multifocal leukoencephalopathy
- Chronic cryptosporidiosis (with diarrhoea)
- Chronic isosporiasis
- Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis)
- Cerebral or B cell non-Hodgkin lymphoma
- HIV-associated cardiomyopathy or nephropathy

3.5 STANDARDIZED ANTIRETROVIRAL MEDICINES

The Ministry of Health, Republic of South Sudan has selected standardized antiretroviral drug regimens in line with the 2016 WHO Consolidated Guidelines for the Prevention and Treatment of HIV. The choice of regimens reflects the imperatives of a public health approach to scaling up ART. Further, regimen selection took into consideration efficacy, tolerability and opportunities for second line treatment. Fixed Dose Combinations (FDCs) are the preferred formulations for the initial combination treatment in the standardized regimen, and are recommended where available. The ministry has agreed to maintain the preferred first line ART regimens as in the previous guidelines.

Recommendation:

In adults and adolescents, the preferred 1st line regimen is tenofovir + lamivudine (or emtricitabine) + efavirenz (**TDF + 3TC + EFV** as a once daily Fixed Dose Combination (FDC) and should be prescribed for all population groups including adults, pregnant women, clients co-infected with HIV and TB or HBV

Rationale for preferred first line regimen:

- This regimen is simple, effective, and well tolerated.
- Available as a single, once-daily fixed dose combination (FDC), it is easy to prescribe, enhances treatment adherence, and simplifies drug procurement and supply chain management.
- It is safe to use in women of childbearing age whether pregnant or breast-feeding
- Effective against HBV infection, and can be used with anti-TB drugs
- Use of this regimen as 1st line provides for better regimen sequencing and maintains future treatment options
- In areas with high prevalence of anemia like South Sudan, it provides a safe alternative to AZT.
- The regimen has relatively low monitoring requirements.

3.6 ART REGIMENS FOR ADULTS AND ADOLESCENTS

Table 3.5: ART regimens for adults and adolescents: 1st line

What to start: First Line ART		
Preferred ARV Regimens: All new clients needing treatment, including pregnant women, TB clients , HBV	TDF + 3TC +EFV 600mg FDC preferred	Replace EFV with NVP in clients with significant psychiatric co-morbidity or intolerance to EFV
Alternative ARV Regimens: Contraindications to EFV	TDF + or 3TC + NVP	Use NVP based regimen: In clients with significant psychiatric co morbidity or intolerance to EFV
Contraindication to TDF	AZT+ 3TC +EFV or (NVP)	Renal disease or the use of other nephrotoxic drugs e.g. aminoglycosides
Contraindication to TDF and AZT	ABC + 3TC + EFV (or NVP)	Renal disease and anaemia or the use of other nephrotoxic drugs, aminoglycosides
Currently on d4T-based regimen	TDF + 3TC + EFV FDC preferred	Switch is mandatory if clients experience toxicity and clients who are at high risk of toxicity (high BMI or pregnant). ***Switch to TDF - based regimen even if D4T is well tolerated.***
Adolescents ≤ 35 kg	ABC + 3TC + EFV	ABC maybe used in adolescents (10 to 19 years) ≤35

		kg in special circumstances
NB Efavirenz 400 mg can be used as a substitute for Efavirenz 600 mg. Studies have shown comparable efficacy between standard dose EFV 600mg/day and the reduced dose EFV 400mg/day containing ARV combinations among non-pregnant adults. However, the 400mg EFV formulation has demonstrated fewer CNS-related side effects. It is important to note that 400mg EFV CANNOT be used among pregnant women, lactating women and TB patients as currently there is insufficient evidence in support of its use in these groups. Once the 400mg EFV formulation is available in the country; the Ministry of Health will issue guidance on transitioning patients to the newer low dose formulation.		

Table3.6: ART regimens for adults and adolescents: 2nd line

Second Line ART		
Management of clinical failure	Do CD4 count and viral load	New or recurrent clinical event indicating severe immunodeficiency (WHO stage 4 condition) after 6 months of effective treatment
Management of immunological failure	Confirm with viral load testing	CD4 count falls to the baseline (or below) OR Persistent CD4 levels below 100 cells/ml
Management of virological failure	If confirmed, change to second line ART	If plasma HIV RNA >1000 copies/ml. Check for adherence, compliance, tolerability and drug- drug interaction and assess psychological issues. Provide enhanced adherence counselling. Repeat VL test 3 months later. If plasma VL confirmed >1000 copies/ml, change regimen to second line therapy
Failing on TDF-based 1st line	AZT+3TC+ LPV/r or ATV/r	Clients with anaemia and renal failure switch to ABC
Failing on AZT based 1st line	TDF +3TC (or FTC) + LPV/r or ATV/r	
Management of HIV and TB Coinfection	NRTI backbone as above plus double dose LPV/r (800mg/200mg BD)	For Patients receiving Rifampicin
Management of HIV and HBV coinfection	AZT+TDF+3TC+ATZ/r or LPV/r	

Table3.7: ART regimens for adults and adolescents: Third line

Third Line		
Adolescents >12 years and adults failing any 2nd line regimen	DTG+DRV/r	Dolutergavir 50mg plus Darunavir (600mg)/Ritonavir (100mg) twice daily (for patients that have taken a PI before) Clients failing on second line therapy will be referred to Specialists at tertiary referral centers and the drugs for third line managed centrally
If DTG is not available	Raltegravir 400 mg BD can be used	
NB. DTG cannot be used in adolescents under 12 years of age and among pregnant women as its safety and efficacy data are not yet available. Consult a Paediatrician for 3rd line options for children under 12 years of age.		

Table3.8: ARV Adult dosing guide

Generic Name	Formulations available	Dose	Comment(s)

Lamivudine (3TC)	Tabs 150 mg	1 tab bd or 2 tabs od	
Abacavir (ABC)	Tabs 300 mg	1 tab bd OR 2 tabs od	*ABC maybe used in adolescents (10 to 19 years) ≤35 kg in special circumstances
Zidovudine (AZT)	Tab 300 mg	1 tab bd	Avoid if severe anaemia (Hb<8g/dl)
Tenofovir	Tabs 300 mg	1 tab od	Contra-indicated in renal disease or the use of other nephrotoxic drugs
Efavirenz (EFV)	Tabs 600 mg	1 tab daily	Avoid if active psychiatric disease
Efavirenz	Tabs 400 mg	1 tab od	Avoid if active psychiatric disease
Nevirapine (NVP)	Tabs 200 mg	1 tab od for 14 days, then 1 tab bd	Should be used with caution with TB treatment Avoid NVP if CD4 is >250cells/mm3
Lopinavir/Ritonavir (LPV/r)	Tabs LPV 200 mg/RTV 50 mg	1 tab bd	
Atazanavir/Ritonavir (ATV/r)	Tabs ATV 300 mg + RTV 100 mg	1 tab od	
Darunavir/Ritonavir (DRV/r)	Tabs 800 mg +100mg	1 tab od	Individuals with no previous use of a PI
Darunavir/Ritonavir (DRV/r)	Tabs 600 mg +100mg	1 tab bd	Individuals with previous use of a PI
Dolutegravir (DTG)	Tabs 50 mg	1 tab od	Avoid among pregnant women, HIV/TB coinfected patients and in adolescents under 12 years of age
Raltegravir (RAL)	Tabs 400 mg	1 tab bd	
Fixed Dose Combination ARVs (FDCs)			
TDF/3TC/EFV	Tab: TDF 300mg +3TC 300mg +EFV 600mg	1 tab od	Preferred 1st line regimen for adults and adolescents (including pregnant and lactating women and TB co-infected clients
AZT/3TC/NVP	Tab: AZT 300 mg + 3TC 150 mg + NVP 200 mg	1 tab bd	
ABC/3TC/AZT	Tab: ABC 300 mg + AZT 300 mg + 3TC 150 mg	1 tab bd	
TDF/3TC	AZT 300 mg + 3TC 150 mg	1 tab bd	
ABC/3TC	ABC 600 mg + 3TC 300 mg	1 tab bd	Alternative regimen in TDF and AZT contraindication
AZT/3TC	AZT 300 mg + 3TC 150 mg	1 tab bd	Alternative regimen in TDF toxicity
NB. *Abacavir can be used in special circumstances where patient has renal disease and anaemia or is using other nephrotoxic drugs, aminoglycosides			

3.7 MONITORING HIV DISEASE

Clinical monitoring should be performed routinely for all ART patients at every visit to ascertain WHO clinical stage and exclude opportunistic infections. This should include medical history, physical examination, and laboratory assessment with CD4 monitoring, TB screening, and pregnancy screening. See Table 3.2

History:

- Demographics (age, sex, residential address, etc.)
- History of OIs & other illnesses e.g. TB symptoms, hospitalizations, surgeries, previous ART
- Symptoms of chronic pain

- Assessment of mental disorder (depression), neurological disorder and alcohol and substance use; using mhGAP intervention guide
- Current medications (including anti TB drugs, traditional and herbal therapies etc.)
- Pregnancy risks: contraception choices, current or planned pregnancy
- Sexual risks and disclosure: willingness to practice safer sex, disclosure of HIV sero-status, use of condoms, HIV counseling and testing of sex partners and children.
- Psychosocial: availability of treatment supporters and identification of potential barriers to ART adherence and retention

Physical exam:

- Weight & height in all clients, plus Mid-Upper Arm Circumference (MUAC) in children 6-59 months
- Nutritional status (wasting, oedema, pallor, nail changes)
- Functional capacity
- Examination of vital signs, skin, eyes, oropharynx (presence of thrush), lymph nodes, lungs, heart, abdomen, genital tract (for STIs), extremities, nervous system

CD4 monitoring

- CD4 cell count serves as a marker of the degree of immunosuppression in clients with HIV. It is also a prognostic indicator for clients initiating ART.
- **CD4 monitoring could be reduced or stopped when viral load becomes routinely available. HIV viral load (VL), is a more reliable tool for monitoring adherence to treatment and efficacy of ART than CD4 cell counts**
- CD4 testing is particularly useful in asymptomatic HIV positive clients some of whom may be severely immuno-compromised and require to be prioritized for ART initiation.
- CD4 testing is recommended for patients on ART, and in suspected treatment failure.
- CD4 testing should be carried out:
    - At entry into HIV care, thereafter at 6-monthly
    - At ART initiation as a baseline test
    - At 6-monthly intervals while on ART (where VL is not routinely available)
    - Whenever treatment failure is suspected – see Table3.10
- CD4 testing performed immediately after the HIV diagnosis enhances linkage to HIV care and treatment and should be encouraged where available.

3.8 ART FOLLOW-UP

Clients on ART need to be monitored regularly to assess for response to treatment, to identify adherence problems, assess for development of toxicity to ART, and management of inter-current illness. Monitoring of treatment involves both clinical and laboratory assessment.

Key activities at ART follow-up:

- Adherence assessment and counseling - 3.8.2, 3.2.1

- Provision of CPT - 8.8
- PWP counseling (including FP) - 8.9
- Clinical assessment (for ART response, ART adherence, toxicity, IRIS, OIs) - 3.7 & 3.8.2
- TB screening at every clinical encounter 8.1.2, Table 12.1, 3.8.3
- Lab assessment (for treatment failure, ART toxicity, etc.) - 11.4, 4.5.3
- Substitution of first line ART (if indicated) - 3.8.4

3.8.1 Follow-up schedule for clients on ART

- At the *first scheduled visit (2 weeks* after initiating ART), assess clinical progress; check for drug side effects; assess adherence and counsel as appropriate; check for proper medicine storage; adjust NVP dose as appropriate escalating the NVP dose.

- Week 4 visit: Manage as above, BUT look out for development of Immune Reconstitution Inflammatory syndrome. If stable, subsequent planned clinical visits should be carried out at *monthly* intervals.

- After 6-12 months following initiation of ART, *clinical* appointments may be scheduled at 6-monthly intervals in clients that are clinically stable and adherent to ART.
  - 3-Monthly drug re-fills will be issued by the pharmacist/pharmacy technician or nurse. See Chapter 9.
  - Clients should be able to see a clinician in case of any medical problems at scheduled or unscheduled visits.
  - All clients on ART should receive basic HIV care including CPT and ITNs
  - Treat any inter-current infections. Appearance of infections within the first 6 months of treatment does not necessarily indicate treatment failure as the immune system takes time to recover.
  - However, in clients who have been on treatment for > 6 months or who have adherence problems, new clinical conditions should trigger an assessment for possible treatment failure.

3.8.2 Monitoring Adherence to ART

Adherence to ART is a major determinant of treatment success. The optimal level of adherence for durable virologic and clinical success is over 95%. Adherence may be measured by:

- *Pill counts* conducted in clinic or at unannounced home visits.
- *Self-report:* of pill-taking behaviour by the client
- *Pharmacy re-fills records.* This provides information on when clients picked their ARV medications
- *Viral load monitoring:* this is however not readily available in real time

3.8.3 Tests for Monitoring Disease Progression and Treatment Safety

This is important for assessment of (a) ART response, (b) diagnosis of treatment failure, and (c) detection of ARV drug toxicity. See Table 4.6 for lab testing during ART follow-up.

- For assessment of treatment response, CD4 cell count should be performed 6-monthly.
- When compared to CD4 monitoring, viral load monitoring provides an early and more accurate indication of treatment failure and the need to switch to second line treatment. However, due to the limited availability of viral load testing in South Sudan, CD4 count (every 6 months) and clinical monitoring should be utilized to diagnose treatment failure, with targeted viral load testing to confirm treatment failure. See Figure 4-1
- For toxicity see 4.5.4 and Table 12-3
- Successful ART results in decrease in viral load, immune recovery and a rise in CD4 cell count.
- An increase of 100-150 CD4 cells/mm^3 in the first 6-12 months is typically seen in an ARV drug-naïve, adherent client.
- In suspected treatment failure, CD4 should be performed following the clinical assessment to confirm immunological failure. See Table 4.8

Recommendation:
- Viral load monitoring is recommended as the preferred monitoring approach to diagnose and confirm ART treatment failure.
- If viral load testing is not routinely available, CD4 count and clinical monitoring should be used to diagnose treatment failure.

Viral Load (Virological) assessment

- HIV viral load (VL), is a more reliable tool for monitoring adherence to treatment and efficacy of ART than CD4 cell counts: *where available, viral load should be performed routinely after 6 months on ART, 12 months after starting ART and then every 12 months (24, 36 months etc.)(See Fig 3-1 Algorithm for Routine viral load testing)*. Where viral load is routinely available, CD4 monitoring could be reduced or stopped altogether.
- For viral load to be scaled up in South Sudan, it is important for the following to be considered:
  - Client education to raise awareness, create demand for testing and ensure understanding of results (clients should know when their viral load should be taken, why it is being taken, and how to interpret the result)
  - Health care worker education on how to prepare the DBS sample, complete the VL request form and complete the actions in the viral load algorithm
  - Counsellor or nurse education on the delivery of enhanced adherence counselling
  - Programmatic clinic systems to ensure uptake of viral load and action on results
- Viral load should be undetectable (full virological suppression) after 6 months of initiating effective ART, although clients starting treatment with very high viral loads may take longer than this to achieve full suppression
- Virologic failure is defined as having plasma viral load above 1,000 copies/ml based on two consecutive viral load measurements at least 3 months apart, with adherence support.
- Capacity for viral load measurements is currently limited in South Sudan, and viral load estimations can only be performed in a few specialized regional centres. For this reason, VL testing in South

Sudan is recommended when confirming treatment failure in all clients on ART i.e. 'targeted viral load testing' (See Fig. 3-2 Algorithm for Targeted Viral Load testing).

- If HIV RNA is below 1,000 copies/ml, maintain client on first line therapy and schedule next VL test at 12 months after ART initiation then yearly thereafter.
-

- If HIV RNA is over 1000 copies/ml , **provide enhanced adherence counselling sessions** and address adherence concerns, repeat viral load testing after 3 months. See Figure 12.1 for Enhanced Adherence Counselling guide. If still over 1000 copies/ml, then switch to second line and repeat viral load test 6 months after initiating patient on 2nd line ART.

  - Clinical failure is suspected when an adult or adolescent develops a WHO stage 4 condition after 6 months of effective ART.
  - Immunological failure in adults is defined as a fall in CD4 cell count to baseline (or below) or persistent low CD4 below 100 cells/mm^3

Figure 3.1: Algorithm for Routine Viral Load Testing

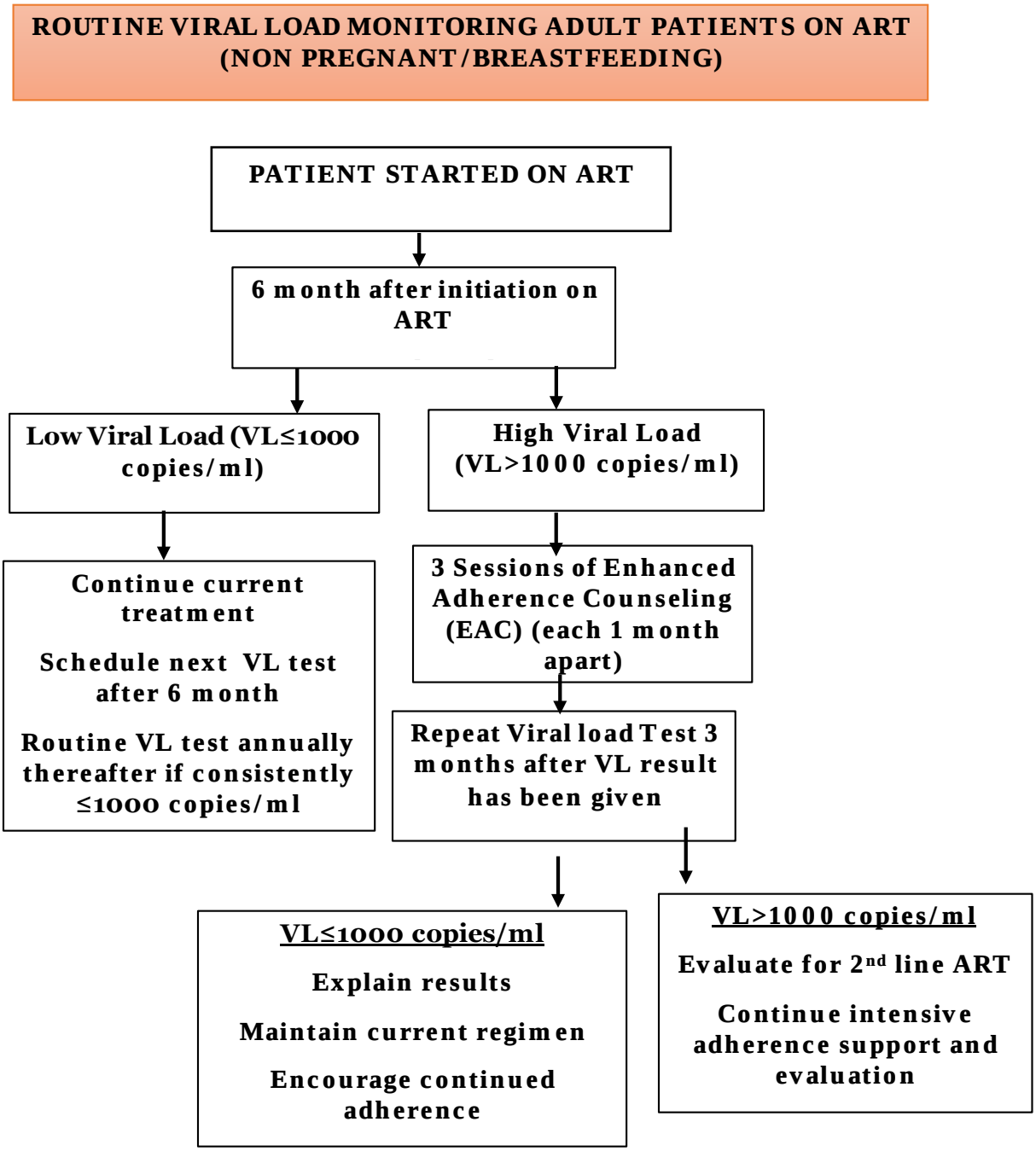


Figure 3.2: Algorithm for Targeted Viral Load Testing

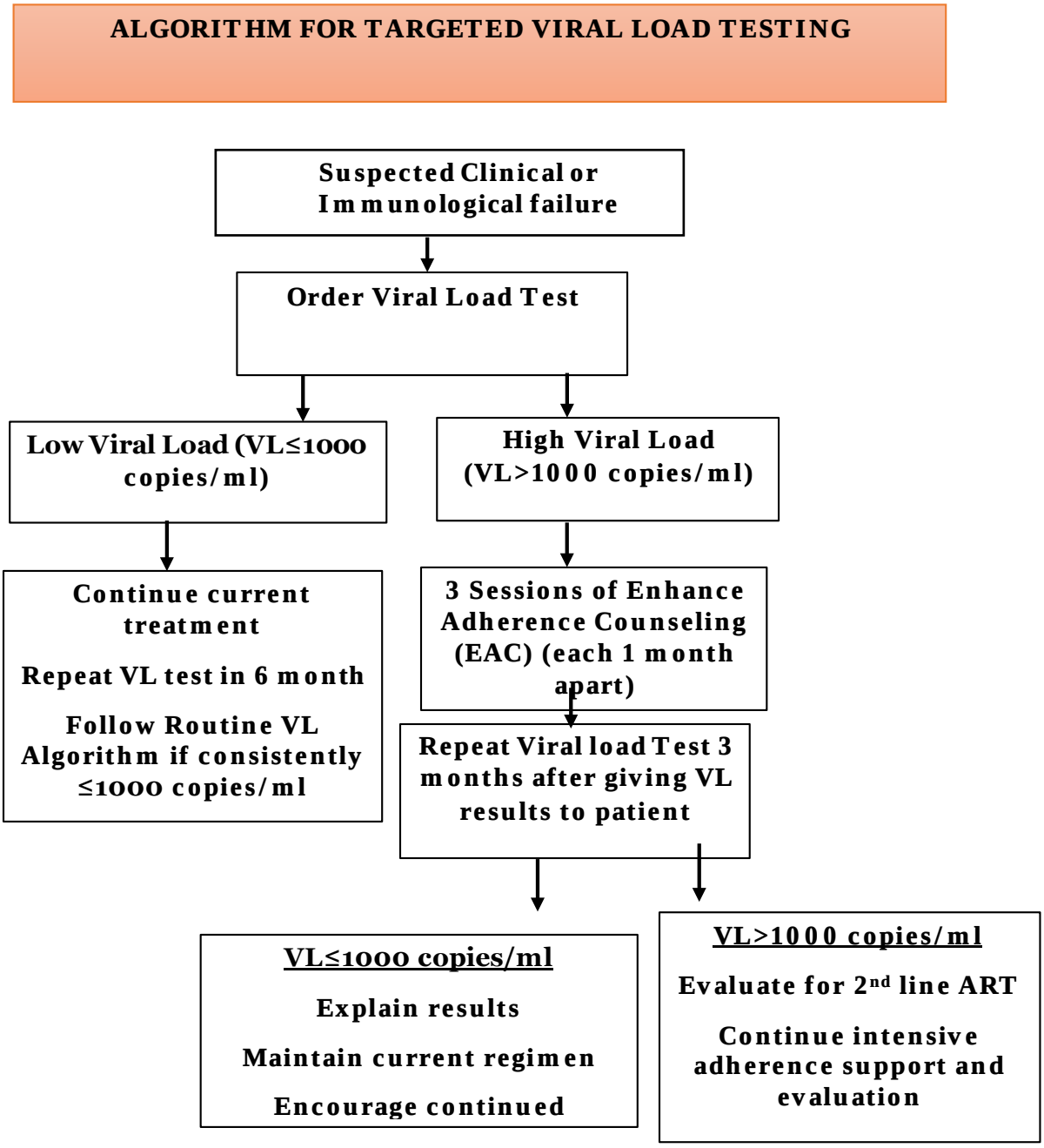


Table3.9: Laboratory Testing During ART follow-up

Test	Purpose	Comment
Recommended tests		
CD4 every 6 months	To monitor immune response to ART	An increase of 100-150 CD4 cells/mm3 in the first 6-12 months is typically seen in an ARV drug-naïve, adherent client
VL at 6 months from initiation of ART, at 12 months and every 12 months Figure 4-1	To confirm treatment failure	Initiate 2nd line if treatment failure is confirmed Table 4-4 and Table 12-1
*TB Screening at every visit		*This is a clinical symptom screening, but lab evaluation (GeneXpert) is recommended if symptomatic
Desirable tests – only performed where available		
ALT only if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity	See table below on what to substitute in case of toxicity Table 4-8 & Table 12-3
FBC at month 1, 3 and 6 if on AZT	To identify AZT toxicity	
Creatinine - if client had signs or symptoms of renal failure	To identify TDF toxicity	if client had signs or symptoms of renal failure
LPV/r , if available	To identify LPV/r toxicity	

3.8.4 Monitoring and substitutions for ARV drug toxicities

Toxicity to ARVs can be monitored clinically based on the client's report and physical examination. It can also be assessed by a limited number of laboratory tests. There are 3 categories of drug toxicities:

- Mild toxicities do not require ART discontinuation or drug substitution; give symptomatic treatment
- Moderate or severe toxicities may require drug substitution, but do not require discontinuation of all ART. See Table 4-7 below.
- Severe life-threatening toxicities require discontinuation of all ARVs and initiation of supportive therapy until the client is stabilized and the toxicity is resolved

For additional information on toxicities, refer to Table 12-3. Regardless of severity, adverse reactions may affect adherence. Before initiating ART, it is important to discuss potential side effects. During the early stages of treatment, offer support during minor and moderate adverse reactions.

Table3.10: Major toxicity substitutions for 1st and 2nd line regimens

ARV	ABC	TDF	AZT	NVP	EFV	LPV/r
Toxicity	Hypersensitivity reaction	Renal dysfunction	Anemia, Mitochondrial toxicity	Hepatotoxicity, skin rash, and hypersensitivity reactions	Persistent CNS toxicity	Severe diarroea or Metabolic syndrome
Suggested substitution	1st line: TDF or AZT 2nd line: TDF	1st line: AZT or ABC 2nd line: ABC	TDF or ABC	EFV	NVP	Refer

TDF toxicity

- TDF use may be associated with increased risk of renal dysfunction.
- However, lab monitoring is not mandatory to initiate TDF treatment. Testing renal function at baseline is desirable for clients who are at increased risk of TDF toxicity to detect and limit renal impairment (older people, low BMI<18.5, body weight<50kg, untreated Diabetes mellitus, untreated hypertension, clients with underlying renal disease, concomitant use of boosted PIs and nephrotoxic drugs).
- Routine blood pressure monitoring may be used to detect hypertension. *Where available*, serum creatinine may be performed for high risk clients (older, underlying renal disease, long term diabetes mellitus, long standing hypertension, concomitant nephrotoxic drugs or PIs).
- Do not initiate TDF in clients with long-term diabetes, uncontrolled hypertension, and renal failure, or when the estimated GFR rate is <50 ml/min.
- Children on TDF should have regular growth monitoring

Efavirenz (EFV)

- The CNS side effects associated with use of EFV typically resolve within weeks. If persistent, then NVP could be substituted. Of note, there is no increase in incidence of birth defects for 1st trimester EFV exposure.

Zidovudine (AZT)

- Associated with increased risk of hematological toxicity. It is desirable to perform Hb estimation before initiating ART especially among adults and children with low body weight, low CD4 counts, and advanced HIV disease. In individuals with severe anemia <7 g/dl, AZT should be avoided as first line therapy.

Nevirapine (NVP)

- It is desirable to monitor liver enzymes in women with HIV who have CD4 ≥ 250 cells/mm^3, and individuals co-infected with HBV or HCV.

3.8.5 Tests for Monitoring Antiretroviral Treatment Safety (Toxicity)

Antiretroviral drugs are known to produce side effects in some clients Clinical follow-up, supported by laboratory investigations, is crucial. The frequency of monitoring depends on the ART regimen used. See Table 11.1 and Table 12-3

Haemoglobin (Hb):

- This is a desirable test to perform in clients on AZT-containing ART regimens. Most AZT-related anemia occurs within the first 3/12 of treatment, is more common in women, those with pre-existing anemia, low body weight, and low CD4 counts/advanced HIV disease.
- In these clients, a full blood count (FBC) or Hb estimation should be performed at baseline, after 3 months and 6-monthly thereafter.
- Hb test is recommended for pregnant and breast feeding women as part of the MCH care package. Hb may also be performed when clinically indicated in clients with anemia, renal impairment etc.

Alanine amino transferase (AL T):

- It is desirable to perform ALT test at enrolment on ART as a baseline test in anticipation of hepatotoxicity may be caused by some drugs especially NVP.
- If ALT is high, do not give NVP but use EFV, and test for Hepatitis B and C if available.
- NVP- related hepatotoxicity is more likely to occur in women if CD4 count at treatment initiation with NVP is >250 cells/mm^3; close monitoring is therefore essential.
- ALT is a recommended test after 1-2 months of treatment when NNRTIs especially NVP are used. If normal, repeat the test at 3 months, 6 months and thereafter at 6-monthly intervals or earlier if clinically indicated.

Serum creatinine:

- A desirable test in monitoring renal function in clients at high risk of TDF toxicity. Advisable to carry out at baseline as well as regular follow up renal function tests for high risk groups (older people, those with underlying renal disease, long term diabetes, and clients with long standing hypertension, concomitant use of PIs or nephrotoxic drugs). For these categories, perform serum creatinine at baseline, month 3 and 6, 1 year then every 12 months if on TDF.
- Routine blood pressure monitoring maybe used to assess hypertension
- Do not give TDF if estimated GFR is less than 50ml/minute or in long term diabetes, uncontrolled hypertension and renal failure. Can substitute with AZT.
- For clients with renal disease, more frequent monitoring may be indicated e.g. clients with proteinuria, decreased glomerular dysfunction) or clients with diabetes, hypertension who are increased risk of renal insufficiency

3.9 WHAT TO EXPECT IN THE FIRST SIX MONTHS ON ART

The first six months on ART are critical. A majority of ART recipients respond well with increases in CD4 cell count; however, some fail to respond as expected. Possible events during this period include;

3.9.1 CD4 Recovery

- In the majority of clients initiated on ART, the CD4 count rises as the immune system recovers. Rises of over 100-150 CD4 cells/ mm^3 are expected in the first 6-12 months in the ARV naïve, adherent client with drug susceptible virus. The response often continues in the subsequent years.
- However severe immunosuppression may persist in a small number of clients and low CD4 cell counts persist. This is more common in clients that initiate ART at very low CD4 cell count.
- Failure to achieve some CD4 recovery should alert the providers to potential adherence problems or primary non-response to ART.

3.9.2 Immune Reconstitution Inflammatory Syndrome (IRIS)

IRIS is an over-aggressive response of the body's defense system caused by a sudden recovery on ART. IRIS occurs in about 10-30% of people initiating ART and usually within the first 4-8 weeks. IRIS is more common among clients with low CD4 counts at ART initiation, disseminated OIs or tumors at initiation, and shorter duration of therapy for the OIs prior to ART.

- May present as *paradoxical IRIS* whereby there is worsening of an opportunistic infection or tumour that was initially responding. Unmasking IRIS, occur when ART initiation triggers disease that was not initially apparent before ART. BCG associated IRIS (localized or systemic) may occur in HIV infected infants following immunization. The most serious and life threatening forms of paradoxical IRIS are for TB, cryptococcal meningitis, Kaposi's sarcoma, hepatitis, and herpes zoster.

- IRIS should only be considered if the more common causes for worsening have been ruled out

- Management of IRIS:
  - Confirm that ART is actually taken as prescribed – check adherence
  - Continue ART if ARV drug toxicity has been ruled out as the underlying cause, and support adherence
  - Treat the Opportunistic Infection (OI)
  - Consider TB treatment failure if worsening occurs after more than one month on TB treatment
  - Admit severe cases to hospital
  - Seek specialist advice on whether non-steroidal anti-inflammatory drugs and/or prednisolone should be given

- To reduce the risk of developing IRIS, ensure earlier diagnosis and initiation of ART before CD4 falls below 200 cells/ mm^3, improve screening for OIs before ART especially TB and cryptococcus, and properly manage OIs before ART initiation. Specific advice on concomitant TB and HIV treatment is given in chapter 8. For Cryptococcus infection, see recommendation on screening and presumptive therapy. See 3.5.4 and Table 3-5.

3.9.3 Toxicity

- **See section 4.5.4**

3.10 TREATMENT FAILURE

- Treatment failure is when ART stops controlling an individual's virus and he/she starts getting sicker. Poor adherence to ART is the commonest cause of treatment failure.
- Whenever treatment failure is suspected, verify if client has been on ART for at least 6 months, has been adherent to the regimen, intercurrent illness has been treated, IRIS has been excluded, and in children, inadequate nutrition is excluded (if considering changing treatment because of growth failure).
- There are 3 criteria for treatment failure; clinical, immunologic, and virological. Virological failure is the most accurate method and is defined as a persistently detectable viral load exceeding 1,000 copies /ml (i.e. Two (2) consecutive viral load measurements within a three-month interval, with adherence support between measurements) after at least 6 months of using ARV drugs.
- Once treatment failure has been detected, select and switch the client to a new regimen as per Table 4-4 for adults and adolescents or Table 12-1.
- Counsel client on the new ART regimen- highlighting reasons for change in regimen, differences in drug type, dosing of ARVs, timing of administration, possible side effects, importance of adherence, and on-going support.

Table 3.11: Clinical, Immunological and Virological Failure in adults

Failure	Definition	Comments
Clinical failure	**Adults and adolescents** • New or recurrent clinical event indicating severe immunodeficiency (WHO stage 4 condition) after 6 months of effective treatment. Must exclude immune reconstitution syndromes.	Must be differentiated from IRIS occurring after ART initiation.
Immunological failure	**Adults and adolescents** • CD4 count falls to the baseline (or below) or • Persistent CD4 levels below 100 cells/ml	Without concomitant or recent infection, to cause a transient decline in CD4 cell count.
Virological failure	Plasma viral load above 1000 copies / ml based on two consecutive viral load measurements after 3 months, with adherence support . Rifer to Figure 4-1	An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed.

3.11 SECOND LINE ART FOR ADULTS AND ADOLESCENTS

- Second-line ART for adults and adolescents should consist of two NRTIs and a ritonavir-boosted PI. The preferred boosted PIs for second line therapy is LPV/r.
- After failure of a TDF based first-line regimen, use AZT+3TC (or FTC) as the NRTI backbone in second line regimens. After failure of an AZT-based, use TDF as the backbone in the second line regimen. See Table 4-4 and Table 12-1 on ART regimens.

3.12 THIRD LINE ART: SALVAGE THERAPY

- ART switch from second to third line should be guided by results of HIV drug resistance testing. The available 3rd line options consist of DTG+DRV/r for adults and adolescents above 12 years of age. Raltegravir may be used as a substitute for DTG if the latter is not available.

3.13 NUTRITION ASSESSMENT, COUNSELING, AND SUPPORT (NACS)

Malnutrition refers to both under nutrition and over nutrition. Under nutrition occurs when the diet does not provide adequate calories and protein for growth and maintenance or they are unable to fully utilize the food they eat due to illness. Under-nutrition can be identified using anthropometric measurements, clinical signs and biochemical tests. The nutrition indicators used to define acute malnutrition include: MUAC, weight for height, and BMI.

Low food intake combined with increased energy demand because of HIV infection and related infections may lead to HIV-related weight loss and wasting. Nutritional assessment, counseling and support (NACS) is a key intervention and should be an integral component of HIV care. This should be part of interventions available to all PLHIV, both adults and children and at the health facility and in the community.

3.13.1 Nutritional Assessment

Nutrition assessment involves collecting information about a client's medical history, dietary patterns, anthropometric measurements, clinical and biochemical characteristics, and social and economic status. Nutrition assessment requires training and should be done by clinicians, dieticians, and nutritionists. For PLHIV, assessment should be performed at enrolment into care and monitored at every clinical visit.

- Nutritional assessment should be conducted to identify;
    - PLHIV at risk of malnutrition for early intervention including referral
    - malnourished clients for treatment and/or referral;
    - behaviors that can increase the risk of malnutrition and food insecurity
    - PLHIV and households that require nutrition education and counseling
- Nutritional assessment should involve; measuring and recording height and weight for adults, and for children, plotting the measurements on a standard growth curve. The mid-upper arm circumference can additionally be used; evaluation of clinical and dietary factors for the individual/household and referral to relevant services. See Figure 3-1
- Weigh and record the weight in kg to the nearest 100gm at every visit (children and adults)
- Measure and Record the length / height (using a head board) to the nearest cm at every visit for children, and once at enrolment for adults
- Use the above measurements to determine weight-for-height z-score (WHZ) for children and BMI for adults.

- To classify nutritional status among non-pregnant adults 15 years and above, use BMI.
- Use MUAC to classify nutritional status in the following groups:
  - Children 0-14 years;
  - Adolescents as an alternative to BMI-for-age
  - Pregnant women and women up to 6 months postpartum;
  - Non-pregnant/postpartum adults whose weight and height cannot be measured (e.g., if they cannot stand or no equipment is available).

Table 3.12: Anthropometric measurements

Anthropometric measurements indude weight, height, and mid-upper arm circumference (MUAC). Body mass index (BMI) and weight-for-height are anthropometric measurements presented as indexes. Each of these indexes is recorded as a z-score. Z-scores are measured in standard deviations (SD), which describe how far and in what direction an individual's anthropometric measurement deviates from the mean (for a healthy person of the same age and sex).	
Weight:	Essential to help determine weight-for-height z-score (WHZ) for children and BMI for adults. Record weight in kg to the nearest 100gm at every visit (children and adults).
Length and height:	Record length / height to the nearest cm at every visit for children, and once at enrolment for adults.
Weight-for-height:	WHZ is an index to assess the nutritional status of children from birth to 59 months of age. WHZ compares a child's weight to the weight of a child of the same length/height and sex in the WHO Child Growth Standards to classify the child's nutritional status. There are separate standards for boys and girls.
Mid-upper arm circumference (MUAC):	The circumference of the left upper arm measured at the mid-point between the tip of the shoulder and the tip of the elbow, using a measuring tape. MUAC is a proxy measure of nutrient reserves in muscle and fat that are unaffected by pregnancy and independent of height. MUAC is quicker and simpler than WHZ to assess nutritional status in children less than 5 years.
Body mass index (BMI):	BMI is an anthropometric indicator based on weight-to-height ratio. It is the preferred indicator of body thinness to classify malnutrition in adults and adolescents 15 years and older who are not pregnant or postpartum. Calculate BMI by dividing a person's weight in kg by the square of the person's height in meters (m).

In addition to anthropometric assessment, general assessment of PLHIV should involve the following;
- Checking for physical signs of nutritional deficiencies such as bilateral pitting edema, wasting, pallor, hair changes.
- Assessing for signs and symptoms of other infections that can increase nutrient needs (e.g., fever) and nutrient loss (e.g., diarrhea and vomiting), conditions that impair ingestion of food (oral candidiasis) and managing appropriately
- Medication history to know if there are dietary restrictions based on ART regimen.
- Dietary assessment to obtain information on dietary quantity and quality, changes in appetite, food allergies and intolerance, and reasons for inadequate food intake during or after illness.
- Food Security Assessment: PLHIV households and communities should be assessed for food security which involves; food availability (having sufficient quantities of food available consistently to all people in a household), food access (adequate resources to obtain a sufficient quantity and quality of food), and food utilization/consumption.
- Biochemical assessment which involves checking levels of nutrients in a person's blood, urine, or stools.

3.13.2 **Nutrition counselling and support:**

Based on each individual's assessment (using BMI in adults and MUAC in children below 14 years of age), specific nutritional support should be provided – education, counselling, therapeutic feeding (TF), supplemental feeding (SF), or other.

Counselling: Nutrition counseling utilizes information from nutrition assessment (above) to enable the PLHIV and affected household members to work with health staff to prioritize actions based on the nutritional assessment to improve nutritional status. Counseling can allow the identification of challenges and discussion of possible locally available solutions to problems. Nutrition counseling can be provided by nurses, nutritionists, or designated counselors. If facility-based health care providers have limited time or training in counseling, task shifting should be considered to train mid-level health workers or community health workers to provide nutrition counseling.

- At the clinic level clients should be provided with group education on key nutrition topics
- At the community level clients and their household members can receive this information through support groups facilitated by community health care workers/expert clients or HCWs

Support: Nutritional support should be provided based on information from the assessment and existing facility and community resources. Nutrition support can include specialized food products to treat malnutrition, micronutrient supplements to prevent or treat micronutrient deficiencies, point-of-use water purification products, and referral to economic strengthening and livelihood support.

- For adult PLHIV, watch out for any weight loss over time. Review documented previous weight whenever available as reported weight loss can be unreliable. Investigate any weight loss for TB. Refer to Annex XX (Algorithm for Classification of Malnutrition in Children 6 months-14 years).
- For children, Plot the weight on a child health card Watch out for flattening of the growth curve (weight for age). Categorize Severe Malnutrition and manage child according to Annex YY Algorithm for Classification of Malnutrition in Adults. Refer to National Nutrition Guidelines for South Sudan for further guidance on the management of malnutrition among PLHIV.

Food and/or micronutrient supplementation should be provided where necessary and where available. Adults PLHIV should be advised to consume diversified diets from locally available foods. PLHIV (and their families) who are food insecure should be referred to existing 'Food Security and Sustainable Livelihood' programs that will help them achieve household food-security and benefit from livelihood assessment and support.

4 ADOLESCENT HIV CARE AND SUPPORT

4.1 ADOLESCENT CLASSIFICATIONS

Adolescents Living with HIV (ALHIV) are in the age category 10-19 years. There are 2 groups of ALHIV: a) adolescents who acquired HIV perinatally, and b) adolescents who acquired HIV during childhood or adolescence. Adolescents may be further classified as younger adolescents (10-14years) and older adolescents (15-19 years). Adolescents are often underserved with poor access to and uptake of HIV testing and counselling and linkage to prevention and care services. Adolescents need special attention because of the unique health, psychological, and social needs. See some of the major challenges in Table 4.1-1 below.

Table 5.1-1: Challenges of Adolescents Living with HIV (ALHIV)

Common challenges faced by all ALHIV	***Challenges of adolescents with perinatally acquired HIV***	***Challenges of adolescents who acquired HIV during childhood or adolescence (through sexual intercourse, sexual abuse, blood transfusion etc)***
• Poor retention in care /high loss to follow-up • Poor adherence to ART • Difficulties in adopting Positive living and positive prevention behaviours • Stigma and discrimination • Finding a partner/ and starting a family	• Disclosure of HIV status to the child • Mother's acceptance of her HIV status • Long term ART use • Potential medical fatigue • For the family: Demands of caring for a child/adolescent with chronic HIV infection • Complexity of living in a home affected by HIV, particularly if caregivers are unwell, unemployed or have died	• Acceptance of HIV status • Disclosure to family, partners, and peers • If raped or abused, dealing with emotional and physical repercussions of that experience

The package of adolescent HIV care and treatment services includes:

- HIV clinical care (HTS, ART, Chrionic care, TB care, PMTCT) 5.21
- Counseling and psychosocial support (including disclosure) 5.2 and 5.3
- Sexual and reproductive health services 5.4
- Family planning and PMTCT services for ALHIV 5.5
- Retention, adherence and disclosure support 5.6
- Youth-friendly services 5.7
- Support for the transition to adult care 5.8
- Community linkages including peer-based activities

4.2 CLINICAL CARE FOR ADOLESCENTS LIVING WITH HIV (ALHIV):

Clinical care (HTS, ART, TB) for ALHIV is generally similar to that of adults. Of note;

- HTS (including disclosure): adolescents should be counseled about the potential benefits and risk of disclosure of their HIV status. They should be empowered and supported to determine if, when and how to disclose. All adolescents should be disclosed to their HIV status and the HIV status of their parents/guardians. Also see 2.3.3

- ART services: Normally, adolescent ART regimen is similar to the regimen for adults (Refer to the adult ART Regimen in this guideline). It is essential to also note that some adolescents living with HIV may be stunted or underweight and hence medicine dosage may require adjustments accordingly. The treatment recommendation for adolescents with weight ≥35kg is the same as that for adults while for adolescents weighing <35kg it is the same as that for children 3-9 years. In order to support retention in care and adherence to ART, health care workers must be trained to understand the adolescent population and to encourage them to utilise the HIV services.

4.3 COUNSELING AND PSYCHOSOCIAL SUPPORT NEEDS OF ADOLESCENTS:

Adolescents have unique psychosocial needs different from those of children and adults. ALHIV may require extra support in several areas including:

- Understanding and coming to terms with their HIV status and that of family members
- Grieving the illness and loss of family members with added responsibilities
- Coping with cycles of wellness and ill health
- Long term adherence to treatment
- Sexual and reproductive health
- Anxiety over physical appearance and body image
- Developing self-esteem, confidence, and sense of belonging
- Dealing with stigma, discrimination and social isolation
- Accessing education, training, and work opportunities
- Managing mental health issues

4.4 DISCLOSURE AND ALHIV:

- Disclosure is an ongoing process of:
  - Telling a child / young adolescent that he or she has HIV,
  - Helping him / her understand what it means,
  - Helping him/her disclose his or her HIV status to others
- Disclosure can help young clients access HIV services. It can also improve adherence, reduce stigma and discrimination, and reduce HIV transmission by helping people protect themselves and their partners.

- Health workers should assess clients and caregivers readiness, work with the caregiver to develop and follow a disclosure plan, prepare the client for different stages in the disclosure process, and support the client and caregiver throughout the process.

4.5 SEXUAL AND REPRODUCTIVE HEALTH SERVICES FOR ADOLESCENTS:

Adolescents in HIV and ART care should be provided with age and developmentally appropriate sexual and reproductive health services.

- Support ALHIV to practice safer sex to protect themselves and their partners from HIV, other STIs and unwanted pregnancy. For sexually active adolescents dual protection with a condom should also be discussed and safe sex with consistent condom use encouraged. Because ARVs reduce the amount of virus in body fluids, safe sex includes maintaining excellent adherence to ART in order to reduce the risk of HIV transmission.
- Sexually active adolescents should be screened for STI symptoms, and managed in accordance with national STI guidelines.

4.6 FAMILY PLANNING AND PMTCT SERVICES FOR ALHIV:

Adolescent pregnancy is associated with many health risks (pregnancy complications), and psychosocial risks (stigma, changes in education, career, or marriage aspirations).

- Health workers should discuss with adolescents the advantages of delayed sexual debut, the right to delay marriage and to decline sex when approached by a man or woman in an inappropriate manner
- Health care workers should counsel ALHIV on the safest times to have children in the future; they should wait until they are adults (due to the risks of adolescent pregnancy), get pregnant when healthy, when CD4 cell count is high (>500), and when adherent to ART.
- ALHIV have high family planning discontinuation rates and are less tolerant of contraceptive side effects. Counsel all clients on correct condom use, whether condoms are their primary contraceptive choice or whether they will be used for dual protection.
- Provide counseling on PMTCT and refer all pregnant ALHIV to ANC for PMTCT services.

4.7 SUPPORTING RETENTION & ADHERENCE TO CARE & TREATMENT FOR ALHIV

- Ensure services are 'youth friendly' –See 5.7
- Provide counseling and education including adherence preparation support to all ALHIV and their caregivers
- Ensure linkages to peer support groups
- Use appointment systems (appointment logbooks) and send sms reminders where possible
- Ensure tracking system is in place including following up clients who miss clinic appointments - by phone, sms or home visits using treatment or adherence support groups
- Use Fixed Dose Combination ARV regimens

4.8 MENTAL HEALTH SERVICES

Adolescents living with HIV deal with challenges such as loss of loved ones, stigma and isolation, gender-based violence and the responsibility of taking care of oneself in the presence of a chronic illness. Adolescents who suffer from depression are more likely to be non-adherent to their medication. To facilitate adherence and retention to care, it is essential to screen for and treat mental health problems. Some of the potential symptoms of an adolescent experiencing depression include the following symptoms: social withdrawal, loss of appetite or increased appetite, difficulty sleeping or too much sleep and poor personal hygiene. Health workers should be trained to screen and manage adolescents for mental health problems.

4.9 YOUTH FRIENDLY SERVICES

Barriers to services' uptake by youth include cost, disapproval by providers and the community, logistical constraints (including inconvenient hours or lack of transportation), fears about violations of confidentiality, uncertainty, embarrassment, or lack of awareness. Stigma keeps many young people living with HIV from receiving the treatment they need. Youth-friendly services (see characteristics below) aim to overcome these barriers to accessibility and use.

Table 4.1: Youth Friendly Services

<table>
<tr>
<td rowspan="3">Programmatic Characteristics

• Package of essential services available
• Sufficient supply of commodities and drugs
• Range of contraceptives offered
• Referrals available
• Affordable fees / free services
• Waiting time not excessive
• Youth are involved in program design
• Both boys and girls are welcomed and served
• Unmarried clients are welcomed and served
• Educational material is available on-site
• Services are well promoted in areas where youth gather
• Linkages are made with schools, youth clubs, and other youth-friendly institutions</td>
<td>Health Facility Characteristics
• Convenient service hours
• Separate space and/or hours for youth
• Convenient location
• Adequate space
• Privacy ensured
• Comfortable setting</td>
</tr>
<tr>
<td>Service Provider Characteristics
• Competent staff / trained in adolescent issues
• Respect for youth
• Privacy and confidentiality are ensured
• Adequate time is given for client-provider interaction
• Peer counselors are available</td>
</tr>
<tr>
<td>Youth Perceptions of the Program
• Privacy is maintained at the facility
• Confidentiality is honored
• Youth including boys and girls below 15 years are welcome regardless of marital status
• Service providers are attentive to youth needs</td>
</tr>
</table>

4.10 SUPPORTING THE TRANSITION TO ADULT CARE

All ALHIV attending pediatric clinics should be prepared to transition to the adult HIV clinic. The goal of transition is to ensure provision of uninterrupted, coordinated, and developmentally and age-appropriate services.

Healthcare workers should support ALHIV become more independent in managing their care. In addition, providers should also support caregivers to understand their changing role. To help ALHIV prepare for transition, ensure the client understands the illness and its treatment, promote linkage to adolescent peer and other support groups at the adult clinic. Service providers should encourage mature adolescents (in consultation with caregivers) to attend clinic visits alone where appropriate. As a last step to transitioning to adult care, adolescents should be familiarized with the adult care setting and procedures.

5 PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT) OF HIV AND IMPROVING MATERNAL, NEWBORN AND CHILD HEALTH (MNCH)

Globally, 90% of children get HIV from mothers during pregnancy, childbirth and breastfeeding. Without intervention, the overall MTCT transmission rates range from 15-35%. The goal of eMTCT is to eliminate New HIV Infections Among Children and Keeping their Mothers Alive by 2025. Services to prevent mother to child transmission may should be provided before pregnancy, during pregnancy (in ANC), during labour, or and during the breastfeeding period. The Ministry of Health (RSS) has adopted the WHO PMTCT Option B+ strategy in 2015 which is currently being rolled out. The guidelines for the implementation of PMTCT Option B+ have been finalized in 2016 and this chapter seeks to harmonize the ARV-related PMTCT recommendations with those in the National PMTCT guidelines.

This chapter outlines the PMTCT services for the mother while interventions for the infant are detailed in Chapter 6 and 7.

5.1 THE PMTCT PRONGS

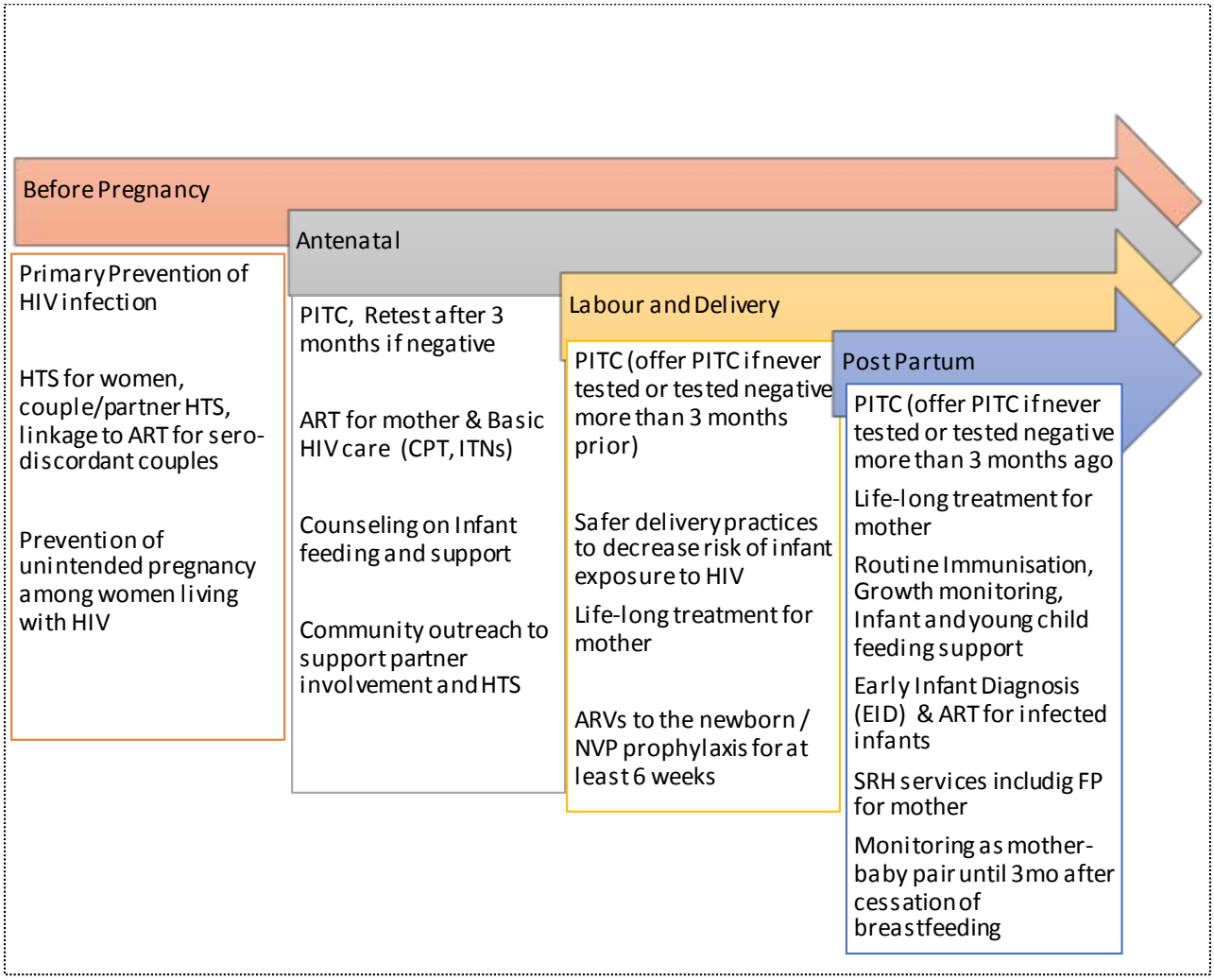
Prevention or elimination of mother-to-child transmission of HIV (PMTCT) comprises of a package of interventions summarized as 4 prongs, which must be implemented simultaneously. See Table 5-1 below:

Table 5.1: The PMTCT Prongs

Element	Target group	Additional information
Prong 1: Primary prevention of HIV infection	Women and men who are sexually active including adolescents	This element aims to prevent men and women from contracting HIV. Interventions include: o Health information and education o HIV testing and counselling - regular retesting for those with exposure o Couple counselling, partner testing, and linkage to care & treatment for the HIV-infected o Safer sex practices, including dual protection (with condom use) o Delay of onset of sexual activity o Behavioural change communications to avoid high risk behaviour o VMMC for eligible men o STI treatment o Safe blood transfusion
Prong 2: Prevention of unintended pregnancies among women living with HIV	Women living with HIV	o FP counselling & services to ensure women can make informed decision about their RH o HTS in RH/FP services and linking those found to be HIV-positive into care and treatment o Safer sex practices, including dual protection (condom promotion)
Prong 3: Prevention of HIV transmission from women living with HIV to their infants	Pregnant women living with HIV	This element focuses on: o Quality antenatal, delivery, and postpartum care o Access to HTS during ANC, labour and delivery, and postpartum period. o ART for all pregnant and breast-feeding women living with HIV o Provision of ARV prophylaxis for HIV-exposed infants for at least 6/52 o Safer delivery practices to decrease risk of infant exposure to HIV o Infant feeding information, counselling and support o Community outreach and efforts to support partner involvement & HTS
Prong 4: Provision of treatment, care and	Women living with	This element addresses the treatment, care and support needs of HIV-infected women, their children and families.

support to women infected with HIV, their children, and their families	HIV and their families	**Package of services for mothers includes:** o ART o Adherence counselling o VL monitoring (if available) o Co-trimoxazole prophylaxis o TB screening and treatment o Continued infant feeding counselling and support o Nutritional counselling & support o SRH services including FP o Psychosocial support o PHDP o Linkage with community support systems for PLHIV including OVC services	**Package of services for HIV-exposed children:** o ARV prophylaxis for at least 6 weeks (NVP) o High-risk infants to be given dual ARV (AZT and NVP) prophylaxis for 12 weeks o Routine immunization & growth monitoring o Co-trimoxazole prophylaxis from 6 weeks of age o Infant HIV testing: EID for HIV at 6 weeks and repeated testing until the end of the breasfeeding period and determination of final status o Continued infant feeding counselling and support o Screening and management of tuberculosis; IPT if indicated o Prevention and treatment of malaria o Nutrition care and support o Psychosocial care and support o Regular re-assessment of HIV status & ART for HIV infected infants o Symptom management & palliative care if needed. o Linkage with community support systems for PLHIV including OVC services

Figure 5.1: The PMTCT continuum of services



5.2 BEFORE PREGNANCY

5.2.1 Primary Prevention of HIV infection among women (Prong 1)

- *Implemented at general population level*
- *Activities include: Behavioral Change Communication (BCC) and promotion of safer sex;* HIV testing and Counseling (HTS); couple HTS; partner testing and early treatment of the HIV positive partner in sero-discordant couples; delay of onset of sexual activity; condom use
- PMTCT messages should be incorporated in school health curricula, community adolescent health programs, and pre-marital counseling programs

Recommendations:

- PITC *is recommended for women as a routine component of the package of care in all antenatal, childbirth, postpartum, and infant/pediatric care settings.*
- Health workers should retest previously HIV-negative women as follows:
  - first trimester of pregnancy or first ANC visit
  - in 3rd trimester during labor/ or delivery

- at 6 weeks and 6 months postnatally

5.2.2 Prevention of unintended pregnancy among women living with HIV (Prong 2)

Family planning among women living with HIV reduces the number of unintended pregnancies, thereby reducing the number of infants exposed to HIV and the overall risk of MTCT.

5.2.2.1 Provider Initiated Family Planning (PIFP)

Key message on Provider Initiated Family Planning:

- Avoid unwanted and /or unintended pregnancies, regardless of HIV infection status
- Unprotected sex is a risk for discordant and concordant HIV infected couples
- Couples should use dual protection – condoms alone are not enough for family planning as they have to be used very consistently and correctly
- Women living with HIV should use a family planning method of their choice as long as it is safe with ART. See table 6-2. *Depo-Provera has fewer interactions with ART and anti TB therapy.*
- Encourage women living with HIV to make an informed choice about pregnancy. HCW should inform women that they can have a safe pregnancy and minimize the risk of HIV transmission to the baby if the mother;
    - Starts ART as early as possible, preferably before becoming pregnant
    - Is fully adherent to ART throughout pregnancy and breastfeeding

A. *Counsel women on FP routinely when they come for ANC, PNC, ART services.*
Encourage HIV-infected women to discuss their RH options and support them as appropriate. Information provided during counseling should cover;
- Family planning methods, advantages, and side effects.
- Common misconceptions about family planning
- Advantages of dual protection and also how to negotiate for condom use.
- Use of contraception is voluntary
- What to do when pregnancy occurs

B. Following counseling, offer FP.

I. For HIV-positive women and couples who desire children, discuss strategies to reduce the likelihood of HIV transmission to infants and sexual partners.

II. Where pregnancy is not desired, offer effective contraception.
- Encourage dual contraception (use of both hormonal contraception and condoms) to prevent pregnancy; prevent STIs, HIV transmission, and re-infection.
- The choice of contraceptive methods in HIV infected women is much the same as in HIV negative women. See Table 6-2

Table 5.2: Available Family Planning

Method	How to use	Effectiveness (pregnancies per 100 women)	Common side-effects	Considerations if HIV-positive
Short Term Methods				
Male condom	Use every time you have sex	Highly effective when used correctly each time (2 pregnancies/ year) Less effective as commonly used (15 pregnancies/year)	None	Condoms are the only contraceptive method that protects against STIs and HIV
Female condom	Use every time you have sex	Effective when used correctly each time(5 pregnancies/year) Less effective as commonly used(21 pregnancies/year)	None	Condoms are the only contraceptive method that protects against STIs and HIV
Oral contraceptive pills	Take a pill every day	Highly effective when used correctly(<1 pregnancy /year) Less effective as commonly used (8 pregnancies/year)	Menstrual changes, spotting, headaches, nausea	HIV-positive women and women on ART should use pills in combination with condoms (dual protection)
Injectables	Get an injection every 1, 2, or 3 months	Highly effective when used correctly (<1 pregnancy/year) Less effective as commonly used (3 pregnancies/year)	Spotting initially or continuously, and sometimes no bleeding	HIV-positive women and women on ART should use injectables in combination with condoms (dual protection)
Emergency contraceptive pills	Take within 5 days after condom breakage/ other unprotected sex	Reduces chances of pregnancy from that one act of unprotected sex to 1/4 or 1/8 of chances if not used	Nausea	Not as effective as other methods for regular use
Long-acting methods				
Implant, IUD, vasectomy, female sterilization	o Provide long-term, highly effective contraception (<1 pregnancy per 100 women per year) and can be used by women with HIV. o Vasectomy and female sterilization are permanent methods, for couples or women who know they will not want more children. o Use in combination with condoms for dual protection. o These methods require a procedure performed by health care provider.			

5.3 DURING PREGNANCY

Key activities:

- Provider – Initiated Testing and Counseling 2.4 , Partner testing & Couples HTS 6.3.1
- Lab investigations and related ANC services 6.3.2
- Comprehensive care for pregnant women with HIV - Section 3
- Risk reduction counseling 6.3.4
- Antiretroviral therapy 6.3.5

5.3.1 PITC in ANC, Partner testing, and Couple testing

- Provider-initiated HIV testing and counselling (PITC) with rapid tests and same day results should be recommended to all women whose HIV-infection status is not known during pregnancy.
- Couple testing and partner testing should be offered in ANC with support for mutual disclosure. Providing HTS to partners improves support for adherence to health care interventions including ART. All HIV positive sero-concordant and sero-discordant couples should be linked to ART.
- For HIV negative pregnant women, re-testing is recommended in the third trimester, or during labour, or shortly after delivery, because of the high risk of acquiring HIV infection during pregnancy.
- Women who are not ready to test for HIV during the visit should be engaged at subsequent visits.

5.3.2 Laboratory investigations and related ANC services

- For all pregnant women (regardless of HIV status), screen and treat for the following conditions: syphilis, HIV, anaemia, urinary tract infections, in addition to performing a blood group test.
- **For all HIV positive women, perform a baseline CD4 count if available. The test result is not a pre-requisite for ART initiation.**
- Nutrition assessment, counseling, and support: counsel mothers on appropriate feeding practices. Counsel mothers to exclusively breastfeed for six months and continue breastfeeding with the addition of complementary foods through at least 12 months
- Provide iron, folic acid and multivitamins for supplementation
- Deworm during the second trimester of pregnancy – single dose mebendazole 500 mg
- Provide tetanus vaccination

5.3.3 Comprehensive care for pregnant women with HIV

- Pregnant and breastfeeding women should receive the same care and treatment services as other HIV+ adults.
- If viral load monitoring is available, it should be a priority to monitor pregnant and breastfeeding women. Ensuring viral suppression will benefit the mother's health and reduce transmission to the infant.
- Pregnant women on CPT should NOT be given Fansidar for intermittent preventive treatment for malaria

5.3.4 Risk reduction counseling and support during pregnancy, delivery and breastfeeding

- Encourage consistent and correct condom use for both HIV positive and HIV negatives at risk of infection
- Encourage women to deliver at the health facilities
- Immediately after delivery, all mothers should receive vitamin A 200,000 IU supplementation – irrespective of HIV status

5.3.5 Antiretroviral therapy for pregnant and breast-feeding women

Key Recommendations:

- All women living with HIV that are identified during pregnancy, labour or while breastfeeding should be started on lifelong ART (option B+) irrespective of CD4 counts or WHO clinical stage.
- A once-daily fixed dose combination of TDF+3TC +EFV is recommended as the first line ART regimen for pregnant and breastfeeding women, including pregnant women in the first trimester of pregnancy and women of childbearing age. See Table 6.3
- Pregnant and breastfeeding women living with HIV should be provided with the same HIV care and treatment services as other adults receiving ART, including VL monitoring if available.
- HIV-positive mothers and their HIV-exposed or –infected children should be provided services together at the same location.

Why lifelong ART for pregnant and breastfeeding women?

- ART prevents further disease progression in the mother, with reduction in maternal HIV-related deaths, opportunistic infections especially TB, and improved survival of their children.
- ART reduces viral load in blood and breast milk thus greatly reducing the risk that the exposed child will get infected with HIV. This makes breast feeding safer, and contributes to child survival.
- Giving the mother ART avoids the need for extended infant ARV prophylaxis.
- Lifelong ART in the mother protects the current pregnancy as well as subsequent pregnancies
- Maternal ART reduces risk of HIV transmission to HIV-negative partners in sero-discordant couples.
-

Table 5.3: First line ART Regimens for Pregnant & Breast Feeding Women

Client	Regimen	Comment
Maternal Regimens **NB: See Table 4-1 for baseline recommended lab tests at ART enrollment**		
Pregnant and breastfeeding women initiating ART (at ANC, in labour, or post-partum, or in post-natal period)	TDF + 3TC +EFV as a Fixed Dose Combination (FDC)	ART should be started as early as possible in pregnancy. Alternative regimens for specific toxicities or side effects can be found in 4.4 Adherence counseling (see 4.2.1) should be expedited and women initiated on ART if agreeable. If a woman declines ART, a follow-up plan including ongoing counseling and active client tracing should be made with the goal of initiating ART at subsequent visit. Ongoing adherence counseling at the visits following ART initiation
Pregnant or breastfeeding women already on ART	Continue current ART regimen	Client may be switched to TDF-3TC-EFV if single FDC preferred If client has evidence of treatment failure, follow guidance for evaluation of treatment failure in 4.7

5.4 LABOUR AND DELIVERY

Key steps

- Ascertain HIV status, offer PITC if never tested or tested negative more than 3 months ago. see 2.4
- Give ART: for mothers on treatment, continue the same ART regimen. Initiate ART for mothers not yet on treatment and consider extended ARV prophylaxis for the infant. see 6.3.5
- Ensure safe obstetric practices – 6.4.1
- ARV prophylaxis for the new born – 6.4.2

5.4.1 Safe obstetric practices

To reduce obstetric risk of HIV transmission:

- *Use a partogram* to allow for early detection and management of prolonged labour. Prolonged labour increases the number of hours the baby is exposed to maternal blood and secretions in the birth canal.
- *Avoid routine (artificial) rupture of membranes (ARM).* If prolonged labour is due to poor uterine contraction, perform ARM at ≥6cm cervical dilation and augment with oxytocin (pitocin)
- *Do not perform routine episiotomy* except for specific obstetric indications (e.g. vacuum extraction)
- *Avoid frequent vaginal examinations*
- *Do not 'milk' the umbilical cord before cutting*
- *Actively manage the third stage of labour:* Active management reduces risk of postpartum haemorrhage which increases exposure of the newborn to maternal blood. This involves 3 important components: (i) *Giving oxytocin* within 1 minute following the birth of the baby (ii) *Delivery of the placenta using controlled cord traction (iii) Massaging the uterus after delivery of the placenta*

NB: *HIV infection in a pregnant woman is in itself no longer considered an absolute indication for Caesarean section. Caesarean section is therefore not recommended specifically for HIV infection in South Sudan; rather it is recommended for obstetric and other medical reasons.*

5.4.2 ARV prophylaxis to the Infant

ARV prophylaxis for HIV exposed infants is administered based on the level of risk of HIV for the infant.

A high risk infant is defined as follows:

1. High maternal viral load >1000copies/ml during the last 4 weeks before delivery or
2. An infant born to HIV infected woman who has received less than 4 weeks of ART at the time of delivery or
3. An infant born to a newly diagnosed HIV infected woman during labor, delivery and postpartum (Incident HIV infection)

All infants who do not meet the criteria for 'high-risk' infants are classified as 'low-risk' infants.
The table below shows infant prophylactic ARV regimens by risk stratification.

Health workers should offer high-risk infants ***dual ARV prophylaxis of AZT and NVP for 12 weeks*** *post-delivery.*

Figure 5.2: Prophylaxis for the high and low risk infants

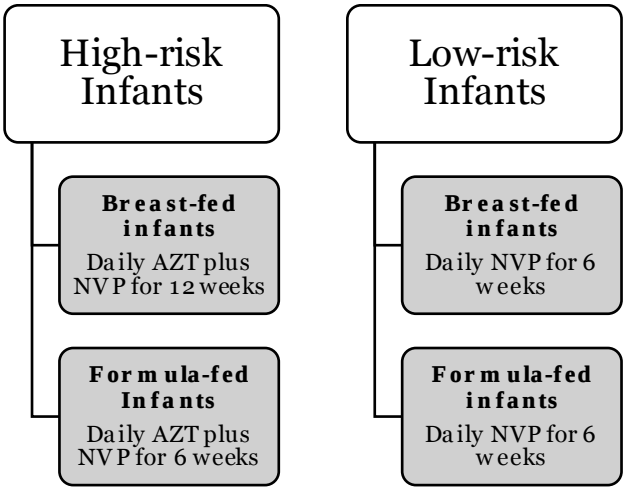


Table 5.4: Infant dosing table for Nevirapine and Zidovudine

Infant age	Dosing NVP	Dosing AZT
Birth to 6 weeks		
Birth weight 2000–2499 gm	10 mg once daily (1 ml of syrup once daily)	10 mg twice daily (1 ml of syrup twice daily)
Birth weight ≥2500 g	15 mg once daily (1.5 ml of syrup once daily)	15 mg twice daily (1.5 ml of syrup twice daily)
>6 weeks to 12 weeks		
	20 mg once daily (2 ml of syrup once daily or half a 50 mg tablet once daily)	No dose established for prophylaxis; use treatment dose 60 mg twice daily 6 ml of syrup twice daily or a 60 mg tablet twice daily)

5.5 POST-PARTUM INTERVENTIONS AND THROUGHOUT BREAST FEEDING

Following delivery, it is important to address the treatment, care and support needs of HIV-infected women, their children and families. This is Prong 4 of PMTCT. Ideally, mothers living with HIV and their HIV-exposed infants should be provided with ongoing HIV care and treatment services together in the same location. This follow-up could be done within MCH or within the ART clinic as appropriate to the human resource capacity and space within the facility.

Services for the mother

For the mother, the services include:

- Antiretroviral therapy (ART) - 6.3 *--throughout breast feeding period*
- Co-trimoxazole prophylaxis 3.6
- TB screening

- Continued infant feeding counselling and support Chapter 7
- Nutritional counselling and support 3.4
- Sexual and reproductive health services including FP 6.2.2
- Psychosocial support
- Viral load monitoring

Women with HIV and women of unknown HIV status who deliver outside health facilities should be assessed at an MCH facility as soon as possible.

Routine follow-up for the HIV infected mother and her infant is usually scheduled at 6 weeks following delivery. At the post natal visit;

- Post –partum check (for sepsis, anemia, high blood pressure etc.); provision of vitamin A
- Family planning counseling and services
- Review of ART regimen and adherence support
- Re-enforcement of safe feeding practices
- Cervical cancer screening - where available

This visit usually coincides with immunization visit for the baby, and infant HIV testing. Thereafter the mother-infant pair should be followed up at 10 weeks, 14 weeks (as per immunisation schedule) and then quarterly. The baby should have an Ab test at 9 months, 18mo and 3 months after cessation of breastfeeding.

5.5.1 Care of HIV- exposed infants

Key Components of the Care Package For HIV- exposed Children:

- ARV prophylaxis for 6 weeks or until 12 weeks for high-risk infants– 6.4.2
- Infant HIV testing: DNA PCR at 6 weeks. Ab testing at 9mo, 18 months – 2.3.1
- Routine immunization, growth and development monitoring 6.5,
- Co-trimoxazole prophylaxis (from 6 weeks of age) – 3.6
- Vitamin A 100,000-200,000 IU every 6 months up to the age of 5 years.
- Continued infant feeding counselling and support – Chapter 8
- Mother and family care Table 6-1: PMTCT Prong 4

NB: WHO clinical staging requires confirmed HIV infection. An infant aged under 18 months with only a positive HIV rapid antibody test can NOT be given a WHO clinical stage because in infants, HIV antibodies do not confirm HIV infection.

5.5.2 Early Diagnosis of HIV among Infants and older children

Key messages

- *Confirm HIV status as early as possible:*
- *Link all HIV-exposed infants to care* by 6 weeks of age for medical care and early diagnosis of HIV. To enhance easy identification of exposed infants, document mothers' HIV status on the MCH passport.
- To identify more HIV-exposed children, *implement PICT in all child care settings* (in-patient wards, clinics for immunization, under five, TB, malnutrition), and *provide HTS to children of adult PLHIV* attending HIV clinics (index-case testing)
- *HIV Testing:* HIV infection among children below 18 months old is confirmed using DNA PCR; HIV infection among children 18 months and older can be confirmed using rapid HIV antibody tests. see Table 2-1, Figure 2-1 and Figure 2-2
    - An infant with HIV antibodies and specific clinical conditions suggestive of HIV see (Table presumptive diagnosis of severe HIV disease) needs to start ART without delay while every effort is made to confirm the diagnosis.
- Following HIV testing, enhance linkages and follow up of lost infants 2.6
- All Infants and children who areHIV infected should be initiated on ART as soon as possible and a sample sent to confirm HIV diagnosis 7.4

5.5.3 Routine Immunization

- HIV-infected infants and children can safely receive most childhood vaccines. All HIV infected and exposed children should be immunized as per South Sudan national Expanded Program (EPI) for Immunization schedule
- Immunization status should be reviewed at every visit
- BCG vaccination is protective against severe forms of TB such as miliary TB and TB meningitis. **BCG should not be given to infants and children with symptomatic HIV infection**. If BCG is administered at the right time (at birth), the majority of children will receive BCG vaccine, since HIV-infected children are unlikely to be symptomatic at birth.
    - If HIV symptomatic children are given BCG, they may develop BCG disease, whereby the BCG vaccination site develops an abscess, the axillary lymph nodes enlarge and the child gets TB symptoms. Children with suspected BCG disease should be referred to tertiary facilities for treatment.
    - When children, especially those below 1 year of age, start ARVs, the recovery of the immune system may lead to BCG disease Immune Reconstitution Inflammatory Syndrome (IRIS). This usually presents as an abscess and axillary lymph node enlargement. Refer to 4.6.2 & 9.6.3

5.5.4 Growth Monitoring

Growth monitoring is the regular measurement of a child's size in order to document growth. The child's size measurements must then be plotted on a growth chart. This is extremely important as it can detect early changes in a child's growth.

- Weight-for-age is usually used to monitor growth. It is particularly useful in small infants who normally gain weight fast. Normal weight gain suggests that the infant is healthy and growing normally. Failure to gain weight normally is often the earliest sign of illness or malnutrition (i.e. under-nutrition).
- Height and head circumference are also important measurements of growth. Height is the best method of measuring linear growth (stature) as height reflects growth over a longer period than does weight. Measuring height is therefore important measure of growth in older children.
- Head circumference can be used to assess brain growth in children under 2 years. During this period brain growth is fast and, therefore, head circumference increases rapidly. A small head (microcephaly) suggests a small brain, while a large head suggests hydrocephaly. Head circumference is less accurate in assessing brain growth over 2 years of age. Therefore, measuring head circumference is most useful in young children, and height in older children.

Frequency of growth monitoring

- **Weight should be measured and recorded every month for the first year of life,** every 6 months between 1 and 5 years. In addition, a child's weight should also be measured and recorded every time the child is seen at a clinic, hospital or by a general practitioner and the weight should be plotted on a growth chart.
- Height should be measured annually.
- Head circumference is measured routinely during the first 2 years of life.

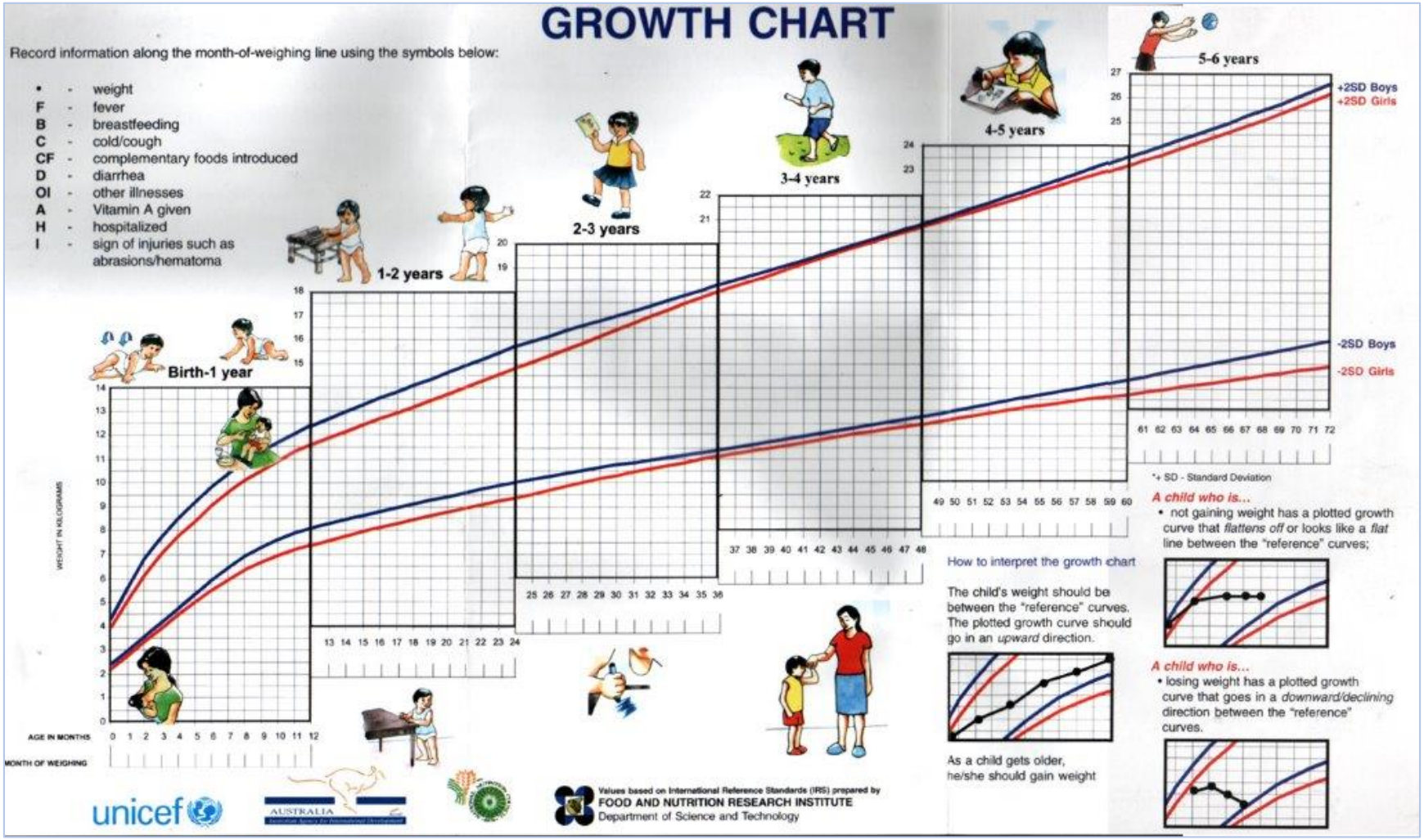
- At all encounters with a child, growth parameters should be taken and recorded on the Child Health Card or ART Care Card.
- Plot the child's weight on a centile chart to compare the child's size (usually the weight) to that of other children using a growth chart. For a given age, the size of most children (94%) falls between the 3rd and the 97th centiles. These children are regarded as having a normal (average or appropriate) size for their age and are growing well.

- Children are underweight if their weight is below the 3rd centile.
- Alternatively, Z-scores (standard deviations from the mean) may be used to assess a child's size. A Z-score of –2 is equivalent to the 3rd centile.
- A growth curve indicates the child's growth rate, and helps identify children who have a growth pattern that differs from the average growth pattern.
    - Wasting is a danger sign and suggests malnutrition or illness. These children usually look very thin and have a weight that falls below the 3rd centile while their height and head circumference often fall within the normal range. These children also have a body mass index below the 3rd centile, i.e. they are underweight for their height. Their growth curve may show weight faltering.

- Infants with growth faltering (failure to thrive or slow growth) have not been gaining weight normally. Their weight may be static (remaining the same) or may even be dropping. Their height and head circumference may also not be increasing normally. Most of these children have a medical, nutritional or social problem, which needs to be urgently diagnosed and managed. Faltering weight gain must be detected as soon as possible so that the cause can be corrected. Growth faltering may be the first sign of HIV infection.
- Stunted children are shorter than normal for their age. As they are often symmetrically small and do not look thin, their stunting is often missed. Usually their growth curves have followed the centiles although their weight, height and head circumference all fall below the 3rd centile. Stunting usually occurs before 3 years of life.

- If failure to gain weight adequately does not respond to management at a primary care clinic, the child must be referred for further assessment and management. This is particularly important in children with a weight that falls or crosses centiles. Usually these children are referred to a special nutritional clinic where the following steps should be followed:
  - Exclude any chronic illness such as tuberculosis or HIV infection.
  - A dietician or nutritional counselor should educate the mother or caregiver.
  - A social worker should interview the mother or caregiver and assist where help is needed.
  - If the child is still not improving, refer to a paediatrician.
- Failure to gain weight or height, slow weight or height gain, and loss of weight may be an indication of HIV infection in an infant/young child: Failure to thrive affects as many as 50% of HIV-infected infants and children. HIV-infected infants and children who are failing to thrive have a significantly increased risk of mortality
- Counsel the mother/ caregiver on the child's growth trend and take appropriate action where necessary as outlined in section 3.4

Figure 5.3: Child Growth Chart



5.5.5 **Development Monitoring**

Development represents maturation of the brain and central nervous system and broadly looks at a child's mental, physical, and social development.

Neurodevelopment:

Neurodevelopment is the progressive, orderly change of behaviour and activities which are seen as a childr becomes older. Their physical ability and understanding of the world around them increases and matures with age. Developmental milestones are used to monitor neurodevelopment in childhood. The neurodevelopmental monitoring of milestones must be part of the routine growth and developmental screening of all children. The following table 5-5 provides guidance on the gross motor, visual motor/problem- solving, language, and social/adaptive milestones of children from one month to five years olds.

Table 5.5: Development milestones

Age				
	Raises head from prone position	Visually fixes, follows to midline, has tight grasp	Alerts to sound	Regards face
2 mo	Holds head in midline, lifts chest off table	No longer clenches fists tightly, follows object past midline	Smiles socially (after being stroked or talked to)	Recognizes parent
3 mo	Supports on forearms in prone position, holds head up steadily	Holds hands open at rest, follows in circular fashion, responds to visual threat	Coos (produces long vowel sounds in musical fashion)	Reaches for familiar people or objects, anticipates feeding
4 mo	Rolls over, supports on wrists, shifts weight	Reaches with arms in unison, brings hands to midline	Laughs, orients to voice	Enjoys looking around
6 mo	Sits unsupported, puts feet in mouth in supine position	Unilateral reach, uses raking grasp, transfers objects	Babbles, ah-goo, razz, lateral orientation to bell	Recognizes that someone is a stranger
9 mo	Pivots when sitting, crawls well, pulls to stand, cruises	Uses immature pincer grasp, probes with forefinger, holds bottle, throws objects	Says "mama, dada" indiscriminately, gestures, waves bye-bye, understands "no"	Starts exploring environment, plays gesture games (e.g., pat-a-cake)
12 mo	Walks alone	Uses mature pincer grasp, can make a crayon mark, releases voluntarily	Uses two words other than "mama, dada" or proper nouns, jargoning (runs several unintelligible words together with tone or inflection), one-step command with gesture	Imitates actions, comes when called, cooperates with dressing
15 mo	Creeps up stairs, walks backward independently	Scribbles in imitation, builds tower of 2 blocks in imitation	Uses 4–6 words, follows one-step command without gesture	15–18 mo: uses spoon and cup
18 mo	Runs, throws objects from standing without falling	Scribbles spontaneously, builds tower of 3 blocks, turns two or three pages at a time	Mature jargoning (includes intelligible words), 7–10 word vocabulary, knows 5 body parts	Copies parent in tasks (sweeping, dusting), plays in company of other children
24 mo	Walks up and down steps without help	Imitates stroke with pencil, builds tower of 7 blocks, turns pages one at a time, removes shoes, pants, etc.	Uses pronouns (I, you, me) inappropriately, follows two-step commands, 50-word vocabulary, uses 2-word sentences	Parallel play
3 yr	Can alternate feet going up steps, pedals tricycle	Copies a circle, undresses completely, dresses partially, dries hands if reminded, unbuttons	Uses minimum of 250 words, 3-word sentences, uses plurals, knows all pronouns, repeats two digits	Group play, shares toys, takes turns, plays well with others, knows full name, age, gender
4 yr	Hops, skips, alternates feet going down steps	Copies a square, buttons clothing, dresses self completely, catches ball	Knows colors, says song or poem from memory, asks questions	Tells "tall tales," plays cooperatively with a group of children
5 yr	Skips alternating	Copies triangle, ties shoes,	Prints first name, asks what a	Plays competitive

	feet, jumps over low obstacles	spreads with knife	word means	games, abides by rules, tasks

Source: Tschudy, Megan M.Arcara, Kristin M. (Eds.) (2012) *The Harriet Lane handbook :a manual for pediatric house officers* Philadelphia, PA : Mosby Elsevier

- HIV-infected Infants are at high risk for HIV encephalopathy, severe neurologic disease and developmental delay. Delayed development or loss of development milestones may be the first sign of HIV infection in an infant or young child. Early identification of developmental delay and neurologic abnormalities can facilitate intervention and remediation.
    - Development monitoring assesses cognitive, motor, language and social skills of a child.
    - Delay in acquisition or loss of these is a sign of severe HIV in infants and children
    - Low head circumference may also be an indicator of developmental delay and suggestive of brain encephalopathy
- It is always important to ask parents to report on milestones achieved by the child since their last visit. All this should be documented on the Child Health Card.

Sexual development:

Puberty is the time when the physical signs of sexual maturity (secondary sexual characteristics) appear due to the secretion of sex hormones in older children. Puberty is earlier in girls (8 to 13 years) than boys (10 to 15 years). A marked growth spurt occurs during puberty. There are also many emotional and social changes.

- Children with early (precocious) puberty and those with late (delayed) puberty must be referred for a specialist opinion.
- Physical changes during puberty can be formally graded into 5 stages (from pre-puberty to full sexual development). Genital development (appearance of penis, testes and scrotum) and pubic hair are scored in boys while breast development and pubic hair are scored in girls. Menstruation in girls starts towards the end of puberty when the growth spurt is almost complete. These are the stages described by Tanner. For adolescents, refer to the *Tanner Staging* chart to assess for development of secondary sexual characteristics.

5.5.6 Cotrimoxazole prophylaxis in children

- All HIV exposed infants from 6 weeks of age until proved to be HIV negative need daily cotrimoxazole prophylaxis.
- All children proven to be HIV infected need cotrimoxazole prophylaxis to be continued for life even after they start ARVs. Refer to 3.6

5.6 COMMUNITY PMTCT INTERVENTIONS

All HIV positive pregnant mothers and their families should be linked to psychosocial and community groups for on-going support. Linkage to community support groups (family support groups, peer mothers) is important in enhancing retention in care. Community involvement is necessary for successful implementation of PMTCT & EID services in the country.

Key community PMTCT interventions include;

- Community mobilization and sensitization to utilize RH/PMTCT services.
- Promotion of male participation in RH/PMTCT services
- Psycho-social support through peer mothers for PMTCT and other groups
- Health Education and Promotion

- Mother-Baby Pair follow up
- Home based HTS
- Community distribution of FP commodities
- Community linkages and tracking to care and support groups.
- Community growth promotion and development monitoring.-
- Sexual and Gender Based Violence (Sensitization, prevention and Support)

6 CARE FOR HIV-INFECTED CHILDREN

Paediatric HIV accounts for about 13% of all HIV infections globally. The majority of children (over 90%) with HIV acquire the infection through mother-to child transmission during pregnancy, at birth, or through breast feeding. HIV infection in children tends to follow a more aggressive course than in adults. Mortality is very high among untreated infants infected with HIV; without HIV treatment, 52% of infected children die within two years. It is therefore essential to have early diagnosis of HIV, prompt return of results, and rapid ART initiation.

To improve access to paediatric care, paediatric HIV diagnosis, care, treatment, and support services should be integrated into existing adult HIV clinical and community services.

- PITC should be offered in all clinics attended by women and children especially targeting children who are malnourished, have TB, are admitted to hospital, or have signs of HIV infection
- All facilities providing ART for pregnant and breast feeding women should be providing paediatric ART and related services
- All maternal, newborn and child health (MNCH) programs should integrate early infant HIV testing (using Ab testing or DNA-PCR where available) into immunization outreaches, and well-child /young child days

Key interventions for HIV infected children *(in addition to services for HIV-exposed children)*

- Prevention and treatment of opportunistic infections (including TB) – 3.5
- Antiretroviral therapy (if confirmed to be HIV infected) – 7.4
- Adolescent care and support – Chapter 5
- Psychosocial support and palliative care

6.1 ANTIRETROVIRAL THERAPY FOR INFANTS AND CHILDREN

Before a child is started on ART one has to ascertain the following;

- If the parents /caretakers or child (if older) are ready to start lifelong ART
- A pre-treatment baseline assessment has been performed

6.1.1 ART eligibility criteria for infants and children

ART eligibility criteria: Infants and children

- All infants and children should be initiated on ART regardless of WHO clinical stage or CD4 cell count (Treat All approach)
- All infants under 18 months of age with a presumptive diagnosis of HIV

6.1.2 **Preparation for Anti-retroviral Therapy**

- Children and infants are dependent parent/guardian to receive regular treatment. Children should be prepared for lifelong treatment.
- Adherence counseling sessions should be attended by the parent/guardian/caregiver and the child. Topics covered are essentially similar to adults' counseling. However, other issues that should be addressed during counseling include timing of disclosure of HIV sero-status, the challenge of sustaining confidentiality and minimizing stigma.
- *Pre-treatment baseline assessment for children* is similar to adults <u>but</u> in addition:
  - Weight, height, head circumference, MUAC (age 6-59mo)
  - Assessment of the child's and caregiver's preparedness for therapy.
  - Measurement of CD4 where available. CD4 test result is not a requirement for starting ART as all children are eligible.

Table6.1: ART regimens for infants and children with HIV: 1st ART

First line regimens		
Category	**Regimen**	• **Comment (s)**
All infants and children between 2 weeks and under 3 years	Preferred 1st line ABC+3TC+LPV/r Alternative AZT+3TC+LPV/r ABC+3TC+NVP AZT+3TC+NVP	• If ABC is contraindicated, give AZT+3TC+ LPV/r • If a child is anemic (Hb <7.5g/dl) do not use AZT. Use ABC based regimen. • Do not use EFV in children under 3 yrs (or 15 kg). • ATV/r can be used as an alternative to LPV/r only for children older than 3 months
Children ≥ 3 years-10 years and adolescents ≤ 35kg	ABC + 3TC + EFV Alternative ABC+3TC+NVP AZT+ 3TC+EFV AZT+ 3TC+NVP TDF+3TC+EFV (or NVP)	• When VL testing is available for monitoring; EFV can be substituted for LPV at 3 years of age after viral suppression • For children above 3 years; EFV is the preferred NNRTI backbone • If EFV is contraindicated, give ABC+3TC+NVP • If ABC is contraindicated, give AZT+ 3TC+EFV (or NVP) • If ABC and AZT are contra-indicated, give TDF+3TC+EFV (or NVP) • If a child is anemic (Hb <7.5g/dl) do not use AZT. Use ABC based regimen.
Infants and Children under 3 years who develop TB while on ART	ABC+3TC+AZT	• For children under 3 years receiving 1st Line ART; substitute AZT for NVP or LPV/r. This recommendation for 'triple nukes' is due to drug-drug interactions between Rifampicin and NVP or LPV/r. Once TB therapy is completed; this regimen should be stopped and patient restarted on the initial regimen

The country has now recommended use of a PI based regimen as the preferred first line ART for children below 3 years. However, where LPV/r is not available; NVP-based regimens can be used for children under 3 years. For children above 3 years; EFV is the preferred NNRTI backbone. It is anticipated that the country will introduce the heat stable Kaletra pellets (LPV/r).

6.1.3 Routine Monitoring of Children on ART

- After starting ART, follow-up visits should ideally be harmonised with the visits of the mother.
- For infants, at weeks 2, 4, 8, and then every 4 weeks for the first year
- For children, at weeks 2, 4, 8, 12, and then every 2 to 3 months once the child has stabilized on therapy.
- Routine clinical assessment should include addressing the child's and/or caregiver's understanding of ART and adherence to therapy, along with their need for additional support.
- Key signs of an infant's and child's response to ART include:
    - Improvement in growth of infants and children who have been failing to grow
    - Decreased frequency of infections (bacterial infections, oral thrush and/or other OIs).

Table 6.2: Monitoring infants and children with HIV

At initiation of ART (Baseline)		
Test	**Purpose**	**Comment**
CD4 count (if not performed in last 6 months)	As baseline reference CD4	DO NOT wait for CD4 count to start ART
On ART		
Height, Weight, Head Circumference (<2yrs) and Development	To monitor Growth and Developmental stage	Growth monitoring must occur at each visit
Clinical assessment	To monitor response to ART and exclude adverse effects	
TB screening	To identify children who are co-infected with HIV and TB	
CD4 at 6 months into ART, and then every 6 months	To monitor response to ART	Can use viral load for monitoring where it is available. CD4 for monitoring purposes should be phased out as VL becomes more accessible
VL after 6mo on ART, annually, and as needed due tosuspicion of treatment failure (clinical and immunological failure)	To confirm treatment failure	VL is the preferred method of monitoring treatment response in children. See definition of ART failure in children in Table 7-4
Hb or FBC at month 1, 2, 3 into ART and then annually if on AZT	To identify AZT-related anaemia	
Clinical drug-related adverse events	To identify drug-related adverse events	If develops jaundice or rash on EFV or NVP do Liver function tests and refer to specialist

6.1.4 Immune Reconstitution Inflammatory Syndrome in children:

- There are limited data on IRIS in infants and children. The onset of IRIS in children most often occurs within the first weeks to months following the initiation of ART and is seen most often in children who initiate ART with very low CD4 levels or percentage (<15%).
- The most common opportunistic infection associated with IRIS in children is TB, Pneumocystis pneumonia (PCP) or Cryptococcal meningitis, herpes simplex virus (HSV), fungal or parasitic infections

- Where BCG immunization of infants and children is routine, BCG-associated IRIS (localized and systemic) may be observed especially among HIV+ children who are undiagnosed or newly diagnosed.

6.1.5 ARV drug toxicity in children:

- Some toxicities are less common in children than in adults e.g. the lipodystrophy associated with use of stavudine (d4T) or the symptomatic hepatotoxicity related to nevirapine (NVP) use, while others are more commonly reported in children than in adults e.g. efavirenz (EFV) related rash. See Table 13-2 and Table 4-7 for more detail on ARV toxicity.

6.1.6 Treatment failure in children

- Children failing first line ART should receive enhanced adherence counselling (EAC) before being considered for switching to second line regimens as seen in Table 6.1-2.

Table 6.3: ART failure in children

Failure	Definition	Comments
Clinical failure	• New or recurrent clinical event indicating severe immunodeficiency (WHO stage 3 and 4 condition with the exception of TB) after 6 months of effective treatment	Must be differentiated from IRIS occurring after ART initiation.
Immunological failure	• Younger than five years : Persistent CD4 levels below 200 cells/ml or less than 10% • Older than five years : persistent CD4 levels below 100 cells/ml	Without concomitant or recent infection, to cause a transient decline in CD4 cell count.
Virological failure	• Plasma viral load above 1000 copies / ml based on two consecutive viral load measurements after 3 months, with adherence support . Refer to Figure 4-1	An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed.

6.1.7 Second line ART for children (including adolescents)

- After failure of first line boosted PI; RAL plus two NRTIs is recommended for second line ART.
- After failure of first line NNRTI-based regimen, a boosted PI plus two NRTIs is recommended for second line ART
- After failure of first line regimen of ABC +3TC, the preferred NRTI backbone option for second line is AZT +3TC
- After failure of a first line regimen containing AZT +3TC , the preferred NRTI backbone option for second line ART is ABC or TDF+ 3TC

The dosing of ARV medicines for infant and children can be seen in Tables 11-X , 11-Y

Table 6.4: ART Regimens for Infants and Children: 2nd Line ART

Second line regimens		
Younger than 3 years		
Failed 1st Line: ABC (or TDF) +3TC + LPV/r	AZT+3TC+RAL	• If RAL is not available; no change is recommended UNLESS in advanced clinical disease progression or patient fails to take LPV/r due to poor palatability, then consider switching to a second-line NVP-based ARV regimen
Failed 1st Line: AZT+3TC+ LPV/r	ABC+3TC+RAL	
3 years and older		
Failed 1st Line: ABC+3TC+LPV/r	AZT+3TC+EFV or RAL	• For patients older than 3 years; EFV can be substituted for RAL
Failed 1st line: AZT +3TC+ LPV/r	ABC+3TC+EFV or RAL	
All Ages: Failed NNRTI-based first line		
Failed: ABC+3TC+EFV (NVP)	AZT+3TC+ATV/r or LPV/r	
Failed TDF+3TC+EFV (NVP)		TDF may be given only to children older than 2 years
Failed AZT+3TC+EFV (NVP)	ABC or TDF +3TC+ ATV/r or LPV/r	

Table 6.5: ART Regimens for Infants and Children: Third Line ART

Third Line ART		
Failing any 2nd line regimen	Refer for specialist opinion	

NRTI drug combinations to be avoided- TDF +ABC -both drugs select for the K65R mutation

6.2 HIV AND TB CO-INFECTION IN CHILDREN

Children living with HIV are at increased risk of acquiring TB infection and progression to active TB disease following exposure to *M. tuberculosis* compared to those who are HIV negative. About 50% of HIV infected children with TB infection go on to develop TB disease. Those who develop TB disease have a poorer prognosis for severe disease. HIV infected children often have co-existing severe malnutrition which is also a risk factor for progression to severe disease.

6.2.1 TB screening in children

- All HIV-infected and exposed infants and children should be evaluated for TB symptoms using the TB screening algorithm at every visit to a health-care facility. In addition, they should be evaluated for contact with a TB source case. See Figure 12-2
- Those reporting either positive contact history, poor weight gain, or any suggestive symptoms should be investigated for TB.

- Infants and children have a wide range of pulmonary and extra pulmonary manifestations of tuberculosis. Clinical conditions suggesting a possibility of TB include bronchopneumonia without improvement on a 7-14 day course of broad spectrum antibiotics, pleural effusion, asymmetrical peripheral lymphadenopathy, spinal deformity, abdominal peritonitis, ascites and meningitis in a setting of the above symptoms.

6.2.2 **TB diagnosis in children:**

- Diagnosis of TB in children is challenging because of the difficulty in obtaining sputum for bacteriological confirmation of the disease. Samples such as sputum (by expectoration, gastric aspiration or induction), fine-needle aspirates of enlarged lymph nodes or pleural fluid should be subjected to microscopy and other available bacteriological investigations. Gastric aspirates should not be undertaken in the absence of culture or GenXpert services.

- Diagnosis of TB in children is often presumptive and based on suggestive clinical signs and symptoms, findings on chest x-ray where available, Tuberculin Skin Testing (TST) and other investigations.

- When making a diagnosis of TB among HIV infected infants and children, one needs to exclude HIV related fevers, weight loss, systemic and respiratory diseases which may mimic TB. The TST may be negative even in presence of TB disease. Chest X-ray features in PTB are often non-specific and/or similar to those seen in other HIV related lung diseases such as bacterial pneumonia, viral pneumonia, LIP (lymphocytic interstitial pneumonitis), *Pneumocystis Carinii/ Jiroveci* pneumonia, Kaposi's sarcoma, fungal lung disease and pulmonary lymphoma.

- The most important diagnostic clue for detecting TB in HIV infected children is a history of contact with an adult who has infectious TB. Since TB may not have yet been diagnosed in this adult, a prompt evaluation for TB in adults who care for the children is a critical part of the evaluation of the children.

6.2.3 **TB prevention in children**

- Protection of HIV infected infants and children from TB can be achieved through early detection and treatment of adult infectious cases and universal use of BCG at birth and IPT (see chapter 8).
- BCG vaccination is protective against severe forms of TB such as miliary TB and TB meningitis. It should not be given to infants and children with symptomatic HIV infection.

7 INFANT AND YOUNG CHILD FEEDING

Breastfeeding accounts for up to 20% of infections acquired through Mother-To-Child Transmission (MTCT) in the absence of interventions. However, breastfeeding is critical for the survival of the infant. Infants that are not breast-fed are at increased risk of death from malnutrition, diarrhoea and pneumonia.

HIV transmission through breastfeeding can be significantly reduced if a mother breastfeeds her child exclusively and if the mother and the baby receive ARV drugs at the same time. The maximum benefit of breastfeeding in preventing mortality from diarrhoea, pneumonia and malnutrition is in the first 12 months of life. To maximize the benefit of breastfeeding and improve infant survival, while reducing the risk of HIV transmission, South Sudan has adopted use of ART with continued breastfeeding by HIV infected mothers until the infant is 12 months of age. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast-milk can be provided. In the absence of safe and adequate diet to children beyond 12 months of age, breastfeeding should continue.

7.1 KEY MESSAGES DURING PREGNANCY AND BREASTFEEDING

- *Diet:* Add extra meals during pregnancy and breastfeeding; drink adequate fluids; eat plenty of fruits and vegetables; eat foods rich in vitamin C to enhance iron absorption; avoid tea or coffee close to (less than 1 hour) or with meals as this may interfere with absorption of iron; and use iodized salt to prevent pregnancy complications (abortions, miscarriages and stillbirths), fetal growth retardation, and maternal goiter.

- *Recommended medications during pregnancy including*: supplemental iron to prevent anemia; folic acid to prevent fetal brain and spinal cord birth defects; de-worming tablets to treat worms and prevent anemia; and vitamin A capsule (200,000 iu) immediately after delivery or within 8 weeks to help build your baby's immunity.

- *Malaria prevention:* Malaria may cause anemia and premature birth. Mothers should sleep under an insecticide-treated mosquito net; take intermittent preventive treatment (IPT) for malaria as per national guidelines beginning in the second trimester.

- Avoid alcohol, narcotics or tobacco products and medicines that are not prescribed by a trained health care provider.

- *Attend ANC:* **at least eight times** during pregnancy (**New WHO Recommendation**) and always follow your health worker's recommendations. Recent evidence indicates that a higher frequency of antenatal contacts by women and adolescent girls with a health provider is associated with a reduced likelihood of stillbirths.

- *Active promotion of breast feeding initiatives;*
  - Counsel pregnant women on the benefits of breastfeeding and management, importance of adhering to ART regimen, and the risk of MTCT.
  - Counsel on the benefits of exclusive breastfeeding for the first six months regardless of the HIV serological status.
  - Link the mothers to support systems such as mother support groups, lactation clinics on discharge from the hospital or clinic.

- Demonstrate to mothers how to position infants when breastfeeding, and how to maintain lactation should they be separated from their infants. Pay particular attention to prevention of conditions such as cracked nipples, mastitis that increase risk of HIV transmission.

7.2 DURING LABOR AND DELIVERY:

- Mothers should be encouraged to initiate breastfeeding within an hour of birth including cases of caesarian section
- Newborn infants should be fed on only colostrum (the first milk) and not be given pre-lacteal feeds such as glucose, dill/ gripe water, mushroom soup; herbal extracts, etc
- Continue to counsel on breastfeeding on demand, exclusive breastfeeding, ways to enhance breastfeeding

7.3 DURING LACTATION

Recommendations:

- All HIV exposed infants should be exclusively breast fed for the first six months. See Table 7-1
- **Mothers with unknown HIV status** should be offered HIV testing and counseling. Breastfeeding mothers with a negative HIV status should be encouraged to test regularly preferably at a 6 month interval and to practice safer sex. Partner involvement at this stage is encouraged and is an opportunity to provide partner testing if not previously done.
- **Mothers known to be infected with HIV** (and **whose infants are HIV uninfected or of unknown HIV** status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter. Mother with HIV should continue breastfeeding for at least first 12 months of life and can continuebreastfeeding for up to 24 months or longer (similar to the general population) while being fully supported for ART adherence. should then only stop once a nutritionally adequate and safe diet without breast-milk can be provided.
- **Mothers who are known to be HIV uninfected** or whose **HIV status is unknown** should exclusively breastfeed their infants for the first 6 months of life and then introduce appropriate complementary foods while continuing to breastfeed for 24 months or beyond.
- **When infants and young children are known to be HIV infected,** stop ARV prophylaxis and initiate pediatric ART as per the guidelines. Mothers should be counselled to breastfeed exclusively for the first 6 months of life and then introduce appropriate complementary foods while continuing to breastfeed for at least 24 months while being fully supported for ART adherence

- .

Table 7.1: Essential Behaviour for Exclusive Breastfeeding

A mother practices optimal breastfeeding during the first six months when she:
- Initiates breastfeeding within one hour of birth - Feeds the colostrum to the baby - Positions and attaches the infant correctly on the breast - Breastfeeds on demand - Breastfeeds frequently during the day - Breastfeeds during the night - Offers second breast after infant empties the first - Gives only breast milk; gives no water or teas or any other liquids or foods. - Continues breastfeeding when she is sick - Increases breastfeeding frequency during and after infant's illness, including diarrhoea. - Seeks help from a trained health worker or counsellor if she has problems with breastfeeding - Eats sufficient nutritious foods herself and takes supplements as recommended by the health provider

7.4 COMPLEMENTARY FEEDING

- *At 6-12 months*
  - After 6 months of age, appropriate complementary foods should be introduced while continuing to breastfeed until 12 months.
  - The mother should be encouraged to breastfeed as often as the infant wants
- *At 12-24 months*
  - Encourage cessation of breastfeeding for mothers, whose infants are HIV negative at 12 monthsonce a nutritionally adequate and safe diet without breast-milk can be provided.
  - Encourage mothers to feed their children 5 times a day - 3 main meals and 2 extra foods between meals (snacks).
- *12-24 months for infants who are HIV infected*
  - Encourage mothers to continue breastfeeding on demand, day and night up to 24 months and beyond to maintain the baby's health and nutrition.
  - Counsel caregivers to:
    Give 1 extra snack to well children and 1 extra meal (or 2 snacks) at onset of sickness.
    Give 3 extra meals (or 2 extra meals and 1 snack) when sick and losing weight
- *Feeding a child 2– 6 years*
  - Encourage mothers to give a variety of foods prepared from the family meal (each meal should consist of a carbohydrate, protein, vegetables) at least 3 main meals a day.
  - Encourage care givers to give nutritious snacks between meals e.g. a fruit, egg, bread, enriched thick porridge or a glass of milk.

Table 7.2: Essential Behaviour for Complementary Feeding

A mother practices optimal complementary feeding during the period 6-23m of the infant's life when she:
- Starts feeding additional foods to the child at the age of 6 months
- Starts with soft or mushy foods at first that are age appropriate and are not too thin or thick, and gradually shifts to foods of a solid consistency if the child is ready.
- Continues breastfeeding up to two years of age or beyond.
- Offers solid or semi-solid foods 2-3 times per day when child is between 6-8 months of age, and 3-4 times per day after that, and offers nutritious snacks 1 or 2 times per day, as desired.
- Offers a variety of foods, from all the food groups (grains, roots and tubers, legumes and nuts, animal source foods and fruits and vegetables) and increases in variety and quantity as the child grows.
- Practices good hygiene in preparation and storage of complementary foods (including washing hands before and using clean water and utensils).
- Continues breastfeeding and feeding complementary foods during illness.
- Gives the child iron-rich foods such as animal source foods or iron supplements if iron-rich foods are less available.
- Uses feeding times for interacting with the child, to teach and stimulate social development as well as encourage the child to eat.

Additional Messages:

HIV positive mothers who decide to stop breastfeeding at any time should stop gradually. This transition period should be between 1-2 weeks which is not too long to increase exposure and not too short to cause physical and psychological trauma to the mother and baby. Mechanism of transition includes:

- Expressing Breast Milk (BM) and feeding infant/child by cup
- Substituting the expressed BM with suitable replacement feed gradually.
- Replacement feeding (using alternative milk other than breast milk in the first 6 months of life) should be discouraged EXCEPT in extreme circumstances such as: mother absent, deceased, or mentally disabled.

8 MANAGEMENT OF HIV-RELATED DISEASE, TB/HIV CO-INFECTIONS, AND OTHER CO-MORBIDITIES

Opportunistic Infections (OIs) are the most important cause of morbidity and mortality in HIV-infected individuals. Improvement in the recognition, treatment and prevention of these conditions in PLHIV has been shown to reduce morbidity and mortality. Prevention of OIs involves client education, behaviour modification, as well as judicious use of chemoprophylaxis. The most common OIs include tuberculosis (TB), bacterial respiratory tract infections, skin conditions and diarrheal diseases.

This section gives a brief overview on the management of selected OIs, common co-infections, and co-morbidities. Refer to Table 3-5, and national Opportunistic Infections (OI) guidelines for further guidance. Refer to Chapter 9 and National TB & Leprosy guidelines for TB/HIV co-management.

8.1 TUBERCULOSIS AND HIV

8.1.1 Introduction

TB is a major public health problem in South Sudan. According to the WHO estimates for the year 2014: i) the prevalence of TB was 319 cases per 100,000 population, ii) 17,000 people were newly infected with TB, indicating an incidence of 146 new TB cases per 100,000 population. Among PLHIV, tuberculosis (TB) is the most frequent life-threatening opportunistic infection and a leading cause of death. TB is responsible for more than 25% of all deaths among PLHIV. There is paucity of data in the prevalence of HIV/TB coinfection in South Sudan. However, some data from the NTP and a survey carried out in 10 states in 2011, suggested that the prevalence of HIV infection in patients with TB was approximately 15% (13% in 2014).

HIV infection increases the risk of acquiring and developing active TB disease following exposure to *M. tuberculosis*. The risk of new tuberculosis disease in HIV-infected individuals can be lowered, by reducing exposure to TB, using Isoniazid Preventive Therapy (IPT), and provision of anti-retroviral therapy (ART).

Interventions for TB and HIV should be integrated in both TB care and HIV care settings.

- ART for PLHIV with TB should be initiated in the TB care setting, with linkage to on-going HIV care and ART, and transition to the ART clinic after completing TB therapy. This will first be implemented at the referral centers such as JTH, Nzara, Yambio and Yei, and later rolled out to other sites.
- For PLHIV attending HIV care settings who are diagnosed with tuberculosis, TB treatment should be provided in the HIV care settings where the TB diagnosis has also been made.
- Immediate referral is encouraged whenever services are not on site.

Key TB/ HIV interventions:

- Provider initiated HIV testing and counseling (PITC), and other HTS approaches 2.2
- Cotrimoxazole Preventive therapy and other General HIV care – 3.6
- The 3 'I's for HIV/TB
  - Intensified Case Finding (ICF) 9.2
  - Infection Control (IC) 9.4

- Isoniazid Preventive therapy (IPT) 9.3
- Anti-TB treatment – see Table 3.5
- Antiretroviral therapy - see Chapter 4 and 9.6

NB: Special attention is given to Multiple Drug Resistant TB (MDR-TB) and TB-HIV co-infection in children

8.1.2 Intensified Case Finding for TB

- TB screening among PLHIV should be done at **every visit** using a clinical algorithm as shown in Figure 12-1 and Figure 12-2
- Evaluate clients for TB using sputum smear for acid-fast bacilli (AAFB), chest X-ray, etc. only if:
  - An adult/adolescent has *current cough, fever, weight loss, or night sweats.*
  - A child has any one of the following symptoms of *current cough, fever, poor weight gain, or close contact with a TB client.* See 8.8.2 on TB diagnosis in children.
- Where Xpert MTB/RIF test is available, it should be used as the initial TB diagnostic test. The country should plan to procure and deploy adequate Xpert MTB/RIF platforms to meet the national requirements.
- Sputum smear-negative TB is common in HIV-infected adults and children, particularly those with advanced immunodeficiency and non-cavitary disease.
- If the Xpert machine is accessible and the test can be carried out reasonably without delay, then the test may show that:
  - There is no active TB, then the patient should be managed for other possible infectious diseases in the HIV/AIDS site if there is no need for hospitalization;
  - There is an active TB:
    - If the test does not show any rifampicin resistance then the PLHIV will be treated and managed for active TB in line with the NTP guidelines;
    - If the test shows a rifampicin resistance then the patient must be urgently referred to the appropriate health facility for treatment and management in line with the NTP guidelines on PMDT;
- If Xpert machine is not accessible or Xpert testing cannot be carried out, then the management should be undertaken as follows:
  - If there are one or more of the following danger signs:
    - Unable to walk unaided;
    - Respiratory rate more than 30 per minute;
    - Fever > 39oC;
    - Pulse rate > 120 per minute
- Then, the clinical condition of the patient should be considered as severe, and the patient should be immediately referred to hospital for appropriate management (See NTP Guidelines). For those confirmed with TB, see treatment of active TB in 9.5 below.

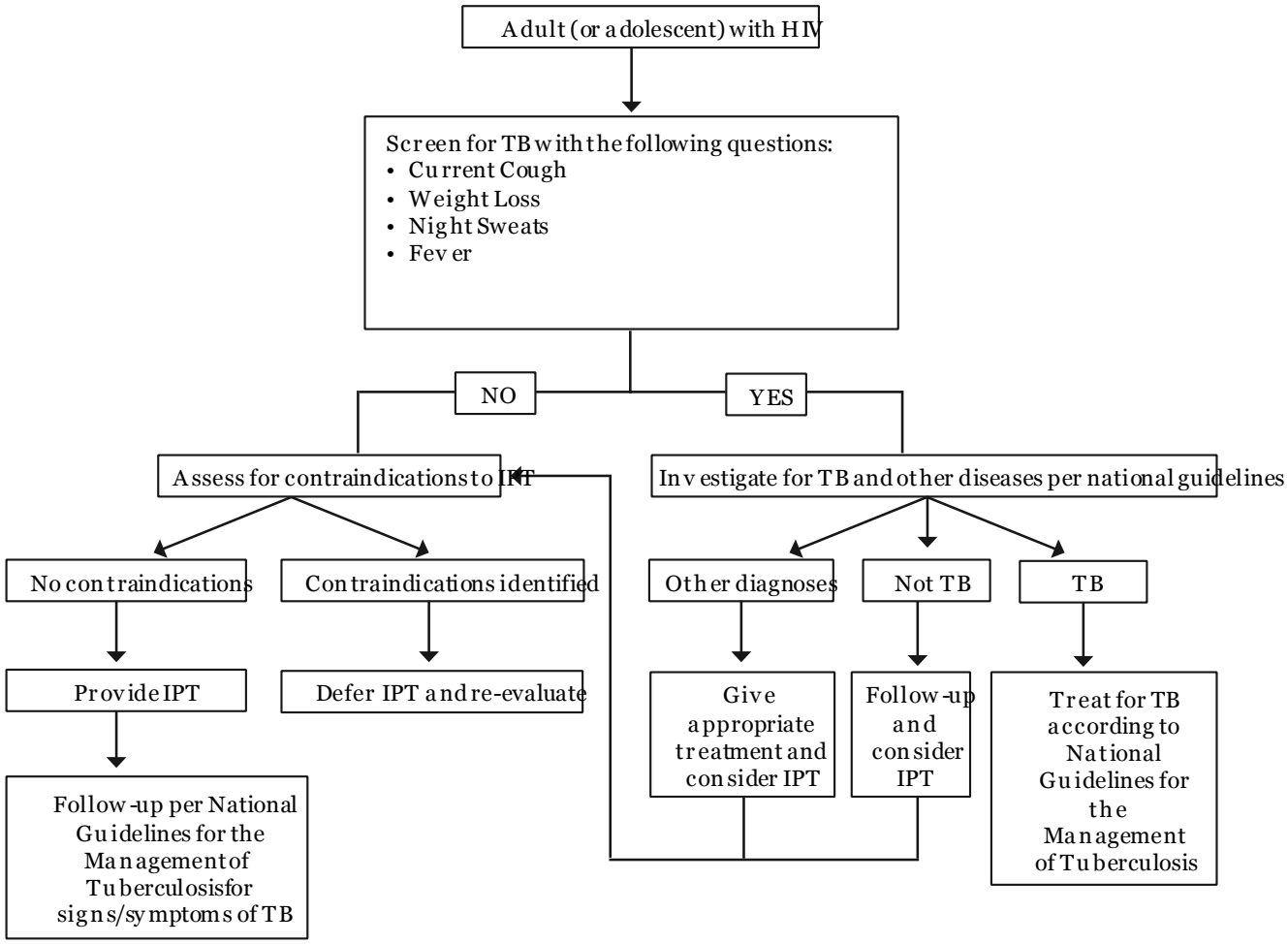
8.1.3 Isoniazid Preventive Therapy (IPT)

Studies have shown that Isoniazid Preventive Therapy reduces TB incidence by about 60% in HIV-infected individuals. Providing IPT to PLHIV **does not** increase the risk of developing isoniazid-resistant TB.

- South Sudan will introduce IPT to be used in combination with ART to reduce the risk of TB disease among PLHIV

See figure 8.1 below for algorithm for TB screening and IPT among adults and adolescents living with HIV.

Figure 8.1: Algorithm for TB screening and TB-IPT among adults and adolescents with HIV



Following the strict criteria for TB-IPT eligibility, along with proper monitoring and follow-up, will minimise these risks.
Patients who have signs and symptoms of TB should never be started on TB-IPT.

To be eligible for TB-IPT the HIV-positive adults and adolescents must:

- Have no symptoms or signs of TB – such as current cough, fever, weight loss, night sweats (*NB: TB-IPT should not be given to patients who are unwell and where there is no explanation of the illness*)

- No current history of alcohol misuse
- Have no history of active liver disease, liver insufficiency, or jaundice
- Have no history of hypersensitivity to isoniazid
- Have no history of exfoliative dermatitis
- Be motivated for TB-IPT after being educated about the benefits, possible side-effects and risks.

DO NOT GIVE IPT TO PATIENTS ON ART FOR MORE THAN 3 YEARS WHO ARE DOING WELL (CD4 >450)

In addition HIV-positive persons who are close contacts of patients with infectious TB should receive IPT even if they have completed a previous course of IPT.

Precautions:

- Persons starting TB-IPT must be informed about the possible side-effects of Isoniazid. Isoniazid-induced hepatitis will present with nausea and vomiting accompanied by passing dark urine and/or generalised itching. Peripheral neuropathy manifests as burning, numbness or tingling in feet and/or hands. If these symptoms develop, the patient must stop taking isoniazid and report immediately to the nearest health facility for assessment and management
- Health workers should always check clients for signs and symptoms of hepatitis, neuropathy and skin itching when they come to collect isoniazid.

TB –IPT regimen for adults and adolescents:

- Isoniazid is given daily for a period of 6 months at a dosage of 300mg/per day.
- Pyridoxine 25 mg daily is administered with the isoniazid to decrease the risk of neuropathy.
- Temporary TB - IPT interruption, although not ideal, is acceptable, as long as the patient completes a total of 9 months of treatment within a 12 month period. In non-adherent patients, prophylaxis should be discontinued and no further efforts should be made to restart TB - IPT.

Recommendations for Isoniazid Preventive Therapy for Children:

- Children living with HIV who do not have poor weight gain, fever or current cough are unlikely to have active TB.
- Children living with HIV who have **poor weight gain, fever or current cough** or **contact history with a TB case** may have TB and should be evaluated for TB and other conditions. If the evaluation shows no TB, they should be offered IPT regardless of their age.
- Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening and have no contact with a TB case should receive six months of IPT as part of a comprehensive package of HIV prevention and care.
- In children living with HIV who are less than 12 months of age, only those who have contact with a TB case and who are evaluated for TB (using investigations) should receive six months of IPT if the evaluation shows no TB disease.
- All children living with HIV, after successful completion of treatment for TB, should receive IPT for an additional six months .
- Use of IPT is recommended for children of breast feeding mothers with active TB. All HIV-infected infants and children exposed to TB through household contacts, but with no evidence of active

disease, should begin Isoniazid preventive therapy (IPT). Before giving the INH prophylaxis, confirm that the child has no ACTIVE TB disease (does not have cough, fever, poor weight gain).

IPT dose for children:

- The recommended dose of Isoniazid (INH) for preventive therapy in HIV co-infection is 10 mg/kg/daily for 6 months.

Follow up of patients on IPT

Review patients on IPT as appropriate and review/reinforce adherence
• Screen for active TB during each clinic visit
• Update TB card at every visit and document outcome on completion of therapy
• Monitor for INH adverse effects (co-administer with pyridoxine to minimize adverse events)
- IPT should be discontinued in symptomatic patients with ALT/AST more than three times the upper limits of normal

8.1.4 TB Infection Control (IC)

Each health facility should have a TB infection control plan to reduce transmission of TB in the health care setting and actively look out for development of TB among the workers. Tuberculosis IC plans need to be developed in line with the current *TB Infection Control Guidelines for South Sudan*. The TB Infection Control Guidelines should also be used for:

- Development of SOPs to triage and identify TB suspects, ensure separation of suspects from cases, promote good cough etiquette and respiratory hygiene, and rapid TB diagnosis and treatment.
- Provision of information to Health Care Workers TB prevention and care, protective equipment such as respiratory masks, and those living with HIV should be offered ART as well as possible relocation to lower risk areas.
- Provision of information on environmental measures such as proper ventilation and lighting.

8.1.5 Treatment of Active Tuberculosis in HIV-Infected Clients

- The principles for treatment of active tuberculosis (TB) disease in HIV-infected patients are the same as those for HIV-uninfected clients .
- Patients co-infected with TB and HIV should receive at least 6 months of a rifampicin- containing anti-TB treatment regimen. Use standard regimen TB regimen 2HERZ/4RH). See Table 3-5
- TB treatment may be provided in either the HIV clinic or the TB clinic
  - Initiate ART as per guidelines taking into consideration the drug interactions. ART should be started within 8 weeks of TB diagnosis or within 2 weeks for persons with advanced immune suppression. See 4.4.1
- Cotrimoxazole prophylaxis should be continued
- Add pyridoxine 50mg daily (adults) in view of the risk of peripheral neuropathy associated with INH.

8.1.6 Antiretroviral Therapy in Patients with Active Tuberculosis

Key recommendations:

- PLHIV diagnosed with active TB should be started on anti-TB therapy immediately
- All PLHIV diagnosed with active TB should be treated with ART within 2 weeks and not later than 8 weeks of anti-TB initiation ((including those with drug resistant TB) regardless of CD4 count.
- The recommended first line ART regimen for adult and adolescent ARV drug-naïve clients with TB/HIV who require ART while still on rifampicin is: TDF + 3TC + EFV. See Table 4-6
- For adults and children diagnosed with TB while on ART (1st and 2nd line), see regimen changes in 4.4.1
- Immune reconstitution inflammatory syndrome (IRIS) may occur after initiation of ART. Both ART and TB treatment should be continued while managing IRIS 4.6.2
- Treatment support, which can include directly observed therapy (DOT) of TB treatment, is strongly recommended for HIV-infected patients with active TB disease.

Concurrent treatment of TB and HIV is potentially complicated by high pill burden, additive toxicities, drug interactions, and the potential for development of IRIS.

8.1.7 Drug Interaction Considerations

- Rifampicin induces liver enzymes thus reducing the serum levels of most ARV drugs including all PIs, and the NNRTIs especially NVP. Rifampicin is not recommended for routine use in combination with PIs and efavirenz is the preferred option in clients on this treatment. However, in circumstances where a PI has to be used e.g. for clients diagnosed with TB while on second line ART, LPV/r can be used with rifampicin-containing regimens, but requires dose boosting. See 4.4.1
- Rifabutin, a weaker enzyme inducer, is an alternative to rifampicin in adults. When used in place of rifampicin, the ART regimens need not be adjusted
- Rifampicin interferes with combined oral contraceptive pills, progestin-only pills, and Norplant rendering them less effective. The most effective family planning option would be Depo-Provera along with condoms to minimise risk of HIV and STI transmission.

8.1.8 ART regimens for adults and children with TB

Not all antiretrovirals should be used in combination with rifampicin. Rifampicin increases metabolism of and hence lowers the blood levels of protease inhibitors by approximately 80%, of nevirapine by 30-50%, and of efavirenz by 25%. Given concurrently with rifampicin, nevirapine is probably not as effective and nevirapine resistance can be selected, which may compromise future ARV choices. At standard doses, efavirenz remains effective in the presence of rifampicin. For this reason, efavirenz is preferred for use in children needing rifampicin-based TB treatment if they are at least 3 years old, 10 kg and have not had previous nevirapine for PMTCT.

If TB is diagnosed before starting ART:

- Start TB treatment (add pyridoxine to reduce risk of INH-induced neuropathy)
- Introduce ART within 2-8 weeks of initiating TB therapy i.e. ART should be started within 8 weeks of TB diagnosis or within 2 weeks for persons with advanced immune suppression:
    - For adults: TDF + 3TC + EFV
    - For children: see Table 9-1 below

For children diagnosed with TB while on 1st ART:

- Continue ART throughout TB treatment
- See table 8-1 for age-appropriate drug options.

Adults and children diagnosed with TB while on second line ARV regimen:

- For adults, the lopinavir/ ritonavir dose should be doubled (from 2 tablets 12 hourly to 4 tablets 12 hourly) while the client is on rifampicin-based TB treatment. Monitor ALT monthly. Reduce lopinavir/ ritonavir to standard dose 2 weeks after TB treatment is completed. For children, consider adding RTV to achieve the full therapeutic dose i.e. increase RTV until it reaches the same dose as LPV in a ratio of 1:1.

Table 8.1: ART regimens for children and adolescents

Recommended regimens for children and adolescents initiating ART while on TB treatment		
Younger than 3 years		Triple NRTI (AZT + 3TC + ABC)
3 years and older		Two NRTIs + EFV or Triple NRTI (AZT + 3TC + ABC)
Recommended regimen for children and infants initiating TB treatment while receiving ART		
Child on standard NNRTI-based regimen (two NRTIs + EFV or NVP)	Younger than 3 years	Continue NVP, ensuring that the dose is 200 mg/m2 or Triple NRTI (AZT + 3TC + ABC)c
	3 years and older	If the child is receiving EFV, continue the same regimen If the child is receiving NVP, substitute with EFV or Triple NRTI (AZT + 3TC + ABC)c
Recommended regimen for children and infants initiating TB treatment while receiving ART		
Child on standard PI-based regimen (two NRTIs + LPV/r)	Younger than 3 years	Triple NRTI (AZT + 3TC + ABC) or Continue LPV/r, adding RTV to achieve the full therapeutic dosed
	3 years and older	If the child has no history of failure of an NNRTI-based regimen: Substitute with EFV or Triple NRTI (AZT + 3TC + ABC) or Continue LPV/r, adding RTV to achieve the full therapeutic dosed If the child has a history of failure of an NNRTI-based regimen: Triple NRTI (AZT + 3TC + ABC) or Continue LPV/r, adding RTV to achieve the full therapeutic dosed Consider consultation with experts for constructing a second- line regimen
• These guidelines recommend use of triple-nucleoside therapy for children who require TB treatment, with substitution of a standard first line regimen upon completion of TB treatment • ARV drug substitutions should be age-appropriate		

8.1.9 **Anti-Tuberculosis/Antiretroviral Drug Toxicities**

- ARV agents and TB drugs, particularly INH, rifampicin, and pyrazinamide, can cause drug-induced hepatitis. Clients receiving potentially hepatotoxic drugs e.g. NVP should be monitored frequently for clinical symptoms and signs of hepatitis and have laboratory monitoring for hepatotoxicity.
- Peripheral neuropathy can occur with administration of INH or may be a manifestation of HIV infection. All clients receiving INH also should receive supplemental pyridoxine to reduce the risk of peripheral neuropathy.

8.1.10 **Immune reconstitution inflammatory syndrome (IRIS) with TB and ART**

- IRIS is more common in clients with advanced HIV disease (particularly those with a CD4 count less than 50 cells/mm^3 or 10% in children) in the first few weeks of starting HAART. This is due to unmasking of a previously occult opportunistic infection by the improving immune function. Previously diagnosed disease may also get worse (paradoxical IRIS).
- Clients with mild or moderately severe IRIS can be managed symptomatically. Those with severe IRIS can be treated with corticosteroids.
- In the presence of IRIS, neither TB therapy nor ART should be stopped because both therapies are necessary for the long-term health of the client.

8.1.11 **Multi-Drug Resistant (MDR) TB and HIV**

- MDR-TB is defined as TB that is resistant to at least isoniazid and rifampicin
- PLHIV with suspected MDR-TB should have drug sensitivity testing performed. Where possible, use Xpert MTB/RIF (GeneXpert) since this is more sensitive for detecting TB among PLHIV and rapidly detects rifampicin resistance.
- All clients with HIV and MDR-TB should be initiated on ART irrespective of CD4 counts
- Refer clients to specialized TB treatment centers for specific MDR anti-TB medication

8.2 MALARIA AND HIV

- PLHIV in malaria endemic regions are at high risk of complications of malaria. Infants, children under five years of age, and pregnant women are at particular risk of severe and complicated malaria.
- Key malaria control interventions include prompt and effective treatment, use of insecticide treated mosquito nets (ITNs), indoor residual spraying (IRS) to control the vector mosquitoes, and intermittent preventive treatment during pregnancy.
- PLHIV (as for the general population) should routinely use insecticide-treated bed nets or have access to indoor residual spraying to reduce their risk of exposure to malaria.
- Treatment or intermittent preventive treatment with sulfadoxine-pyrimethamine should not be given to clients with HIV receiving cotrimoxazole prophylaxis.
- PLHIV who develop malaria should receive prompt and effective anti-malaria treatment using artemisinin based combination therapies (ACTs)
- Refer to *National Malaria treatment guidelines* for more detail.

8.3 HEPATITIS B AND C

- Viral hepatitis is an increasing cause of morbidity and mortality among PLHIV including those on ART. The sero-prevalence of hepatitis B virus infection in South Sudan is estimated at 12.8% in the general population. Among the PLHIV, 11.8% are co-infected with HBV (program data 2012).
- Patients on ART are at risk for hepatotoxicity due to ART regimens in addition to the liver damage caused by chronic HBV co-infection. Patients may also experience accelerated liver damage following immune reconstitution (HBV-associated IRIS).
- All PLHIV should be assessed at enrolment to care for hepatitis B surface antigen. All patients in whom HBsAg is positive shall have ALT at ART initiation, 2, 6, and 12 weeks, 6 months and 6-monthly thereafter if the repeat HBsAg result remains positive at 6 months. Elevated ALT arising during therapy may have many causes, and needs to be carefully evaluated for each patient.
- Clients co-infected with HIV and HBV (requiring treatment for their HBV infection) should be initiated on ART immediately irrespective of CD4 count or clinical stage using a TDF/3TC (or FTC) containing regimen. Lamivudine (3TC) and tenofovir (TDF), have antiviral effects on HBV and should be used together to effectively suppress HBV replication.
- Patients with HIV/HBV coinfection on ART require close monitoring for clinical signs and symptoms of hepatotoxicity and laboratory monitoring for ALT.
- Patients needing second line should be screened for HBsAg and if positive, TDF should be continued as part of the second line regimen
- Initiating ART among PLHIV and hepatitis C should follow the same principles as for the general population of people living with HIV.

8.4 PREVENTION AND TREATMENT OF SEXUALLY TRANSMITTED INFECTIONS (STIS)

- HIV is a sexually transmitted infection with the majority of adults acquiring the infection sexually.
- STIs are important co-factors in the transmission of HIV infection; the presence of either inflammatory or ulcerative STIs facilitates both the acquisition and transmission of HIV infection.
- All health care settings should deliver HIV prevention services including prevention counseling, routine PITC, access to condoms, RPR or VDRL testing for syphilis, and syndromic screening and treatment of other STIs. For more detail on syndromic management of STIs refer to national STI guidelines.

8.5 CRYPTOCOCCUS NEOFORMANS: SCREENING AND TREATMENT

Cryptococcal meningitis is a major cause of morbidity and mortality even after ART has been initiated. Early diagnosis and identification of asymptomatic patients and provision of presumptive therapy for patients with a positive cryptococcal antigen test remarkably improves outcomes for these patients. . Prevalence of cryptococcaemia is higher at low CD4 counts. NB: Data on prevalence of cryptoccocal disease in South Sudan is currently unavailable.

- Health workers should screen all HIV-positive adults with CD4 count <100 cells/mm^3 for cryptococcal antigenaemia
- *Screening for Cryptococcus neoformans and pre-emptive therapy for asymptomatic infection:*
    - Where test kits are available (lateral flow assay - LFA), ART-naive adults with a CD4 count of less than 100 cells/mm3 should have routine serum or plasma *cryptococcus neoformans* antigen (CrAg) screening performed using LFA prior to ART initiation. CrAg-positive adults

should be treated with pre-emptive antifungal therapy. Treatment of asymptomatic CrAg positive infection is by use of fluconazole 800 mg daily for 2 weeks followed by 400mg daily for 8 weeks. Initiate ART after 2 weeks of starting fluconazole pre-emptive treatment.

- *Treatment of symptomatic cryptococcal disease:*
  - Immediate ART is not recommended in PLHIV with cryptococcal meningitis due to the high risk of life threatening IRIS
  - In HIV-infected clients with recent diagnosis of cryptococcal diseases, ART initiation should be deferred until there is evidence of sustained clinical response to antifungal therapy (2-4 weeks of treatment with Amphotericin B containing regimens and 4-6 weeks with high dose Fluconazole containing regimens)
  - Patients diagnosed with and treated for cryptococcal meningitis should receive secondary prophylaxis with fluconazole 200mg daily for at least one year. This should only be stopped after 2 successive CD4 count results at least 6 months apart are >100 cells/mm3 and a suppressed viral load.

8.6 PALLIATIVE CARE AND OTHER CO-MORBIDITIES

- *Palliative care- symptom management and end-of-life care:* PLHIV may experience various forms of pain and other discomfort. Care providers should identify and treat the underlying cause when possible, while controlling the pain using the WHO analgesic ladder.
  - Step 1 mild pain: Non-opioid (e.g. paracetamol)+/- adjuvant
    Step 2 for moderate pain: Weak opioid (codeine phosphate) +/- non-opioid +/- adjuvant
    Step 3 for severe pain: Strong opioid (e.g. morphine) +/- non-opioid +/- adjuvant

Adjuvants include:

- **NSAIDs** (non-steroidal anti-inflammatory drugs): can be used as co-analgesics and are useful in reducing inflammation
- T**ricyclic anti-depressants** - e.g. Amitriptyline, useful in treatment of burning nerve pain e.g. that due to post herpetic neuralgia
- **Anticonvulsant medications** – e.g. Carbamazepine, phenytoin useful in treatment of stabbing type nerve pain

See http://www.who.int/cancer/palliative/painladder/en/ for more detail

8.7 NON-COMMUNICABLE DISEASES:

- PLHIV are at increased risk of developing a range of non-communicable diseases (NCDs), including cardiovascular disease, diabetes, chronic lung disease and some types of cancer such as Kaposi's sarcoma, cervical cancer and non-Hodgkin's lymphoma. Blood pressure should be routinely monitored for all PLHIV.
- *Cervical cancer*: In many African countries, cervical cancer is the number one cancer causing death in women. HIV infected women are more likely to develop both pre-invasive and invasive cervical cancer and have a poorer outcome than their HIV negative counterparts. HIV Infected sexually active women should be screened for cervical cancer annually. The screening programme should be an integral part of HIV care. South Sudan

ART programme in collaboration with the Reproductive Health programme will adopt simple and cost-effective screening interventions such as visual inspection using acetic acid (VIA) methods and refer clients with abnormal results for further evaluation and management at designated health facilities where such services are available; this takes into account the lack of infrastructure to support more complex screening systems.

- *Mental Health:* PLHIV and their caregivers may have a wide range of mental health needs. The most common mental health comorbidities among PLHIV include depression, anxiety, dementia and other cognitive disorders and substance use disorders.
    - PLHIV with depression are less likely to achieve optimal treatment adherence and hence poor retention in care
    - Health workers should assess for and manage depression as part of HIV care services for all individuals living with HIV

NB: Refer to the relevant national guidelines for detailed management of the above conditions.

Table 8.2: Common opportunistic infections and management

	Clinical Signs	Diagnosis / investigations	Primary Management	Secondary Management
Oral candidiasis	Multiple whitish or red patches anywhere inside mouth		**Nystatin oral suspension** Treat for 7-14 days; keep in mouth as long as possible; apply to mother's nipples if breastfeeding **Adult:** 4ml 6-hourly **Child:** 1ml 6-hourly	*Secondary Management* 3 Alternative treatment options if severe or no response to nystatin: **Fluconazole tablets** Treat for 14 days **Adult:** 100 mg 24-hourly **Child:** 6mg/kg on day 1 then 3mg/kg **Ketoconazole tablets** Do not give with NVP **Adult:** 200mg 24-hourly for 14 days **Child:** 5mg/kg 24-hourly for 14 days **Miconazole gum patch or gel** Use for children > 4 months and adults Treat with 1 patch 24-hourly for 14 days
Oesophageal candidiasis	Retrosternal pain on swallowing; infants & children refusing to eat; +/- oral thrush		**Fluconazole tablets** Treat for 14 days **Adult:** 200mg 24-hourly for 14 days **Child:** 12mg/kg day one then 6mg/kg	
Chronic diarrhoea	More than 3 loose non-bloody motions per 24 hours for more than 2 weeks	Based on response to stepwise empirical treatment: **Step 1** treats: isospora, cyclospora, bacterial **Step 2** treats: giardia, clostridium, amoeba, microspora. **Step 3** treats: microspora., helminths	**ORS** Drink 5ml/kg 4-hourly and after every episode of diarrhoea. Drink 5ml doses every 5 min if vomiting occurs **IV Fluids** If severe de-hydration **Loperamide tablets** **Adult:** 2mg after every loose stool (max 12mg in 24 hours) **Child:** Do NOT use for children **Step 1: Cotrimoxazole tablets** **Adult:** 960mg 8-hourly for 7 days **Child:** 80 mg/kg 8-hourly for 7 days **Zinc tablets** Give for 10 days **Child 0-6mths:** 10 mg 24-hourly **Child 6mths – 5 yrs:** 20 mg 24-hourly	Continue with step 2 and 3 if no improvement **Step 2: Metronidazole tablets** **Adult:** 800mg 8-hourly for 7 days **Child:** 15mg/kg 8-hourly for 7 days **Step 3: Albendazole tablets** **Adult:** 400mg 12-hourly for 14 days

	Clinical Signs	*Diagnosis / investigations*	*Primary Management*	*Secondary Management*
TB	Cough (of any duration), fever, weight loss, and night sweats are most predictive. PLHIV may not have productive cough. Children may have failure to thrive; Extra - pulmonary TB signs and symptoms variable, but can include enlarged lymph nodes; meningeal signs	2x sputum for AFB and Xpert MTB/Rif (where available); CXR if smear-negative; fine needle aspiration nodes (for microscopy); pleural tap for biochemistry: straw coloured effusion; lumbar puncture: CSF for biochemistry, microscopy, Xpert and mycobacterial culture. **/ TB contacts in household should be assessed for symptoms; if symptoms present, diagnostic testing as above.**	**1st Line TB treatment** **New smear-positive or negative PTB:** Intensive phase: 2 RHZE Continuation phase: 4 RH **TB Meningitis:** Intensive phase: 2 SRHZ Continuation phase: 6 RH	**Relapse/ return after default/ treatment failure/ recurrent TB. Important to obtain Xpert MTB/Rif and mycobacterial culture and DST to diagnose MDR** Admit for Intensive phase: 2 SHRZE 1 RHZE (in hospital) Continuation phase: 5 RHE **Chronic/MDR-TB** Specialized treatment
Cervical cancer	No early symptoms therefore active screening needed; abnormal vaginal discharge	**Acetic acid visualization (VIA)** Use good light source Expose cervix with cusco speculum, visualise cervix after washing for 2 minutes with a large cotton swab immersed in 4% acetic acid	**Cryotherapy/ Surgical, depending on stage**	
Herpes zoster (Shingles)	Grouped blisters in one patch; intense pain /burning; +/- fever; +/- body pains; lesions do not usually cross the body's mid-line		**Analgesic Ladder** Rigorous pain control **Acyclovir tablets** Must be started before blisters burst **Adult:** 800mg 5 times per day for 7 days **Child:** 20 mg/kg 8-hourly for 7 days If face affected: Refer to Eye specialist Monitor for secondary bacterial infection	
Pruritic papular eruptions	Severe itching, evenly distributed normal or dark-coloured papules on trunk, arms or legs, often scratch-lesions		**Calamine Lotion** **Antihistamines**	**Corticosteroid cream or tablets** **Metronidazole tablets** 250mg 12-hourly for 7-14 days
Seborrhoeic dermatitis	Greasy, scaly rash in axilla, groin, scalp, neck, face		Clotrimazole or Miconazole cream / ointment	**Ketoconazole tablets** 200 mg twice daily for 7 days
Tinea corporis / cruris / pedis	Round reddened plaques with scaly edge in multiple sites,		**Whitfield's ointment** **Clotrimazole cream or Gentian-Violet paint** Apply twice daily for 3-4 weeks	**Griseofulvin tablets** **Adult:** 500 mg 12-hourly for 4-6 weeks **Child:** 20mg/kg per day for 4-6 weeks

	Clinical Signs	*Diagnosis / investigations*	*Primary Management*	*Secondary Management*
	poss. Widespread			
Pneumocystis carinii (jiroveci) pneumonia (PCP)	Extreme shortness of breath; dry cough; +/- fever Severe pneumonia in infants <12 months	**O_2 saturation**: hypoxia **CXR:** Diffuse interstitial infiltrates or hyperinflation; bats wing shadow Treat for empirically for PCP any HIV exposed or confirmed infected infant presenting with severe pneumonia	**Admit** **Oxygen** **Cotrimoxazole tablets** **Adult:** 4 x 480mg 8-hourly for 21 days **Child:** 80mg/kg 8-hourly for 21 days Lifelong maintenance (CPT) IV Cotrimoxazole if unable to swallow and NGT impossible to place **Prednisolone tablets:** Give 15-30 minutes before cotrimoxazole **Adult:** 8 tablets 12-hourly for 5 days 8 tablet 24-hourly for 5 days 4 tablets 24-hourly for 11 days **Child:** 2mg/kg 24-hourly for 7 days 1mg/kg 24-hourly for 7 days 0.5mg/kg 24-hourly for 7 days	**Clindamycin** 300mg 6-hourly for 3 weeks + **Primaquine** 30mg 24-hourly for 3 weeks
Cryptococcal meningitis Refer to 3.5.4 for screening to prevent cryptococcal meningitis)	Slow onset severe headache; confusion; convulsions; +/- fever; +/- neck stiffness	**CSF** India ink stain; **CrAg:** cryptococcal antigen in serum or CSF	**Admit** Therapeutic spinal tap (up to 20ml per puncture) **Fluconazole tablets** **Adult:** 1200mg 24-hourly for 14 days 400mg 24-hourly for 42 days 200mg 24-hourly for life **Child:** 12mg/kg 24-hourly for 2 weeks 6mg/kg 24-hourly for life	**Amphotericin B** (Specialized sites only) **Adult and Child:** 0.7-1mg/kg IV over 6 hours 24-hourly for 14 days **Fluconazole tablets** **Adult:** 400mg 24-hourly for 42 days 200mg 24-hourly for life **Child:** 6mg/kg 24-hourly for life For asymptomatic infection see 3.5.3
Pneumonia	Productive cough; chest pain; fever; tachypnoea / dyspnoea	***Diagnosis / investigations*** Infiltrations on CXR Rule out tuberculosis	Child: Mild: Tachypnoea but no dyspnoea Adult: Mild to moderate presentation: **Amoxicillin tablets** 500mg 8-hourly for 5 days **Doxycycline or Erythromycin if no response**	Severe presentation: **Chloramphenicol + Benzyl Penicillin** **Add Gentamycin if no response**
Sepsis	Severe illness; fever (can be absent, especially in children); fast heart rate; fast breathing	+/- Malaria parasites; do not rule out sepsis if malaria parasites are seen; blood culture for culture and sensitivity (if available)	**Health Centre Level:** Immediate presumptive treatment Referral to hospital Child: **Benzyl Pen** 50,000 IU/kg IV or IM stat + **Gentamycin** 7.5mg/kg slow IV / IM stat + **Quinine** 10mg/kg IM stat Adult: **Chloramphenicol** 1g IV or IM stat + **Gentamycin** 240mg slow IV or IM stat +	**Health Centre Level:** Immediate presumptive treatment Referral to hospital Child: **Benzyl Pen** 50,000 IU/kg IV or IM stat + **Gentamycin** 7.5mg/kg slow IV / IM stat + **Quinine** 10mg/kg IM stat Adult: **Chloramphenicol** 1g IV or IM stat + **Gentamycin** 240mg slow IV or IM stat +

	Clinical Signs	*Diagnosis / investigations*	*Primary Management*	*Secondary Management*
			Quinine 1200mg IV in 5% dextrose over 4 hours	**Quinine** 1200mg IV in 5% dextrose over 4 Hours
Toxoplasmosis	Focal weakness, headache , confusion fever, seizures	**Clinical** **CT / MRI –** mass lesion	Preferred Adult: **pyrimethamine** 75 mg od **+** **sulfadiazine** 1.5gm 6 hourly + **leucovorin** 10-25mg od for 6 weeks Then maintenance therapy	**Option 2:** **Pyrimethamine 75 mg od + clindamycin 600mg qid + leucovorin for 10-25mg od for 6 weeks** *or* **TMP-SMX (TMP 5 mg/kg and SMX 25 mg/kg)** IV or PO BID for 6 weeks
Kaposi sarcoma	Single or multiple purple patches or nodes, mainly mouth, skin, conjunctiva, lung, GI tract; +/- enlarged nodes; +/- Oedema	Usually clear picture; children often present with lymphadenopathy only; consider KS even without skin or oral lesions if no response to EPTB therapy within 4 weeks	For all clients : **Analgesia** **Symptomatic treatment** **ART** For KS stage T0 (skin KS without oedema): **Delayed chemotherapy** if no improvement after 3 months on ART For KS stage T1 (KS in mouth or internal organs, nodular skin KS, skin KS with oedema): **Immediate chemotherapy** Contraindications for chemotherapy: Severe PN; Hb<10g/dl; platelet count <50/mm3; jaundice; pregnancy **1st Line: Vincristine** Each cycle consists of 6 doses; ensure strictly IV injection as infiltration causes burns; document therapy and response in health passport; examine for recurrence at every visit **Adult:** 2mg vincristine IV **Child:** 0.05 mg/kg vincristine IV (max 2mg) Review after every cycle: • Severe neuropathy / constipation: stop • Lesions cleared: stop • Good response but residual lesions: continue next cycle • Poor response: Start 2nd line chemotherapy 1) Initial cycle: 1 dose every 7 days for 6 weeks 2) 2) Second cycle: 1 dose every 14 days for 12 weeks 3) Final cycle: 1 dose every 28 days for 6 months	**2nd Line: Vincristine + Bleomycin** Cumulative max. lifetime dose for Bleomycin is 400 units for adults and 17 doses for children; stop bleomycin immediately if any sign for lung fibrosis (incl. cough, shortness of breath) are seen; give one combined dose every 14 days until cumulative max. dose is reached or until response is achieved; refer for 3rd line chemotherapy (doxorubicin) if poor response **Adult:** 15 units bleomycin IM / IV / SC **plus** 2mg vincristine IV **Child:** 0.5 mg/kg bleomycin IM **plus** 0.05 mg/kg vincristine IV (max 2mg)

8.8 COTRIMOXAZOLE PREVENTIVE THERAPY (CPT)

Cotrimoxazole is effective against common bacterial infections, including bacterial pneumonia, septicemia; diarrhoea including that caused by *Isospora belli; toxoplasmosis; Pneumocystis Carinii (jiroveci) pneumonia (PCP);* and malaria.

- All PLHIV including those on ART, regardless of age, or immunological status (CD4 count), should be given cotrimoxazole unless contraindicated. This includes all PLHIV diagnosed with TB.
- *Where CPT is contraindicated, give dapsone 100 mg OD or 50 mg BID in adults. Paediatric dose is 1 mg/kg of body weight per day*
- In HIV-exposed infants, CPT should be initiated at 6 weeks after birth and continued until the risk of HIV transmission is excluded (breast feeding has ended and infant is confirmed HIV negative).
- Do not give Sulfadoxine – Pyrimethamine (SP) to HIV infected pregnant women on CPT
- *See below dosing chart for cotrimoxazole and toxicity grading.*

Table 8.3: Dosing of cotrimoxazole in HIV-exposed infants, HIV-infected children and adults

Daily dose for age	Child tablet (100mg/20mg)	Single strength adults tablet (400mg/80mg)	Double Strength adult tablet (800mg/160mg)
Child 6wk-6mo:	1 tab od	¼ tab od	
6mo-5y: 2 tablets daily	2 tabs od	½ tab od	
6 months – 14 years		One tablet od	½ tablet od
Adult		Two tablets od	1 tablet daily

Table 8.4: Cotrimoxazole toxicity grading

Toxicity	Clinical description	Recommendation
GRADE 1	Erythema	Continue CPT with careful and repeated observation and follow-up. Provide symptomatic treatment, such as antihistamines, if available
GRADE 2	Diffuse maculopapular rash	
GRADE 3	Vesiculation, mucosal ulceration	CPT should be discontinued until the adverse effect has completely resolved (usually two weeks), and then reintroduction or desensitization can be considered
GRADE 4	Exfoliative dermatitis, Stevens-Johnson syndrome or erythema multiforme, moist desquamation	Co-trimoxazole should be permanently discontinued

8.9 PREVENTION WITH POSITIVES (POSITIVE HEALTH, DIGNITY, & PREVENTION)

At every visit, assess and counsel for;

- High risk sexual activity
- Partners' and children's HIV status
- Disclosure to partner /guardian / treatment supporter
- Signs and symptoms of STIs
- Pregnancy status
- Adherence to ART and other medications
- Abuse of alcohol and other substances

Prevention with Positives (PwP), also known as Positive Health, Dignity, and Prevention (PHDP), is a set of HIV prevention interventions for PLHIV with a focus on keeping PLHIV healthy physically, mentally and psychologically, as well as preventing transmission of HIV. PLHIVs should be provided with information about ways they can protect their own health:

- *Prevention of HIV transmission:* Encourage PLHIV to adopt safer sexual behaviour including abstinence, partner reduction, correct and consistent condom use. Condom use prevents HIV transmission, reduces risk of other STIs, and prevents unintended pregnancies.

- *Promote adherence to treatment:* Adherence to HIV treatment facilitates viral suppression, thus reducing HIV transmission risk, and also reduces risk of developing HIV drug resistance (HIVDR).

- *Disclosure and partner testing:* Discuss with PLHIV strategies for disclosing HIV status to sexual partners and family members. Offer HTS to the sexual partners and children born to all PLHIV. Provider- and/or counselor-mediated or supported disclosure are options for those who do not feel comfortable disclosing on their own.

- *PMTCT, Family Planning and safer pregnancy:* Encourage HIV-positive women and young people to discuss their reproductive options and supported to adopt PMTCT. See PMTCT section 6.2.2

- *STI care:* Provide education, diagnosis and treatment of sexually transmitted infections (STIs): Presence of active STIs can increase chances of HIV transmission.

- *Alcohol and other risk reduction:* Give PLHIV information about the risks of alcohol abuse. Heavy drinking can cause poor treatment adherence and increase disease progression. Under the influence of alcohol, individuals may be more likely to engage in risky behaviours, placing themselves at increased risk for acquiring STIs and placing their HIV negative partners at risk of infection.

- *Referral to community-based programmes:* Prevention messages and strategies can be included in counseling, support groups or peer-led interventions, or through Home Based Care providers. Interventions including Income Generation Activities (IGAs), economic empowerment of women and girls decrease their likelihood that such individuals will engage in high-risk behaviours.

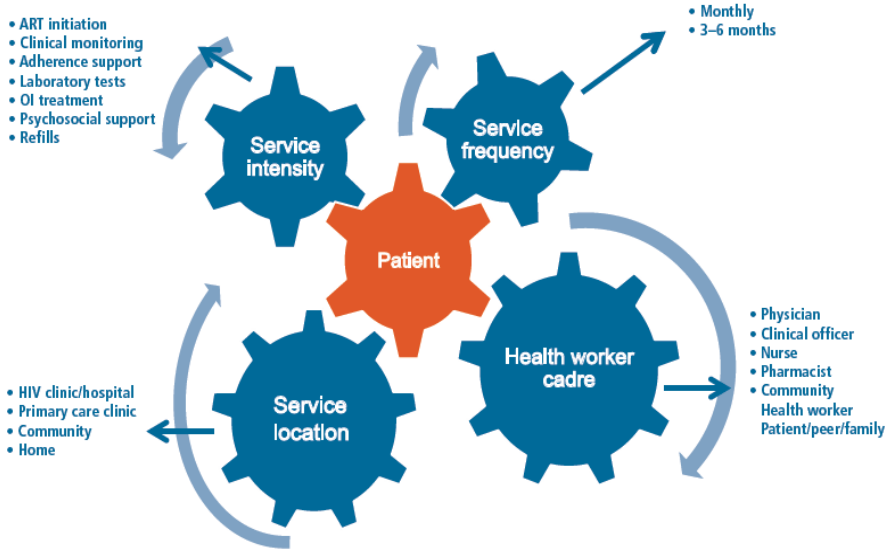
9 HIV DIFFERENTIATED SERVICE DELIVERY MODELS

9.1 INTRODUCTION

This section aims at providing guidance to programme managers and service providers on the 'Differentiated Service Delivery ' models and some key operational and service delivery issues that need strengthening to support comprehensive delivery of HIV and AIDS prevention, care and treatment services. The section covers the following areas: *differentiated care, models for ARV delivery, service integration and decentralization of ART services, adherence and retention in care and contingency interventions in crisis situations.* It is estimated that the majority of HIV service delivery in countries is 'clinic-based' with a 'one-size- fits- all' approach and yet PLHIV present with different needs. As HIV treatment guidelines evolve through widened eligibility criteria for ART initiation; different sub-populations of PLHIV emerge that require HIV services that are tailor-made to meet their specific needs.

The 'Differentiated Care' Framework by WHO includes specific service packages based on care needs and is characterised by four delivery components which are highlighted in the framework below i.e. **the type of services delivered, the location of services, the provider of the services and the frequency of the services.** This frame-work will form the basis of the guidance on 'Differentiated Care' in this chapter.

Figure 9.1: Implementation framework for differentiated care model



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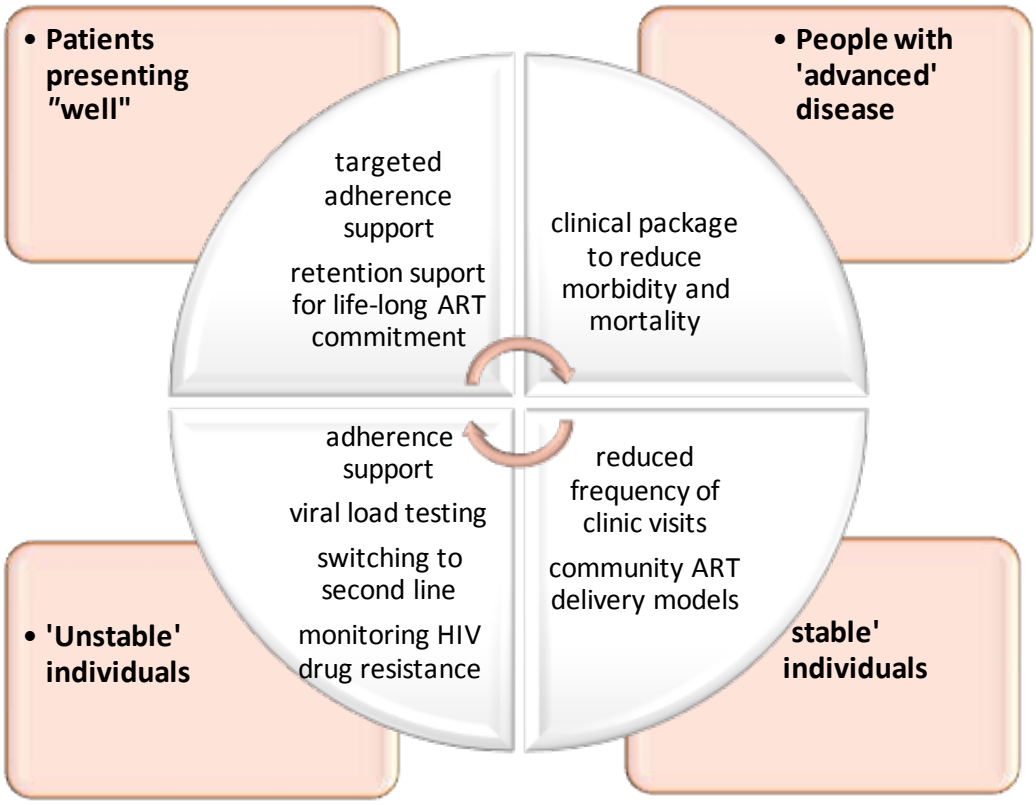
Source: WHO 2015 Policy brief: consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: what's new.

- Differentiated care is a **client-centred approach** that simplifies and **adapts HIV services** across the cascade to reflect the healthcare needs, preferences and expectations of various groups of people living with HIV (PLHIV) while reducing unnecessary burdens on the health system. The health system can refocus its resources to those most in need by providing differentiated care.

- WHO has grouped four categories of patients that need attention namely: **'well' patients** who present with relatively high CD4 count; people with **'advanced'** disease who require more intense care and regular follow up; **'stable' patients** who are the majority of patients that are already on ART and doing well and hence may require less frequent clinic visits and benefit from community ART delivery services; and lastly the **'unstable'** patients who are already on ART but present with emerging OIs that may require prompt management and possible drug switching to second or third line ARV regimens.
- The principles of differentiated care are aimed at supporting both the achievement of the 90-90-90 targets and the introduction of "Treat All" while improving the quality of services for clients and responding to the increasing workload faced by health care workers.

Figure 9.1-2 below summarizes the four groups of patients and the specific interventions they may require.

Figure 9.2: Categories of patients presenting for HIV care



Many aspects of HIV services targeting these different groups of patients have been discussed in detail in the previous chapters. However, this section will describe the different aspects of care that promote adherence, retention in care along the HIV care cascade including models of care outside the 'standard' HIV service delivery model.

9.2 DECENTRALIZATION OF ART SERVICES

As of end of 2015, there was differential decentralisation of HIV services with ART available at **35** accredited sites, countrywide, comprehensive PMTCT services to **65 sites**, and TB services at **65 sites**

and **114 sites** offering HTS. To ensure access to comprehensive HIV prevention, care and treatment services, a number of strategies will be adopted including service integration, enhanced referral and linkages, and accreditation of additional sites. The national HIV programme should continue to build the capacity of lower level health facilities to offer comprehensive HIV and AIDS services in order to bring the services closest to where people live. ART services will be scaled up to 67 sites by 2017; with priority for site accreditation given to regions with higher HIV burden, and existing PMTCT and TB sites to support roll out of Option B+ and enhance linkage to ART. In the long term, it is envisaged that ART will be available at all teaching hospitals (3), state hospitals (10), and county hospitals (79) and selected PHCC – Primary Health Care Centers. In addition to the static ART services at health facilities, outreach models of ART delivery are needed to improve service availability especially to the hard to reach communities and to the internally displaced persons (IDPs).

9.3 SERVICE INTEGRATION, ENHANCED REFERRAL/LINKAGE:

Whenever possible, services should be integrated:

- All ART and HIV care sites should be able to provide TB screening, TB evaluation services, and TB therapy on site.
- Clients with TB and HIV should initiate treatment for both TB and ART in the TB clinic and transition to ART clinic after completing treatment.
- For PMTCT, mothers should transition from MCH to ART after the baby has reached 18 months of age and the HIV status is established.
- In the short term, facilities without ART on site will rely on strong linkages and referral to ensure access to treatment for eligible clients. ANC sites (without ART) will provide PITC and refer HIV – positive clients to ART sites.
- TB sites will provide PITC, and for the HIV infected provide CPT and refer for ART. Isoniazid Preventive therapy (IPT) will be offered to eligible PLHIV within the ART clinics.

9.4 MODELS OF ARV DELIVERY FOR STABLE PATIENTS

South Sudan is a vast country with a low population density especially in the rural areas. It receives rains during the months of March to November yearly. A large proportion of its land mass lies within the Nile basin and therefore prone to flooding which results in disruption in transport services and displaced communities. Geographic barriers to accessing ART services are quite significant, as patients have to travel long distances to the nearest ART centre, due to the limited number of health facilities accredited to offer ART services. Differentiated care and treatment approaches should be applicable in all health care settings based on patient needs, preferences and expectations. In high-volume settings, client sub-groups are likely to be large enough to justify dedicated services. The approaches should increase cost-efficiency by optimizing staff workload and responding to unique patient needs.

Experiences from other countries within the sub-Saharan Africa have provided evidence in support of community ARV delivery models. These models have potential to **improve treatment outcomes** of patients through higher adherence to treatment and retention in care through **targeted counseling, peer support, reduced waiting times and reduced congestion at the facility**. The approaches will relieve overburdened health-care personnel and enable them to pay more attention to patients who are unwell or unstable.

People living with HIV (PLHIV) have other challenges such as transport costs, repeated absence from work or schools, and stigma. On the other hand, health facilities are already congested and with the increasing number of PLHIV put on ART services, there is a decrease in the health care provider and patient ratio. These challenges are negatively impacting the quality of health services.

Community led approaches also have the added advantage of **fostering community ownership** and sustainability.

For all the differentiated models of ART delivery for stable clients, the following eligibility criteria should be met across the different sub-populations.

A **stable adult client** on ART (first- or second-line) is defined as someone who:

- **Where viral load is available,** has no current OIs, has a VL <1000 copies/ml and is at least six months on their current ART regimen
- **Where viral load is not available,** has no current OIs, a CD4 >200cells/mm^3, been at least six months on a current ART regimen.

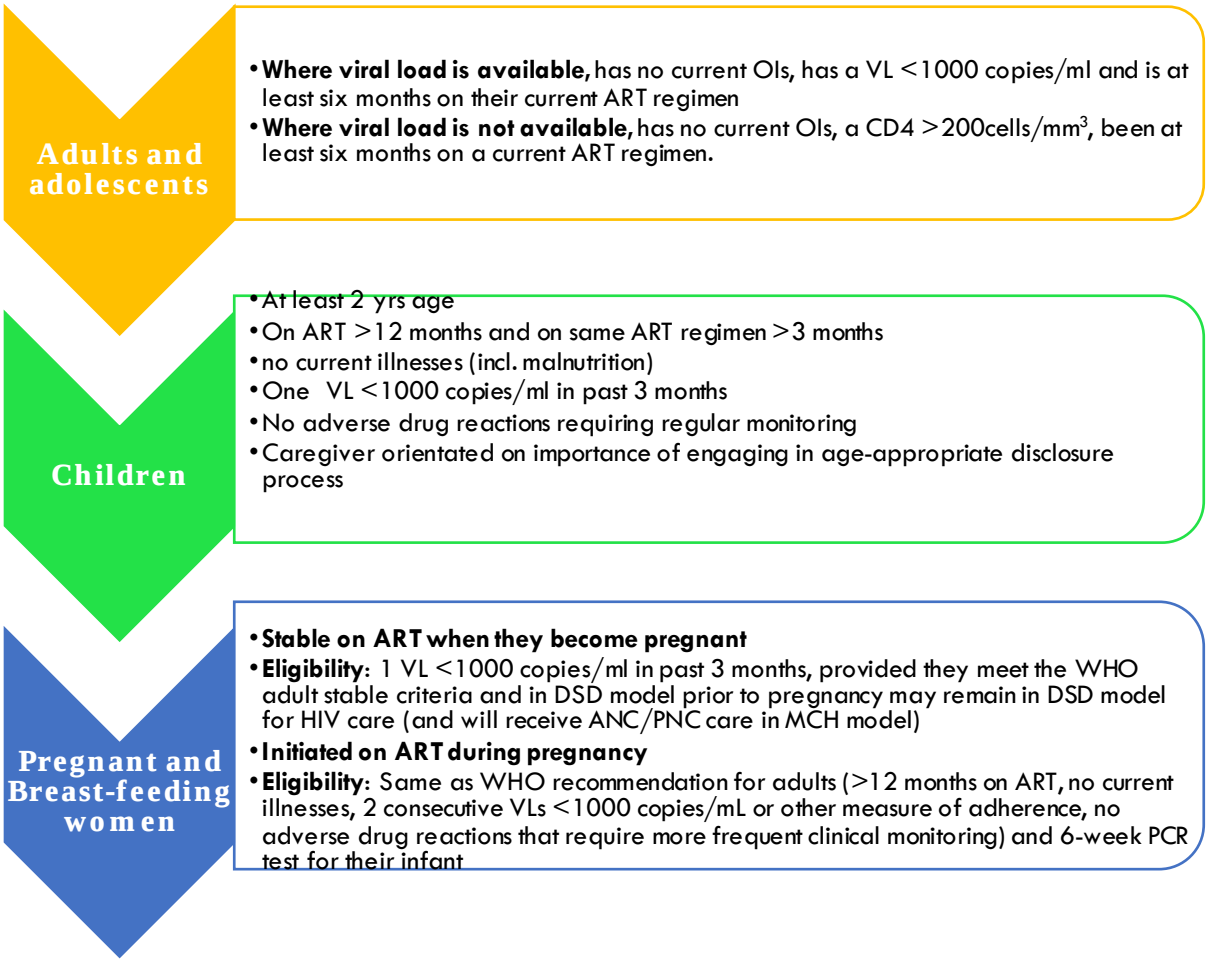
When assessing eligibility, a psychosocial assessment should be made.

Children who meet the following criteria may participate in the DSD models:

- At least 2 yrs age
- On ART >12 months and on same ART regimen >3 months
- no current illnesses (incl. malnutrition)
- One VL <1000 copies/ml in past 3 months
- No adverse drug reactions requiring regular monitoring
- Caregiver orientated on importance of engaging in age-appropriate disclosure process

Fig 10.4-1 is a summary of the eligibility criteria across the different populations.

Figure 9.3: Eligibility criteria for clients to participate in DSD models for stable clients



NB. Eligibility criteria for KPs is similar to that for adults.

Frequency of clinic visits:

Stable clients on ART who are being **monitored clinically and with CD4** should be seen for a clinical assessment and repeat CD4 **ONCE EVERY SIX MONTHS. Two 3-month refills of ART and cotrimoxazole** can be written so that the client attends for one refill before the next clinical visit. Appointment dates should be updated in the diary on the day of each refill.

Less frequent clinic visits may be considered in the future when viral load testing becomes more available.

The following are **ART refill options for 'stable' patients in South Sudan:**

The following five DSD models for stable clients on ART may be considered when planning how to differentiate ART services:

1. Fast-track ART Refill model
2. Club refill model
3. ART Outreach model
4. Community ART Refill Groups
5. Family Member Refill model

The choice of model should be guided by client's preferences and capacity of health facility and community structures to deliver the model.

9.4.1 Fast-track ART Refill model

Facility-based individual refill from pharmacy – target duration 30 minutes. This option should be available at all sites where drugs are dispensed from a separate room to where the clinical consultation is performed.

The client collects their refill directly from the dispensing point. They do not queue to see the clinician. The client can collect the medication any time during clinic opening hours on his/her refill day. This model has most value in sites where dispensing is performed in a separate room by a different health care worker to the clinical consultation.

Table 9.1: Standard Operating Procedures for Fast-Track ART Refill Models

Description	• This model is offered to stable ART clients who wish to refill at the facility **individually.** The minimum standard is that **clinical reviews must be conducted every six months coupled with laboratory tests as appropriate. In between the clinical visits (i.e., at every three months), refills should be fast-tracked.** Stable ART clients eligible for fast-track should be educated on basic self-care management and empowered to conduct self-assessments to decide whether they can directly pick up their ARVs from the pharmacy or return to mainstream care for unscheduled visits if unwell. Adequate client empowerment is critical to limit loss to follow up, non-adherence to their ARVs, disease progression and treatment failure.
Eligibility Criteria	• Refer to Fig 9-3
Recruitments of clients into Fast Track model	• Facility nurse should identify clients that meet the eligibility criteria and wish to be fast-tracked for their ARV refill • Patient should be booked for the next refill and clinical visits
During the clinic visit	• The client should go straight to the pharmacy to collect their medication • If unwell, the client can visit nurse/doctor for a clinical consultation • The pharmacist will update the client's care booklet
After the visit	• The patient monitoring books are taken for data entry into ART register

9.4.2 Club refill

Facility-based health care worker-led group refill – target duration 30-60 minutes. Experience to date suggests that this model is more popular in sites with large cohorts and in urban areas. As a group model, it does provide the additional benefit of peer support.

For clinics with larger cohorts, clients booked for refills on a given day can be organised into groups of 10-20. The group is then booked at the same time for each refill. On arrival, a health care worker (nurse, counsellor or expert client) facilitates discussion, identifies any group member who has a new clinical problem requiring review, and then distributes the medication. Medication can be pre-packed and labelled prior to the group meeting.

Table 9.2: Club refill model

Description	• This model is often more appropriate in high-volume or urban sites and provides peer support • Groups can be between 10 and 20 clients. In order to facilitate group formation, a designated health care worker in the clinic (nurse or counsellor) should be allocated to coordinate group formation. • Groups are formed primarily by the health care worker, and may be formed as the health care worker screens clients as eligible and refers them to the designated focal point for the groups • If there are pre-existing support group members or a sub-group of clients that would like to receive refills within the same group, then this should be facilitated • Health care workers should be trained on the model SOPs and completion of documentation for the patient care and treatment book • If required, agreement with staff dispensing ART to pre-pack and label ART for the group refill session. Pre-packing of medication will facilitate groups being led by non-clinicians, such as the counsellors or expert clients
Eligibility Criteria	• Refer to Fig 9-3
Where is the refill given	• The medication refill is given in the allocated facility room or location nearby the clinic (waiting area) where the group meets. Each group is booked at a specific time to collect their refill and preferably seen by the same health worker or lay cadre
During the clinic visit	• Once group members arrive the HCW leading the group facilitates discussion. • Clients are asked as a group if they have any specific clinical problems or any cough, sweats or weight loss. • Any client with a clinical issue is then directed to see the clinician. • Clients are then asked to share any other challenges or positive experiences they have faced with the group members. • The length of the discussion is dependent on the participants, but the entire refill session should not take longer than 60 minutes. • The HCW then distributes pre-packed and labelled medication to each group member individually. • Patient files may be kept according to groups and replaced for cohort analysis or pulled individually at each group meeting.
Clinical reviews	• All the group members should receive their clinical review at the same time twice a year • They are seen individually by the clinician and assessed clinically and have blood drawn for investigations • Aligning the clinical visit for the group facilitates uptake of services and allows the

	group to discuss their results and other relevant issues

9.4.3 Outreach

Community-based individual ART delivery through mobile outreach. This option should be considered for clients from hard-to-reach areas or where existing outreach activities are already occurring to a fixed location. Logistics to support regular visits to the location must be ensured.

Refills may be collected by the individual client and may be distributed by the nurse or, if pre-packed, by a primary counsellor, community health worker or expert client.

Table 9.3: ART Outreach model

Description	• This model should be used if significant numbers of clients will benefit from provision of ART at a designated mobile outreach point in a hard-to-reach area. Commitment to continue visiting the site must be assured • This refill option should be chosen only where it is guaranteed that the logistics for regular outreach to the point would be made available every three months. • A decision should be made on whether ART refill through mobile outreach will be integrated into existing outreach activities, or whether a stand-alone ART refill outreach is required due to numbers of people who may benefit in a specific hard-to-reach area. • Prior to the day of outreach, prepare the HIV care and treatment booklets and medication required for refill. Formal pre-packing of medication may facilitate distribution at the outreach site. • The refill is given at a pre-defined community-based outreach location • A fixed date and time is booked for the mobile outreach activity.
Eligibility Criteria	• Refer to fig 9-3
Services during the outreach visit	• The client is seen individually either by the nurse or a counsellor or expert patient who distributes pre-packed ARV medicines • If a clinical problem is identified, the client is reviewed by the clinician who is performing the outreach. • If feasible and privacy can be ensured, it may be possible to perform the 6 monthly clinical review at the same outreach site. • The nurse would review each client individually and take blood to perform viral load testing. If this is not possible, then the client should attend the facility for review twice a year according to the criteria • The patient care and treatment books should be filed according to the standard cohort system

9.4.4 Community ART refill groups (CARGs)

Community-based client-led group refill (see Table 9.4). This refill option has been shown to be more popular in rural areas and where distance is a major challenge to the client. As a group model, there is the additional benefit of peer support, which some clients may wish to benefit from even where distance is not a major challenge.

Community ART refill groups are self-formed groups of clients on ART. They are usually from the same geographical area and are willing to disclose their HIV status to each other. The system ensures that all members attend the clinic for their clinical visits and monitoring blood tests together as a group. For refill appointments, the group members nominate one member to collect the drugs from the facility and distribute the refill to all group members.

Table 9.4: Standard Operating Procedures for Community ART Groups (CARGs)

Description	• Self-formed groups of clients on ART comprised of 6-12 members. They are usually from the same geographic area and usually in hard-to reach communities with limited access to a health facility. Members should be willing to disclose their status to each other. They rely on pre-existing social networks, such as support groups, workmates and family relations. Each member should attend the clinic and seen by doctor or nurse for their clinical visits and monitoring blood visits every 6 months. However, group members take turns to collect each other's medicines. • Group members must meet at least 24 hours prior to the members' scheduled refill date. During this initial meeting, the booklets for group members are handed over to the group representative. The representative, with the support of the group leader, will also ask general screening questions as elaborated in the standard operating procedures. Unwell group members should accompany the representative to the clinic so that their conditions are reviewed. The ARV refills will be for a period of 1-3 months depending on the available stock of ARV medicines. • After the visit to the facility, the group representative should meet with the group members within 24 hours preferably on the same day of collection, to distribute and return the members' medicines and booklets
Eligibility Criteria	• Refer to Fig 9-3
Setting up CARGs	**At facility level:** • A multidisciplinary team (MDT) should meet to discuss client flow, roles and responsibilities and identify focal persons. Facilities should also work together with community partners and community support groups to facilitate demand creation in the community. • Each group's files should be stored at the same place, facilitating recording of information, finding test results and identifying which member has come to represent the group. Group folders containing all members' files can be used to improve filing efficiency.
	Recruitment of clients: • The health care worker should screen dients to assess them based on eligibility criteria for the groups during a clinical visit. • Once assessed as stable by the HCW, the client can choose to join a CARG and be referred to the HCW focal point coordinating CARG formation. • If the clients wish to form a group; they should visit a clinic as a group for screening

	• All clients joining a CARG group should undergo an orientation session • Each group should identify a group leader who will ensure that group ethics are adhered to • The newly formed group is trained on: (a) the approaches, roles and responsibilities of members; (b) how to monitor the adherence of members and (c) how to provide group counselling and education sessions.
Group meeting in the community prior to clinic visit	• CARG members meet in the community at a convenient venue and time • Each member of the group reports on his/her adherence. The representative or focal person (if other group members are illiterate) will collect the information of each member's adherence assessment result. • Clients must be empowered to self-screen for TB and report symptoms of TB or any other condition. Group members who are unwell or have TB symptoms must join the group representative to attend a consultation at the health facility. • Unwell group members will be identified and must join the group representative to attend a consultation at the health facility. • The group representative attending the facility for consultation and on behalf of the other members must collect all ART booklets and other group monitoring tools for the group members and bring them to the clinic for refill. • Members of the group may opt to all contribute financially for transport fare. • Members discuss the venue for meeting when the representative is back from the facility to distribute the drugs.
Procedures during visit at health facility	• During consultation, the group representative will report back on the adherence and general health of other group members. • ART booklets are updated (visit date, comment on refill, i.e., group representative refilled, and next visit date to be written). • Chronic care files must also be updated with this information for each group member file. • The visiting group representative has the opportunity to have a clinical review, as well as adherence counselling. • All routine and other required laboratory investigations must be done on this visit day. • Pending results for any member who might have been consulted prior to this must only be communicated as "normal" if there are no abnormalities. Otherwise, individual clients with abnormal results are supposed to be called at the time of receipt of their results by healthcare workers. • Any member requiring additional clinical follow up should be identified and asked to attend the clinic. • Prescription sheets should be written for all group members. • The community ART group tools including registers should be updated by the nurse whenever there are any changes in CARG composition or an outcome occurs.
CARG group meeting after clinic visit	• The group must meet within 24 hours at a convenient place for drug distribution. • When necessary and as advised by the staff at the health facility, the group representative may request a group member to go to the clinic for a special consultation.

9.4.5 **Family member refill**

This model follows the same steps as the CARGs, but the group is defined by being made up of family members. When a number of family members are on ART, it may be possible for one member to collect for the others. For families, it is important to ensure that ART is provided to all the family members on the same date, venue and provider. If a child is involved, it is essential that the child follows the paediatric follow-up schedule in order to ensure that drug **doses are adjusted correctly** according to weight

9.5 APPOINTMENT SYSTEMS AND DEFAULTER TRACING

At all steps of the cascade, the ability to identify that a client **has not attended for their appointment** will be dependent on the **use of an appointment system**. **All sites should have an appointment system for HIV-positive clients.** In primary care clinics, all clients should be booked in the same clinic diary. In larger facilities, each clinic (OI, MCH, TB) will have their own appointment diaries.

The list should indicate who is due to attend, the refill model they are in, whether VL is due, and if the last VL was >1000 copies/ml. Clients should be traced three days after their appointment if they have not attended (i.e., this is about tracing clients to prevent them becoming lost to follow up).

- At enrolment, clients should be asked **if they agree to consent to tracing**. Their decision should be clearly indicated on the patient care and treatment booklet.
- **The nurse in charge of the clinic must be clear which staff member is responsible** for updating the diary on a daily basis and for initiating the defaulter tracing process.
- **All clients registered for ART preparation, ART and PMTCT (including the exposed infant)** services should be given an appointment date, which is recorded in the clinic appointment diary. In some sites, it may be appropriate to give a booked time (morning or afternoon), as well as a day in order to stagger appointments. If group club refills are implemented, the group number should be recorded in the appointment diary and a booked time for the group allocated.
- The OI number, client's name, telephone number and the reason for the next appointment (clinical consultation +/- counselling, refill for drugs, blood draw for VL) should be listed in the diary.
- The diary can be used to pull the patient care and treatment booklets the day before and also to pre-pack refills in larger sites.
- When the client arrives, it should be marked off in the diary that they have attended.
- At each visit, whoever is registering the client should check that an up-to-date phone number is available and is documented in the appointment diary.
- If the client does not attend for their appointment, their patient care and treatment booklet should be kept aside in a tray or shelf allocated for late-attenders. Tracing is not triggered immediately and patients' files coming 1-3 days late should be found in this tray.

9.6 ADHERENCE AND RETENTION IN CARE

Optimal health, clinical and social outcomes require early diagnosis, timely linkage and initiation of ART, and consistent adherence to ART (Tanser F., 2013). Unfortunately, loss to follow-up at each step of the HIV cascade (e.g., pre-ART and after ART initiation) remains a key challenge for HIV programmes. Systematic reviews (Fox MP, 2010) show that retention rates are estimated to range from as low as 64% to as high as 94% at 12 months after ART initiation. Poor patient retention undermines programme and patient outcomes including the attainment of viral suppression. In south Sudan, ART retention at 12, 24 and 60 months is 75%, 67% and 42% respectively (National ART Programme data, 2017). It is worth noting that only 27% of the treatment cohort consists of men. Specific interventions that target men are urgently needed. Multiple barriers to adherence and retention of patients during Pre-ART and while on ART has been documented in literature.

Retention in care refers to a situation whereby a client has attended the health care clinic within the last 90 days—for medicine collection, laboratory testing, and/or clinical review—and is not documented as having transferred-out, died, or stopped treatment.

Key barriers to adherence and retention include:

- Poor understanding of why it is important to enrol & remain in care
- Long distance to the clinic & lack of transportation funds
- Fear of disclosure & stigma
- Poverty
- Lack of customer-friendly services at receiving facilities

- Client re-location or movement
- Use of medicines with many side effects

To enhance adherence and retention in care;

- Ensure proper registration with contact information – telephone number, home address
- Give clients/clients appointments and record in register
- Counsel clients on disclosure, stigma, etc.
- Provide clients with a client-held card and counsel on what to do in the event they travel or move elsewhere
- Provide medical care as needed including timely delivery of lab results or on-site testing
- Trace clients that have missed appointments, defaulted, or are lost to follow-up (CD4 count).
- Link clients in care to peer support groups for education and support
- Decentralize services to help improve access and to minimize transport costs
- Use of fixed-dose combination medicines

9.7 CONTINGENCY ACTIONS FOR CRISIS SITUATIONS

The national HIV programme should put in place measures to mitigate against adverse health outcomes following emergency situations. The ministry of health supported by its partners including humanitarian agencies should be prepared to provide minimal package of services to avoid treatment interruptions resulting in poor treatment outcomes.

The following actions listed in table 9.5 below adopted from ICAP in South Sudan; summarizes key actions to be implemented at various levels in preparedness for an emergency situation. Health workers at all levels should be sensitized and capacitated to implement this contingency plan for HIV services.

Table9.5: Contingency Plan for Emergency Preparedness

Actions Areas	Facility level	State Level	National Level
adherence education	Provide adherence education and support Discuss with the patient about plan in case of emergency		
Treatment information cards	Provide client held card with basic care & treatment information		
Duplicate medical records	Keep **back up** list and basic patient information records When possible, keep patient level data base with back up	Ensure facilities have back up records through supervision	Have a national patient level data base with back up
Communication networks	Discuss/plan for back communication channels in case of emergency	Plan for back up communication national MoH, CHDs, facilities and partners including humanitarian agencies	Plan for back up communication with states, CHDs, facilities and partners including humanitarian agencies
Emergency drug stocks	Provide emergency drug stocks of 3-6 months (ARVs & CTX)	Reposition emergency drug stocks at state level	Ensure emergency stocks are quantified, procured and kept
Secure drug storage	Divide drug stocks and store in different locations	Keep emergency drug stores in secured storage facilities	Divide drug stocks and store in different locations
Human resources capacity	Strengthen continuous medical education at facility level Train as many staffs as possible so that all staffs have basic HIV/AIDS management skills	Support continuous medical education on basic HIV care and treatment	Support continuous medical education on basic HIV care and treatment
Decentralization of care		Scale up service to more peripheral, hard to reach areas	Scale up service to more peripheral, hard to reach areas
Cooperation with HIV treatment facilities in neighbouring regions	Compile addresses and contact persons of HIV care & treatment facilities in nearby regions and share with patients	Facilitate communication between facilities, especially to move drugs where there is a surplus to where needed	Map out groups of facilities for possible referral in the event of emergency

(adopted from ICAP, South Sudan)

10 ARV DRUGS FOR HIV PREVENTION

Prevention of new HIV infections remains the cornerstone in HIV control in the absence of a cure. This will be achieved through implementation of Combination Prevention – a mix of biomedical, behavioural and structural interventions. The South Sudan HIV response prioritizes Combination Prevention as a measure to curb new HIV infections and reduce AIDS related mortality.

Behavioural interventions reduce the frequency of potential transmission events. These include Behavioural Change Communication (BCC) programs designed to encourage people to adopt safer sex behavior such as delay in sexual debut, reduction in number of sexual partners, use of male and female condoms correctly and consistently, and knowledge of ones' HIV status and that of sexual partners.

Structural and supportive 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, including legal and policy reform, measures to reduce stigma and discrimination, the promotion of gender equality and prevention of gender-based violence, economic empowerment, access to schooling and supportive interventions designed to enhance referrals, adherence, retention and community mobilization. The rest of this chapter will focus on biomedical interventions.

Antiretroviral drugs (ARVs) are used as additional tools in combination prevention. Effective ART decreases the level of plasma HIV viraemia and has been associated with reduction in levels of HIV viraemia in seminal fluids, vaginal fluids, and breast milk. Through a reduction in maternal plasma viraemia, ART given to a pregnant or breast feeding woman reduces the risk of HIV transmission to her unborn baby (See Chapter 6). Among sero-discordant couples, ART is effective in reducing HIV transmission risk by up to 96%. For Pre-exposure and Post-exposure prophylaxis, see below.

10.1 PRE-EXPOSURE PROPHYLAXIS

Pre-exposure prophylaxis (PrEP) is defined as the use of ARVs by people who are not infected with HIV before HIV exposure in order to prevent the acquisition of HIV The ARV drugs may be administered orally, or topically as a vaginal gel (microbicide). When oral PrEP is given it should be offered as part of the 'Combination Prevention' package that includes HIV Testing Services (HTS), male and female condoms, lubricants, ART for HIV-positive partners in sero-discordant couples, voluntary medical male circumcision (VMMC) and STI prevention and management.

10.1.1 Indications for PrEP

Oral PrEP will be provided to individuals who are HIV negative and are at substantial risk of HIV infection. Initially, oral PrEP will be offered at some selected demonstration sites (geographic areas considered as hot-spots) where funding for medicines and related commodities is assured. PrEP will be targeted at sub-populations considered high risk for HIV

including sex workers, fishermen, long distance truck drivers, men who have sex with men (MSM), uniformed forces, adolescents and young women engaged in transactional sex. The ministry of health will issue specific guidance on the rollout of PrEP within the public sector in due course. The guidance below will support PrEP programme implementation at the selected sites.

Eligibility Criteria for PrEP:
Oral PrEP will be made available to all individuals who are HIV uninfected and are at substantial risk of HIV infection (after an individual risk assessment) as follows:

- Have multiple sexual partners
- Engage in transactional sex including sex workers
- Use or abuse of injectable drugs and alcohol
- Have had more than one episode of an STI within the last twelve months
- Discordant couples, especially if the HIV positive partner is not on ART or has been on ART for less than six months
- Recurrent users of PEP (3 consecutive cycles of PEP)
- Individuals who engage in anal sex
- Key populations who are unable and or unwilling to achieve consistent use of condoms

10.1.2 Contraindications for PrEP

- HIV positive status
- Evidence or suspicion of HIV primary infection (characterized by a flu-like illness)
- Unknown HIV status
- Allergy to any of the PrEP medicines
- Unwilling/unable to adhere to PrEP
- Known renal impairment
- Estimated creatinine clearance of <60 cc/min

Note: it is critically important to take a complete history and thorough physical examination (particularly sexual) to rule out recent HIV infection. When there is suspicion of HIV primary infection and/or when there is a history of possible recent HIV exposure; PrEP can be deferred for 4 weeks and the client re-tested to ascertain HIV status.

10.1.3 Recommended medicines for Oral PrEP

- Daily oral tenofovir/emtricitabine (TDF/FTC 300mg/200mg) or TDF/3TC as FDC is preferred

When administering PrEP it is important to take note of the following:

- PrEP may be used intermittently during periods of perceived HIV acquisition risk, rather than continually and lifelong, as is the case with antiretroviral treatment.
- PrEP medications should be continued for 28 days after the last potential HIV exposure in those wanting to stop taking PrEP.
- These should also be borne in mind in users who stop and start PrEP according to their periods of risk.

- It is important to bear in mind that it takes about 7 days of daily dosing PrEP to be effective. During this period, other protective precautions must be used, such as abstinence or condoms.
- PrEP is safe without side effects for 90% of its users. However, some individuals may experience some short-term and mild side-effects such as gastro-intestinal symptoms (diarrhea, nausea, decreased appetite, abdominal cramps), dizziness and headaches.

10.1.4 **Procedures for offering PrEP**

The table below summarizes procedures including laboratory investigations to be conducted during first visit and follow up services for individuals receiving PrEP:

Table10.1: Procedures for offering PrEP

Process	Description
Screening for PrEP eligibility	After meeting the eligibility criteria, the following screening tests should be done before initiating PrEP. • Confirm HIV-negative status • Use symptom check-list to rule out acute HIV infection • Assess for hepatitis B infection • Assess for contra-indications to TDF/FTC
Steps to Initiation of PrEP	Provide risk-reduction and PrEP medication adherence counseling, • Provide condoms and education on their use. • Initiate a medication adherence plan • Prescribe a once-daily pill of TDF (300mg) and FTC (200mg). • Initially, provide a 1-month TDF/FTC prescription (1 tablet orally, daily) together with a 1-month follow-up date. • Counsel client on side effects of TDF/FTC
Follow-up / Monitoring clients on PrEP	• After initiating PrEP, the client should be reviewed after one month to monitor adherence and side effects as well as resupply of medicinest, subsequent clinic visits should be every three months • Perform an HIV antibody test every three months and document negative HIV status • For women, perform a pregnancy test based on clinical history. Pregnancy is not a contraindication for PrEP use • Review the patient's understanding of PrEP, any barriers to adherence, tolerance to the medication as well as any side effects • Review the patient's risk exposure profile and perform risk reduction counseling • Evaluate and support PrEP adherence at each clinic visit • Evaluate the patient for any symptoms of STIs at every visit and treat as needed
Guidance on when to discontinue PrEP	• Can be stopped 28 days after the last possible exposure to HIV when the client is no longer at substantial risk of HIV infection • It's a personal Choice • Changed life situations resulting in lowered risk of HIV acquisition • Intolerable toxicities and side effects • Chronic non-adherence to the prescribed dosing regimen despite efforts to improve daily pill taking

- Acquisition of HIV infection
- In sero-discordant couples when HIV infected partner on ART has achieved viral suppression (VL <1,000 copies/ml)

10.2 ART FOR PREVENTION AMONG SERO-DISCORDANT COUPLES

- Among sero-discordant couples, ART *(for the HIV-infected partner)* is effective in reducing HIV transmission risk by up to 96% to the uninfected sexual partner.
- Provision of ART for prevention among discordant couples requires provision of couple HTS in order to identify the discordant couples, followed by linkage to ART.
- The recommended regimens are similar to the standard ART regimens for adults Table 4-4
- Follow-up of couples is important to monitor for HIV seroconversion.

10.3 POST-EXPOSURE PROPHYLAXIS (PEP)

Post-exposure prophylaxis is short-term use of ARVs to reduce the likelihood of acquiring HIV infection after potential exposure either occupationally or through sexual intercourse. The biological rationale for prophylaxis with antiretroviral therapy is that initial virus uptake and antigen processing after inoculation may take several hours, or even days. This presents a window for therapeutic intervention before virus propagation occurs. Factors that increase the risk of sero-conversion include exposure to large inoculums of infected blood (indicated by a deep injury, visible blood on the device, and procedures involving needles placed directly in arteries or veins) and a source patient with advanced HIV infection.

10.3.1 Post – exposure Prophylaxis (PEP) in the Occupational Setting

To minimize the risk of exposure to HIV contaminated blood or body fluids in the health care setting, standard precautions should be observed: all blood and blood stained body fluids should be treated as if contaminated with HIV and other blood borne viruses such as Hepatitis B and C. Every staff member of a health facility should be sensitized to know what to do in the event of an occupational injury. Every health care facility in the public and private sectors should implement the minimum standards for the prevention of occupational accidental exposure to blood-borne pathogens.

The following Universal precautions should always be taken;
- Use of appropriate barriers such as gloves, gowns and goggles
- Care with sharps including minimizing blind surgical procedures and proper handling and disposal of sharps
- Safe disposal of contaminated waste
- Safe handling of soiled linen

- Adequate disinfection procedures
- Universal Hepatitis B vaccination of non-immune at risk groups including health care workers, police and prison staff, and rescue workers

Health facilities should ensure continuous supply of personal protective equipment, educational materials, disposable syringes and needles, and sharps bins. Medicines for post-exposure prophylaxis should be available and accessible at all times.

Basic steps in the clinical management of PEP in the occupational setting:

- First aid / Immediate care
- Establishing eligibility for PEP
- Counselling and obtaining informed consent
- Prescribing and dispensing PEP medication
- Conducting laboratory evaluation
- Ensuring record-keeping; and
- Providing follow-up and support

I. ***Immediate care*** - *depends on type and site of exposure*

After a needle stick or sharp injury

- Do not squeeze or rub the injury site
- Wash the site immediately with soap or mild disinfectant (chlorhexidine gluconate solution)
- Use antiseptic hand rub/ gel if no running water
- Don't use strong irritating antiseptics (like bleach or iodine)

After a splash of blood or body fluids in contact with intact skin

- Wash the area immediately
- Use antiseptic hand rub/ gel if no running water
- Don't use strong irritating antiseptics (like bleach or iodine)

After a splash of blood or body fluid in contact with eye(s):

- Irrigate the exposed eye immediately with normal saline or water
- Sit in a chair and let a colleague help you to rinse the eye with water, and pulling up and down the eye lid
- Do not use soap and disinfectant in the eye
- In case of contact lenses: leave them in, while cleaning the eye. Remove them later and clean them in the usual way.

After a splash contacts the mouth:

- Spit the fluid out immediately
- Rinse the mouth thoroughly, using water or saline, and spit again.
- Repeat this several times

- Do not use soap or disinfectant in the mouth

II. *Establish eligibility for PEP:*

Individuals are eligible for PEP if:

- Exposure occurred within the past 72 hours, and
- the exposed individual is not infected or not known to be infected with HIV, and
- the 'source' is HIV-infected or has unknown HIV status, and
- exposure was to blood, body tissues, visibly blood-stained fluid, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid or amniotic fluid, and
- exposure penetrated the skin with spontaneous bleeding or deep puncture or splash of significant amount of fluid to mucous membrane or prolonged contact of an at-risk substance with non-intact skin and
- If the skin was penetrated, exposure was from a recently used hollow bore needle or other sharp object visibly contaminated with blood.

III. *Counsel and obtain informed consent:*

- Counseling should address benefits and risks of PEP, the risk of acquiring HIV infection from the specific exposure, importance of adherence, drug side effects, and risk of HIV transmission.

IV. *Prescribe and dispense PEP medication;*

- For recommended regimens, see Table 10-1
- Provide adherence information and support
- A complete course of PEP comprises 28 days of ART
- The first doses should not be delayed by baseline HIV Testing: starter packs of medicines may be used especially in emergency settings and at lower facility levels

Table 10.2: Recommended Regimens for Post-Exposure Prophylaxis for HIV

Preferred	Alternative
TDF + 3TC (or FTC) + EFV	TDF + 3TC (or FTC) + LPV/r

V. *Conduct laboratory evaluation:*

- Perform HTS using standard algorithm Figure 2-1. Performing HIV testing minimizes the use of PEP for people who are already infected with HIV, thereby reducing drug waste and possible drug side effects. In addition, when the source person tests negative for HIV infection, this prevents the exposed person from having to take PEP unnecessarily.

- If HTS test results are not immediately available, PEP should be prescribed based on the risk evaluation and the likelihood that the source person is HIV positive; further evaluation should be made after the test results are known.
- People who have a positive rapid test result should be referred into HIV care
- Where possible Hepatitis B testing should be done followed by vaccination for HBV if test is negative.
- Other desirable lab tests include pregnancy testing for women of childbearing age

VI. Ensure proper record-keeping:

- Proper documentation and reporting of event and client management.
- Maintaining the confidentiality of client data

VII. Provide follow-up and support:

- To monitor adherence and manage side effects
- Perform follow-up HIV testing after 3-6 months after exposure to exclude sero-conversion
- Provide or refer for counseling and psychosocial support

10.3.2 HIV PEP for people who have been sexually assaulted

Eligibility criteria for PEP following sexual assault:

- less than 72 hours has elapsed since exposure; and
- the exposed individual is not known to be HIV infected; and
- the person who is the source of exposure is HIV infected or has unknown HIV status; and
- a defined risk of exposure, such as: receptive vaginal or anal intercourse without a condom or with a condom that broke or slipped; or contact between the perpetrator's blood or ejaculate and mucous membrane or non-intact skin during the assault; or receptive oral sex with ejaculation; or the person who was sexually assaulted was drugged or otherwise
- unconscious at time of the alleged assault and is uncertain about the nature of the potential exposure; or the person was gang raped.

NB: The clinical management is only one of the components of care needed.

Table 10.3: Clinical management of HIV Post-Exposure Prophylaxis

Item	Recommended action and notes
Immediate care / First aid	- Depends on type and site of exposure
Establish PEP eligibility	- Exposure occurred within the past 72 hours - Exposed individual not known to be infected with HIV - Significant exposure - Person who was the source of exposure is HIV infected or has unknown HIV status
Informed consent for PEP	- Information about risks and benefits - Consent may be given verbally
ART Regimen	- See Table 10-1
Time to initiation	- The initial dose of antiretroviral medicines should be given as soon as possible but no later than 72 hours after exposure
Duration of therapy	- 28 days
HIV testing and counseling	
Additional laboratory evaluations	- Pregnancy testing - Hepatitis B screening if available
Counseling	problems; and social support and safety
Referral	- As appropriate
Record-keeping	- Maintain accurate, confidential records
Follow-up	- Assess and manage side effects - Assess and support adherence - HIV test after 3 months

10.4 OTHER BIOMEDICAL INTERVENTIONS

- Male and female condoms: Male condoms reduce heterosexual transmission by at least 80% if used correctly and consistently. Female condoms have a similar prevention benefits.
- Voluntary Medical Male circumcision reduces acquisition of HIV by men by up to 66% and offers lifelong protection.

11 HEALTH SYSTEMS IN SUPPORT OF GUIDELINES IMPLEMENTATION

The MOH will provide leadership in the operationalization of these guidelines and will engage with key stakeholders to develop detailed implementation plans.

11.1 MONITORING AND EVALUATION

The Ministry of Health (Ministry of Health) will monitor implementation of these guidelines through routine service data collected in the Health management Information System (HMIS), as well as specialized periodic surveys, surveillance, census and vital statistics, and research. There are standardized data collection and monitoring tools for reporting on HIV prevention, care and treatment data. See Table 12-1

Table 11.1: Client care and health facility records collection tools

	HIV care /ART care	MCH/PMTCT	TB/HIV
Client held cards	HIV care/ Appointment card	Maternal /Child Health card Mother child booklet /passport with PMTCT code. HIV care / Appointment card	TB card HIV care / Appointment card
Facility held cards	HIV care /ART card	Labour record/ Partogram card/ form. HIV care /ART card	TB treatment card HIV care /ART card
Registers tracking diagnostic tests	HCT register (PITC, VCT)	ANC , labor and delivery registers (contains PMTCT data)	TB lab & Presumed TB registers
Longitudinal care and treatment registers	Pre-ART and ART registers	ANC and L&D registers HIV-exposed Infant register	Basic Management Unit TB register
Reporting tools	Monthly summary form Cohort reporting form	Monthly summary report	Monthly summary report on Case finding, Treatment outcome

- Other data collection tools include: commodity management tools used for ordering medicines, reagents and supplies; drug dispensing logs; appointment registers; referral forms; supervision checklists

- *At the health facility*, the responsibility of completing the client-held cards, facility held cards, registers, reporting tools etc. primarily rests with the nurse-in-charge of the clinic ensuring all tools are completed; reports are accurate, and submitted in a timely manner to the state/district. Personnel to support the process include:
  - *Records clerks:* responsible for issuing of cards / registers, filling clients' demographic data in cards, extracting register data into reporting tools, filing /retrieval of client records, and submission of reports
  - *Health care providers* (nurses, clinicians, nutritionists, social workers): responsible for completion of information on the client held card, facility held cards and registers, preparing cohort summaries, and completing client referral as needed
  - *Pharmacists/ pharmacy technicians:* complete the drug inventory records, drug dispensing details for each client, and prepare and submit supplies orders

- *At the State level*, the HIV/AIDS coordinator prepares the state program summary report for onward submission to Ministry of Health headquarters.

- MOH is responsible for production of monthly, quarterly and annual reports using data from the HMIS. The performance indicators are detailed in the National HIV/AIDS Strategic Plan.

11.2 HEALTH WORK FORCE

The provision of HIV prevention, care and treatment services requires a multidisciplinary team of health care providers at the different levels of service delivery. The major roles of each team member are described in the table below;

Table 11.2: Summary of the roles and responsibilities of staff in ART sites

Cadre	Roles and responsibilities
Medical Officers / Clinical Officers	Clinical supervision and facility / district management Management of HIV clients in all aspects*
Nurses, midwives	Nursing care Triage of clients Continuation of clinical care of stable clients Adherence counseling supervision and training of community workers Post pharmacy counseling
Nutritionists	[α]Nutritional assessment, counselling, and support
Laboratory technologists /technicians	Phlebotomy Lab services provision Lab commodity management
Counselors	**Counseling for HIV testing Client education **Adherence counseling
Community health workers	Community and home treatment support including tracing clients lost to follow up and missed appointments
Health records information officers / data clerks	Client records management
Pharmacist/ pharmacy technicians	Adherence counseling, rational drug prescription (following national treatment guidelines), ARVs dispensing, effective commodity/inventory management
Store keeper	Commodity management (with lab and pharmacy staff)
Social worker and /or community health worker	Adhere support Defaulter tracing Community linkage Health education

- Due to staffing shortages especially at primary health facilities, task shifting (of responsibilities) will be adopted to support service delivery:
  - *Nurses and midwives may initiate ART and manage clients on HIV treatment;
  - **Counselling, [α]nutritional assessment and support may be provided by any cadre with the requisite training;
  - Community based organizations and PLHIV may provide services such as counselling support, client tracing, and health education

- Task shifting will be supplemented by mentorship, on-going support supervision, and continuous quality improvement.

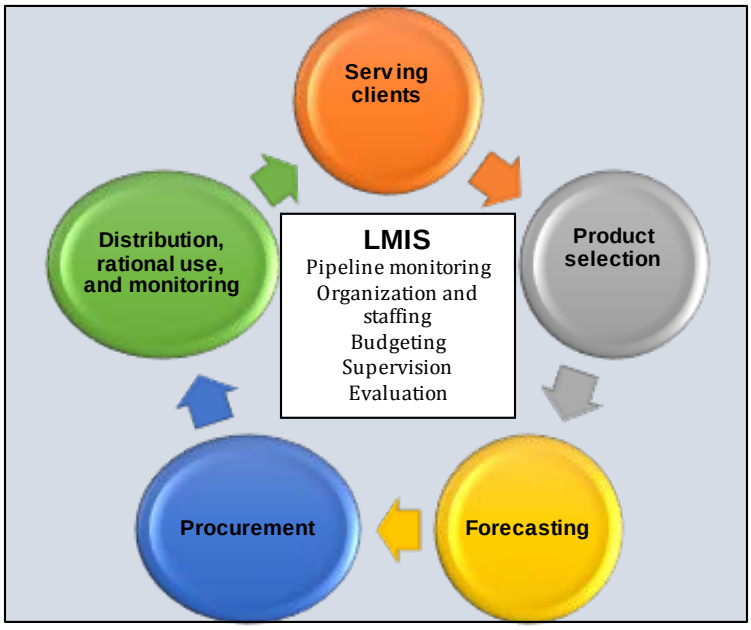
- To ensure quality services' delivery, all staff is expected to have undergone basic training in provision of HIV services – prevention, care and treatment.

- Guidelines, job aids, and SOPs should be provided to support consistent service quality.

11.3 SUPPLY CHAIN MANAGEMENT SYSTEMS

Ensuring adequate and continuous availability of quality and affordable essential medicines, diagnostics and other consumables at service delivery sites is a critical role of procurement and supply management systems. For HIV services, commodities include ARV drugs, laboratory reagents, HIV testing kits, cotrimoxazole among others. Figure 12.1 below outlines the key activities in the logistics management cycle.

Figure 11.1: The Logistics Cycle



At national level:

- The selected products/commodities required for HIV services delivery (ARV drugs, HIV testing kits, cotrimoxazole, and lab reagents) have been specified in national guidelines.
- The *procurement, supply, storage and distribution systems* should ensure uninterrupted availability and minimize loss due to damage and expiry, theft and fraud
- *Quantification & forecasting:*
    - Coordinated centrally by Ministry of Health through the PSM TWG that meets regularly on a quarterly basis.
    - Estimates short, medium, and long term requirements
    - Requires reliable data on consumption, and stock status from health facilities/ sites
    - Should take into consideration the revised treatment guidelines such as the newly introduced ARV drug regimens.
- *Procurement:* Coordinated by the Ministry of Health. On receipt of supplies in the country, there is clearance at port of entry and payment of taxes. The Drug and Food Authority

conducts physical inspections and randomly samples medicines and related commodities from each consignment on arrival for lab testing as a measure to assure quality. See list of ARV formulations approved for procurement in South Sudan in Table 12-3 and Table 12-5

11.4 LABORATORY SAFETY PROCEDURES

Adherence to safety precautions in the laboratory is required at all steps, including specimen collection, storage, transportation and disposal of biohazard wastes, so as to minimize occupational risks such as the risk of transmission of HIV, hepatitis B virus (HBV) and other blood-borne disease agents. All specimens should be treated as infectious.

11.4.1 Sample Storage Procedures

All samples should be stored in tightly closed, labelled tubes and kept in an upright position in racks. Workers must observe temperature requirements during specimen storage, keep a record of all samples, and always dispose used or old specimens in a timely fashion by autoclaving and incineration.

11.4.2 Sample Transportation Procedures

Whenever the capacity for a particular test does not exist in the laboratory on-site, the laboratory staff should make efforts to prepare samples for transportation to the nearest facility with such capacity.

When transporting samples from the clinic to laboratory or from one laboratory to another, the following should be observed:

- Specimens should be packaged appropriately according to the Standard Operating Procedures (SOPs) and put in appropriate and safe containers before transporting them by road (bus or vehicle) or air.
- Dried Blood Spot (DBS) samples on blotting paper are considered to be non-infectious and can be put in a letter envelope and transported by mail or courier. Consult courier and receiving laboratory for procedures and timing.
- A specimen delivery checklist should be used to verify that there is a requisition form for all samples transported.
- Dispatch and receipt records of transported samples should be maintained.

At facility level:

Effective commodity management by the relevant health care workers is critical to ensure continuous availability of supplies and program quality. The staff should promote good inventory management practices and rational use of commodities utilizing all the necessary tools such as SOPs.

i. *Ordering / requesting of commodities*: The facility is responsible for ordering commodities in an appropriate and timely manner based on facility-specific requirements. Quantities to be ordered should be determined by past consumption and projected future need.
ii. *Receiving, storage, and issuing of commodities*: Items in stock should always be stored in a proper storage place. The store should be secure, in good condition, and well organized. All supplies should be kept in the store and requisitions made for what is required for dispensing. Receipt, storage and issuance of commodities should follow set down SOPs. Accurate inventory records should be maintained.
iii. *Dispensing of medicines*: When a medicine is given to a client, it is important to ensure the client has received the right medicine, the correct quantity, correct information on how to take the medicine and potential side effects, and correct information on how to store the medicine.

Inventory control:

- Should happen at all storage levels central, intermediate and at facility. This ensures stock status monitoring- (tracking of quantity and use span of commodities to determine how long supplies will last).
- Inventory control helps detect potential stock-outs/ expirations and enables appropriate and timely action particulary for ARV drugs. The information needed includes:
    - stock on hand – through performing physical inventory or looking at the stock card
    - monthly consumption - dispensed to user or consumption data and issues data
    - stock status

Rational use and monitoring pharmaceuticals

- Providers at facilities have to be adequately trained in rational drug use
- Systems for monitoring and reporting , including monitoring adverse effects (pharmacovigilance) feed into the selection of products, rational use, prescription, and forecasting. See the list of ARVs approved and available in South Sudan in Table 12-3

Logistics Management Information systems (LMIS)

- Critical for monitoring the supply chain
- Essential LMIS data items include – stock on hand, consumption, losses and adjustments, service statistics
- Sources of LMIS data include; stock keeping records; transaction records; consumption records; reports

Recommended antiretroviral formulations for procurement

A consolidated antiretroviral formulary should include both recommended drugs and formulations which are solid, heat-stable, and fixed dose combinations whenever possible. Liquids, even for children, are often difficult to administer, store, transport, and are frequently more sensitive to temperature. Solid child-friendly formulations, which can be crushed or dispersed in water, are available and more optimal for clinical environments in South Sudan. Table 12-3 shows the recommended first-line antiretroviral regimens for treatment of HIV infection when initiation criteria are met.

- Using the consolidated formulary, all first-line HIV treatment needs for children and adults, as well as post-exposure prophylaxis, can be met with 4 relatively easy-to-administer drug commodities
- Alternative regimens are zidovudine-based in the proposed formulary consolidation.
- Unless there is a medical contraindication, it is recommended clients not on these regimens be switched to them in order to simplify the supply chain and improve the likelihood the client will continue to access treatment without excessive future drug and formulation switches. Regimen switches should be minimized thereafter within the available formulary unless indicated by treatment guidelines for toxicity or treatment failure.

Bundling PMTCT packs

Given the challenges in access to facilities, and based on experience from HIV programs impacted by conflict, strong consideration should be given to bundling PMTCT-packs to be provided during the first ANC which includes all ARVs and CTX needed, including one bottle of NVP syrup for the infant.

Table 11.3: Bundled PMTCT medications for sites implementing Option B+

Population	Antiretroviral Formulation	Dosing	Comment
HIV-infected pregnant and breastfeeding women	Tenofovir/Lamivudine/Efavirenz tablet (300mg/300mg/600mg) CTX 960mg tablet	1 tablet once daily	Same regimen as for adults
HIV-exposed infants	Nevirapine syrup 10mg/ml	Weight and age dosing	For the first 6 weeks of life
	CTX 120mg scored tablet		From 6 weeks through final diagnosis

NB. Note that high risk infants will require dual ARV prophylaxis for 12 weeks from birth

Additional General Considerations

- ***Buffer stock and multiple month drug disbursements:*** Procurements and buffer stock that allows for clients to receive a 3-month medication supply is optimal to maximize maintenance of therapy during periods of erratic service or commodity delivery. Increasing buffer stock, accessible at State or regional level, is recommended as feasible during periods of increased logistical challenges with transporting commodity out of the central warehouse.

Treatment interruption due to supply chain challenges: Treatment interruptions either due to insufficient stock at the ART site or due to unexpected displacement of an individual and lack of access to ART supplies increase the risk of ARV resistance. This should be avoided whenever possible.

Table 11.4: List of formulations for procurement (ARVs, Cotrimoxazole)

Formulation (ARVs, Cotrimoxazole, etc)	Dosing[1]	Comment
First-line ARVs		
TDF/3TC/EFV tablet (300mg/300mg/600mg)	Adult/adolescents: 1 tablet once daily	treatment month
TDF/FTC/EFV tablet (300mg/200mg/600mg)	Adult/adolescents: 1 tablet once daily	Adolescents and Adults: 1 tin = 1 treatment month
TDF/FTC (300mg/200mg)		
TDF/3TC	Adults and adolescents 1 tab od	Adolescents and Adults: 1 tin = 1 treatment month
EFV 600 mg tablet		
ABC/3TC dispersible tablet (60mg/30mg)	Pediatric weight band dosing	
EFV 200mg tablet (scored)	Pediatric weight band dosing	
Nevirapine 50mg tablet (dispersible)	Pediatric weight band dosing	
AZT(300mg)/3TC (150mg) /NVP (200mg)	Adult: 1 tablet twice a day	Alternative regimen for TDF toxicity
AZT/3TC (300mg/150mg) tablets	Adult: 1 tablet twice a day	For use as alternative 1st line NRTI backbone for adults/adolescents.
NVP 200mg tablet	Adult: 1 tablet bd, except with 14-day lead-in dosing	For use in alternative 1st line in situations of EFV toxicity.
AZT /3TC/NVP (60mg/30mg/50mg)	Paediatric	
AZT/ 3TC (60mg/30mg) dispersible tablet	Pediatric weight band dosing	Alternative regimen only -for ABC toxicity
Nevirapine 10mg/ml syrup	Pediatric weight/age band dosing – once daily dosing	For HIV-exposed infant PMTCT only
AZT oral suspension 10mg/ml		
3TC oral solution 10ml/ml		
Cotrimoxazole prophylaxis		
Sulfamethoxazole/trimethoprim 800mg/160mg tablets (Cotrimoxazole 960mg scored tablet)	Child 6-14y: ½ tablet once daily Adult: 1 tablet daily	
Sulfamethoxazole /trimethoprim 100mg+20mg/5ml Cotrimoxazole 120mg scored tablet	Child 6wk-6mo: 1 tablet daily 6mo-5y: 2 tablets daily	For HIV-exposed infants and HIV-infected children
Sulfamethoxazole /trimethoprim 200mg+40mg/5ml		

[1] ***Dosing information for procurement informational purposes only.***

12 ANNEXES

Table 12.1: TB Screening card: adult and adolescents

TB SCREENING CARD: Adult & Adolescent

Screening for TB should be done at every visit

Name of /client_____ Age …… Sex …… Address……

Pre ART/ Unique ART _____ Client ID No. _____

Health Facility _____ State _____ County _____

		Insert dates below					
Adult & Adolescent TB screening questions		___/__/__	___/___/___	___/___/____	___/___/____	____/____/___	___/___/____
1. Current cough (Y/N)							
2. Fever (Y/N)							
3. Weight loss (Y/N)							
4. Night sweats (Y/N)							
Evaluate for TB if "Yes" to any of the above (Positive TB screening)							
Bacteriology : sputum for AFB	Done = Yes/No						
	Result (AFB+, -ve, unknown)						
Radiology: CxR, etc	Done= Yes/No						
	Results (Suggestive, inconclusive, other Dx, unknown ,etc						
FNA, culture, ultrasound, etc	Done : Yes/No						
TB diagnosed	Yes (write type of TB)/ No						

Table 12.2: TB Screening Card: Children (0-14 years)

TB SCREENING CARD: Children (0-14 yr)

Screening for TB should be done at every visit

Name of /client_____ Age …….. Sex ……. Address……

Pre ART/ Unique ART _____ Client ID No. _____

Health Facility _____ State _____ County _____

Child TB screening questions		Insert dates below						
		___/__/__	___/___/___	___/___/____	___/___/____	____/____/___	___/___/____	___/___/_____
1. Current cough (Y/N)								
2. Fever (Y/N)								
3. Poor weight gain* (Y/N)								
4. Close contact history with TB client (Y/N)								
Bacteriology : sputum for AFB	Done = Yes/No							
	Result (AFB+, -ve, unknown)							
Radiology: CxR, etc	Done= Yes/No							
	Results (Suggestive, inconclusive, other Dx, unknown ,etc							
FNA, culture, ultrasound, etc	Done : Yes/No							
TB diagnosed	Yes (write type of TB)/ No							

*__Poor weight gain is defined as__: *reported weight loss, or very low weight (weight-for-age less than –3 z-score), or underweight (weight-for-age less than –2 z-score), or confirmed weight loss (>5%) since the last visit, or growth curve flattening.*

Table 12.3: Toxicities associated with first and second-line ARV drugs

ARV drug		Major toxicity	Risk Factors	Minor toxicity	Suggested management
ABC		Hypersensitivity reaction	Presence of HLA-B*5701 gene	Lactic acidosis	If ABC is being used as first line ART, substitute with TDF or AZT, of d4T If ABC is being used as second line ART, substitute with TDF
AZT		Anemia, neutropenia, myopathy, lipoatrophy or lipodystrophy	Baseline anemia or neutropenia CD4 count ≤ 200 cells/mm^3	Blue to black discoloration of nails, nausea and headache	If AZT is being used in first line ART, substitute with TDF or ABC. If AZT is being used in second line ART, substitute with d4T. For severe anemia: may transfuse. For myopathy, discontinue if CPK high
d4T		Peripheral neuropathy , lipoatrophy or lipodystrophy	Older age CD4 count ≤ 200 cells/mm^3 Concomitant use of INH or DDI	Insomnia, anxiety, panic attacks	Severe peripheral neuropathy, abnormal serum amylase and transaminases, discontinue therapy
		Lactic acidosis or severe hepatomegaly with steatosis, acute pancreatitis	BMI > 25 (or body weight >75kg) Prolonged exposure to nucleoside analogues		
EFV		Persistent CNS toxicity (such as abnormal dreams, depression and mental confusion)	Depression or other mental disorder (previous or at baseline) Daytime dosing	Dizziness, Rash in 10% but rarely severe <1%	NVP. If the person cannot tolerate either NNRTI, use a boosted PIs CNS symptoms often resolve 2-4 weeks. Stop if hepatitis is confirmed.
		Hepatotoxicity	Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs		
		Convulsions	History of seizure		
		Hypersensitivity reaction, Steven Johnson Syndrome Potential risk of neural tube birth defects (very low risk in humans) Male gynaecomastia	Risk factors unknown		
3TC		Peripheral neuropathy, pancreatitis (more common in children)		Skin rash, headache	Do serum amylase, stop if elevated. Restart when resolved or change to ABC
LPV/r		Electrocardiographic abnormaities (PR and QT interval prolongation, torsades depointes)	People with pre-existing conduction system disease Concomitant use of other drugs that may prolong the PR interval	Headache, weakness, diarrhea rarely severe	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 If LPV/r is used in second line for adults, use ATV/r or DRV/r. If boosted PI are contraindicated and the person has failed on treatment with NNRTIs in first line ART,
		QT interval prolongation	Congenital long QT syndrome Hypokalemia Concomitant use of other drugs that may prolong QT interval		
		Hepatotoxicity	Underlying hepatic disease		

ARV drug		Major toxicity	Risk Factors	Minor toxicity	Suggested management
			HBC and HCV co-infection Concomitant use of hepatotoxic drugs		consider integrase inhibitors
		Pancreatitis	Advanced HIV disease		
		Risk of prematurity, lipoatrophy or metabolic syndrome, dyslipidemia or severe diarrhea	Risk factors unknown		
NVP		Hepatotoxicity	Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs CD4 ≥250 cells / mm3 in women Cd4 ≥400 cells/mm3 in men First month of therapy if lead in dosing is not used		EFV. If the person cannot tolerate either NNRTI, use a boosted PIs Low-dose over first 2 weeks minimizes rash occurrence. If mild or moderate continue cautiously or substitute with EFV. If severe stop NVP and permanently if hepatitis +ve
		Severe skin rash and hypersensitivity reaction Steven Johnson syndrome	Risk factors unknown		
TDF		Tubular renal dysfunction, Fanconi syndrome	Underlying renal disease older age BMI <18.5 (or body weight below 50kg) Untreated Diabetes mellitus Untreated hypertension Concomitant use of nephrotoxic drugs or a boosted PI		If TDF is being used in first line ART, substitute with AZT or d4T or ABC If TDF is being used in second line ART (after d4T + AZT use in first line ART), substitute with ABC or DDI Monitor renal function at baseline and every 6 months.
		Decreases in bone mineral density	History of osteomalacia and pathological fracture Risk factors for osteoporosis or bone loss		
		Lactic acidosis or severe hepatomegaly with steatosis	Prolonged exposure to nucleoside analogues Obesity		
		Exacerbation of hepatitis B (hepatic flares)	Discontinuation of TDF due to toxicity		Use alterative drug for hepatitis B treatment (such as entecavir)

Table 12.4: Drugs that commonly interact with ARVs

	Drug name	NVP	EFV	TDF	LPV/r
Antimycobacterial	Rifampicin	NVP levels reduced by 20-58% Potential of additive hepatotoxicity Use of this combination is not recommended however if used, careful monitoring should be instituted	EFV level reduced by 25%	No significant change No dose adjustment necessary	Reduces LPV levels by 75% and reduced ritonavir level by 35%. Where available, use rifabutin in place of rifampicin
	Rifabutin	Reduces NVP Levels by 16%. No dose adjustment.	EFV levels unchanged; Rifabutin 35% Dose: rifabutin dose to 450-600 mg Once daily or 600 mg 3x/week. EFV: Standard		Levels: Rifabutin AUC 3-fold. 25 Decrease rifabutin dose to 150 mg once daily or 3x/week LPV/r: Standard.
Antifungal	Ketoconazole	Ketoconazole level reduced by 63% NVP level increased by 15-30% Not recommended to co-administer	No significant changes in ketoconazole or EFV level		Ketoconazole level increased 3-fold Use with caution; do not exceed 200mg/day ketoconazole
	Fluconazole	NVP levels increased by 100% No change in fluconazole level Increased risk of hepatotoxicity if coadministred; monitor closely for NVP toxicity	No significant changes in EFV or fluconazole		
Oral contraceptives	Ethinyl estradiol	Ethinyl estradiol reduced by 20%. Use alternative or additional methods	Ethinyl estradiol levels reduced by 37%. Use alternative or additional methods	No significant change No dose adjustment necessary	Ethinyl estradiol level by 42% Use alternative or additional methods
Lipid lowering agents	Atorvastatin	No data	Atorvastatin AUC reduced by 43% EFV level unchanged Adjust atorvastatin dose according to lipid response, not to exceed maximum recommended dose		Atorvastatin AUC 5.88 fold Use lowest possible starting dose with careful monitoring

Table 12.5: Paediatric Dosage chart for NRTIs

Weight	Abacavir* (ABC)		Lamivudine (3TC)		ABC/3TC		AZT/3TC/ABC	Zidovudine (AZT)		AZT/3TC		Stavudine (d4T/3TC)		Stavudine (d4T)	Tenofovir (TDF)			
	Once daily (od) Max 600mg daily		Twice daily Max 150 mg bd		Once daily (od) Max 600mg/300 mg daily		Twice daily (bd) Max 600mg/ 300mg/ 600mg	Twice daily Max 300mg bd		Twice daily Max 300/150mg bd		Twice daily Max 30mg/150mg bd		Twice daily Max 30mg bd	Once daily Max 300mg			
Kg	Dispers tablet 60mg	Tablet 300mg	Oral solution 10mg/ml	Tablet 150 mg	Dispersible tablet 60mg/ 30mg	Tablet 300mg / 150mg	Tablets 300mg/150 mg/ 300mg	Dispers. tablet 60mg	Tablet 300mg	Dispers. tablet 60mg/30 mg	Tablet 300mg/ 150mg	Dispersible tablet 6mg/30 mg	Tablet 30mg d4T/ 150mg 3TC	Syrup 1mg/ml	Tablet 150mg	Tablet 200mg	Tablet 250mg	Tablet 300mg
3-5.9	2 tabs od		3ml bd		2 tabs od			1 tab bd		1 tab bd		1 tab bd		5mls bd				
6-9.9	3 tabs od		4ml bd		3 tabs od			1.5 tabs bd		1.5 tabs bd		1.5 tabs bd		10mls bd				
10-13.9	4 tabs od		5ml bd		4 tabs od			2 tabs bd		2 tabs bd		2 tabs bd		15mls bd				
14-19.9		1 tab od		0.5 tab bd		1 tab od	0.5 tab bd	2.5 tabs bd	0.5 tab bd		0.5 tab bd	2.5 tabs bd						
17-21.9															1 tab od			
22-27.9		1.5 tabs od		1 tab am 0.5 tab pm		1.5 tabs od	1 tab am 0.5 tab pm	3 tabs bd	1 tab am 0.5 tab pm		1 tab am 0.5 tab pm	3 tabs bd	1 tab am 0.5 tab pm			1 tab od		
28-34.5		2 tabs od		1 tab bd		2 tabs od	1 tab bd		1 tab bd		1 tab bd	4 tabs bd	1 tab bd				1 tab od	
≥35																		1 tab od

Table 12.6: Paediatric Dosage chart for NNRTIs, NNRTI-containing FDCs

Weight	Efavirenz (EFV)	Nevirapine (NVP)						Etravirine (ETR) (for use in 3rd line regimens)			D4T/3TC/NVP		AZT/3TC/NVP	
	Once daily at night (nocte) Max 600mg od	Twice daily* Max 200 mg bd						Twice daily* Max 200 mg bd			Twice daily* Max 30/150/200mg bd		Twice daily* Max 300/150/200mg bd	
		Induction dose* once daily (od) for first 14 days			Maintenance dose* twice daily									
Kg	200mg 600mg	Oral susp. 10mg/ml	Dispers. tablet 50 mg	Tablet 200mg	Oral susp. 10mg/ml	Dispersible tablet 50mg	Tablet 200mg	Tablet 25mg	Tablet 100 mg	Tablet 200mg	Dispersible tablet 6mg d4T/ 30mg 3TC/ 50mg NVP Maintenance dose*	Tablet 30mg/ 150mg/ 200mg Maintenance dose*	Dispersible tablet 60mg AZT/ 30mg 3TC/ 50mg NVP	Tablet 300/150/ 200mg
3-5.9		5ml od	1 tab od		5ml bd	1 tab bd					1 tab bd		1 tab bd	
6-9.9		8ml od	1.5 tabs od		8ml bd	1.5 tabs bd		1 tab bd			1.5 tabs bd		1.5 tabs bd	
10-13.9	200mg nocte	10ml od	2 tabs od	0.5 tab od	10ml bd	2 tabs bd	0.5 tab bd				2 tabs bd		2 tabs bd	
14-16.9	300mg nocte			0.5 tab od			1 tab am 0.5 tab pm		1 tab bd		2.5 tabs bd		2.5 tabs bd	
17-19.9				1 tab od										
20-24.9											3 tabs bd	1 tab am 0.5 tab pm	3 tabs bd	1 tab am 0.5 tabs pm
25-29.9	400mg nocte						1 tab bd		1.5 bd		4 tabs bd	1 tab bd		1 tab bd
30 – 34.9										1 bd	4 tabs bd			
35-39.9														
≥40 kg	600mg nocte			1 tab od			1 tab bd					1 tab bd		1 tab bd

**any child or adolescent initiating nevirapine instead of efavirenz should start with an "induction" dose which is generally half of the daily maintenance dose for 2 weeks. If there is no rash or other sign of hypersensitivity, the patient can be given the bd maintenance dose. This means that if a child is initiating ART with an FDC that contains nevirapine, the child should take the triple FDC in the morning and the dual FDC (e.g. ABC/3TC or AZT/3TC) in the evening for the first 2 weeks.*

Table 12.7: Paediatric Dosage chart for PIs and ISTIs

Weight	Lopinavir/ritonavir (LPVr) Twice daily Max 400mg/100mg bd				Atazanavir (ATVr) *ALWAYS GIVE RITONAVIR BOOST* Once daily (od) Max 300mg					Darunavir* (DRVr) (for use in 3rd line regimens) *ALWAYS GIVE RITONAVIR BOOST* Twice daily Max 600 mg bd					Raltegravir** (RAL) Twice daily Max 600mg bd	
Kg	Pellets (Capsule) 40mg LPV/ 10mg RTV	Liquid 80mg LPV/ 20mgRTV per ml	Heat stable tablet ***Must swallow whole*** 100mg LPV/ 25mg RTV	Tablet 200mgLPV/ 50mg TV 1 tab bd	Powder (Satchet) 50mg	Capsule 200mg	Syrup 80mg/ 5ml **Ritonavir** for Boosting ATV	Tablets 100mg **Ritonavir** for Boosting ATV	Tablet Boosted Atazanavir (ATV 300 /RTV100)	Tablets 75mg	Tablets 150mg	Tablets 600 mg	Syrup 80mg/ 5ml **Ritonavir** for Boosting DRV	Tablets 100mg **Ritonavir** for Boosting DRV	Chewable tablets 25mg	Chewable tablets 100mg
3-4.9	2 caps bd	1 ml bd														
5-5.9					4 sachets od		**5 ml od**									
6-9.9	3 caps bd	1.5 ml bd														
10-13.9	4 caps bd	2 ml bd	2 tabs am 1 tab pm Pm												3 tabs bd	
14-14.9		2.5 ml bd	2 tabs bd	1 tab bd												1 tab bd
15-19.9					5 sachets od					1 tab bd	2 tabs bd		**0.6ml bd**			
20-24.9		3 ml bd				1 od		**1 tab od**			3 tabs bd			**1 tab bd**		1.5 tabs bd
25-34.9			3 tabs bd	2 tabs am 1 tab pm												2 tabs bd
35-39.9				2 tabs bd												
≥40 kg									1 tab od			1 tab bd				3 tabs bd

**These medicines will be used in the management of pediatrics on 3rd line regimens*
*** In special circumstances, raltegravir may be used in 1st or 2nd line, otherwise it will be reserved for 3rd line treatment*

Table 12.8: Super boosting LPV/r in children on TB treatment

Weight	Lopinavir/ritonavir (LPVr) Twice daily Max 400mg/100mg bd							
Kg	Pellets (Capsule) 40mg LPV/ 10mg RTV	Super Boosting RTV	Tablet 200mgLPV/ 50mg RTV 1 tab bd	Super Boosting RTV	Liquid 80mg LPV/ 20mgRTV per ml	Super Boosting RTV	Heat stable tablet ***Must swallow whole*** 100mg LPV/ 25mg RTV	Super Boosting RTV
3-4.9	2 caps bd				1 ml bd			
5-5.9								
6-9.9	3 caps bd				1.5 ml bd			
10-13.9	4 caps bd				2 ml bd		2 tabs am 1 tab pm pm	
14-14.9			1 tab bd		2.5 ml bd		2 tabs bd	
15-19.9								
20-24.9								
25-34.9			2 tabs am 1 tab pm				3 tabs bd	
35-39.9			2 tabs bd					

Figure 12.1: Enhanced Adherence Session Guide

Enhanced adherence session 1 **Counsellors should document their findings in the patient care and treatment booklet notes section**	
Timing	Session 1: Date high viral load result received
Duration	Minimum 15 minutes
Mode	Individual

Introduce yourself to the patient

Step 1: Viral load education review

Assess patient's understanding of viral load, high viral load and suppressed viral load. Ask the patient to explain to you what each means. If patient requires more explanation, you can say things like:

The main job/work of your ARVs is to reduce the HIV in your body to a very small amount.

We can measure this amount of HIV by taking a blood test that we call a viral load test. If ARV treatment is successful, the amount of HIV in the blood will be very low/small/suppressed and you will be healthy.

The reason it is important to take your medication every day is to make sure that treatment is successful and the amount of virus in the blood is low.

We have noticed that your viral load is going up. This is not something that can be ignored. We have to find the cause, overcome it, and make sure that your viral load becomes suppressed. We are here to help you achieve this.

Most of the time, the cause for a high viral load is when you sometimes forget to take your medication.

Learning to take these medicines is complex, but very possible. Just like learning anything new, it can be overwhelming at first and may take a lot of effort, but with practice, can become part of your daily routine.

Step 2: Discuss the patient's reason/explanation for his or her high viral load

Sometimes the patient already knows why his/her viral load is going up. Here you can give them a chance to give their own explanation. Often they will already tell you at this point that they are struggling with their adherence.

If they really don't know why their viral load is high, you can say:

We notice that when people sometimes forget to take their ARVs every day, it gives the virus a chance to multiply. Do you think that you sometimes forget?

Make a short note of the patient's explanation. Then move on to the next step. Don't linger too long on this step.

Step 3: Review time the medication is taken (dosing times) & create a medication schedule

This step is to review the time that the patient has chosen to take their ARV doses. Establish what the patient is doing and where they are at the time they have chosen. For example, if the patient has chosen 9pm, but is already asleep in bed by 9pm, then that is not a good dosing time.

Establish with the patient whether the time they are meant to take their medication is appropriate or whether the time is a problem.

If the time is a problem, then determine a new, more appropriate time with the patient based on their schedule. Remind them that the time chosen is just a suggestion; medicines should always be taken even if not on time.

Then write down the new medication schedule in the counsellor's notes and in their patient-held record.

Other reminders that may be used include a cell phone alarm, a specific TV programme, radio programme, or taking the medication with meals.

Step 4: Plan for storing medications

Help the patient identify where at home they are going to keep their medications. If they are afraid of people seeing or finding the medication, then brainstorm a good place to hide them.

Storage place: _____

Deciding on where to keep extra or emergency doses

Keeping an extra supply of tablets in specific places is always helpful in emergencies.

Help the patient identify where they can keep an extra supply of medication in case they don't get home in time to take their medication This could be: handbag, locker at work, backpack, wallet, jacket pocket, briefcase, car, etc.

With women, you might identify their handbag as an item they always carry with them.

These tablets are then only to be used when not home in time to take the next dose.

Extra/emergency supply will be carried in: _____

Step 5: Motivation cards

This step can help patients learn strategies for remembering to take medications and for thinking helpful thoughts each time they look at their tablets. It is especially helpful for patients who have treatment fatigue, are depressed or are stigmatising themselves.

Introduce the patient to the notecard. Ask the patient to think of their own personal goals/dreams for their future. What are the 3 most important things they still want to achieve in their future?

Have them write it in their own language on a notecard:

e.g. *"I want to see my children grow up", "I want to be healthy for my job"*

Ask the patient if they think that their ARVs can help them achieve these goals for the future? The answer will be yes, because ARVs will prolong life.
Encourage the patient to place the notecard where they will read it every day, preferably right before they take their medication. This will associate taking ARVs with the positive things they want for their future.

Top 3 goals for the future: _____

_____

_____

Do you think that your ARVs can help you achieve your goals for the future?

Step 6: Discuss patient's support system

Has the patient disclosed his or her status to any family, friends, or co-workers?

You can ask the patient:

Do you have any people in your life who you can talk to about your HIV and ARVs?

Suggest to the patient that they enlist the support of their family, friends and co-workers in reminding them to take their medication if they have not already done so.

The members of the patient's support system are: _____

If they have not disclosed to anyone, write "none".

Step 7: Planning for substance use

In the past, the message given to patients was that they shouldn't mix ARVs with alcohol or drugs; the result is that patients decide not to take their ARVs on the day that they use alcohol or drugs. In time, we can support the patient to stop abusing alcohol or drugs, but for the meantime we want to help them to adhere to ARVs while using alcohol or drugs.

You can ask the patient in a casual way (not in an accusing way) if they sometimes like to have a few drinks.

Explain to the patient:

"*We know now that taking ARVs together with alcohol or drugs in NOT a problem.*"

"*Taking alcohol or drugs sometimes makes it difficult for us to remember to take treatment. If possible, it is best to limit your use, but if you are planning to take any alcohol or drugs, it is important to plan ahead so that you don't forget to take your treatment.*"

"*Can you think of ways to still remember to take ARVs while drunk or high?*"

"*It is a good idea to take ARVs before you start drinking, even if it is before your schedule dosing time.*"

"*If you are already out, ask a friend who is not drinking to make sure that you take your ARVs.*"

"*Ask your wife or a family member to bring your medication to you and remind you to take them on time.*"

"*If you feel that your alcohol or drug use is affecting your adherence, would you feel ready to be referred to some professionals that may help you to work on that problem?" (Refer this patient to alcohol support service if available.)*

Write the patient's plan down in the counsellor's notes.

Step 8: Getting to your clinic appointment

This step helps the patient solve problems associated with getting to his or her appointments.

Make a plan for getting to appointments:

How do you get to your medical appointments?

What would you do if your usual way of getting to your appointments was not an option (e.g., if there was a taxi strike, the train was not working, or it was raining when you usually walk)?

How do you usually get to clinic: _____

Back-up plan: _____

If they are not able to come on appointment date: remind the patient that if they are unable to make their appointment, they must make sure to go to the clinic the next day, BEFORE they run out of medication.

Step 9: Review plans and plan way forward

Briefly summarise plans made above.

Identify the steps that the patient needs to complete at home before your next visit, i.e., placing emergency doses in their handbags, their new dosing time, etc.

Give a short motivational summary on how you believe in the patient! You know they can do this! Together you will make sure

that they suppress their viral loads!!

Plan a way forward

Inform the patient that they will be seen after 4 weeks.

VL will be repeated after 12 weeks.

VL results will be reviewed together and a way forward will be discussed.

Enhanced adherence session 2	
Timing	Session 2: One month after 1st EAC
Duration	Approximately 10 minutes
Mode	Individual
Tools	EAC session guide of Job Aide

SESSION 2 (to be done the following month)

Step 1: Identify any difficulties with plans & problem solve any new issues

- Review action plan from previous session: e.g., motivation card and emergency doses.
- Ask the patient if he/she thinks that adherence has improved in the last month. Enquire in a friendly way if any doses have been missed.
- If the patient experienced any difficulties implementing the plans, brainstorm solutions to the identified problem.
- Also problem solve any new issues that may have come up in the past month.

Step 2: How to learn from mistakes

- This step may help clients prepare to recover from missing doses, which, in the long run, is likely to occur.
- If a mistake occurs, the best choice is to return to one's adherence programme as soon as possible instead of acting on hopeless thoughts and giving up.
- Identifying what led to the mistake can provide important information that can help avoid future mistakes.
- It should be stressed that mistakes are normal and not a big problem. They only become a big problem when they lead to giving up.
- **Inform the patient that if they are meant to take their medication every 12/24 hours and they forget a dose, they must take the dose as soon as they remember, no matter how late it is. The next dose must then be taken as normal/back to the usual time.**
- It is important to tell the patient that they must not beat themselves up if they miss a dose. They must tell themselves that they are only human and that mistakes happen, but that they must return to their medication schedule as soon as possible. If they continue to have many mistakes, then the patient must speak to their medical team as soon as possible.
- Make a plan with the patient:
    - *Positive thoughts you can think after you made a mistake*

_____

- *What can you learn from a mistake that will help you avoid another in the future?*

_____

Step 3: Check your notes to see whether the patient has been referred to other services – if not, skip this step

- This includes referrals to psychology services, substance abuse groups, social services, etc.
- Ask patient if they attended the appointment? Assure them that if they answer "no", the topic will not be brought up again during these sessions (e.g., we won't force them to go to substance abuse groups).
- If they answer "yes", then check in on their experience with the referral services.

Step 4: Preparing for travel

- Holidays are always a risk for poor adherence or default of treatment. Encourage patient to plan for holidays, to make sure that they have enough medication on hand before they leave town, and to remember to pack it !
- Make sure that all relevant information is on the patient's notebook – clinic's phone number, patient's current regimen and doses, latest CD4 and VL, etc.
- Explain to them that if they are ever away from home and they run out of medication, they must go to the closest ARV clinic and show their patient notebook. Hopefully that clinic can help them access medication.
- As back up, have the patient programme their local clinic phone number AND file number into their phone. This way, they have it on their phone in case they lose their patient notebook.
- Save on phone: Clinic number
  My folder number
- Identify where the patient usually travels to and ask if they know where the closest ARV clinic is.

Step 5: Review plans

- Give another short motivational discussion on how you believe in the patient! You know they can do this! Together you will make sure that they suppress their viral loads!!
- Book for repeat VL in 2 months. Give 2-month supply of ART.
- If additional EAC sessions are needed, schedule appointment earlier.
- Repeat viral load should still be taken 12 weeks after result was given.

Figure 12.2: Algorithm for Classification of Malnutrition in Adults

<table>
<tr><th colspan="2">ASSESS</th><th rowspan="2">CRITERIA</th><th rowspan="2">CLASSIFICATION</th><th rowspan="2">TREATMENT/CARE</th></tr>
<tr><th>HISTORY</th><th>LOOK FEEL AND MEASURE</th></tr>
<tr>
<td rowspan="4">Ask the client or refer to records:
1. Has the client lost weight in the past month/since the last visit?
2. Has the client had:
– Active TB (on treatment)?
– Another chronic opportunistic infection (OI) or malignancy (e.g., oesophageal infections)?
– Mouth sores/oral thrush?
3. Has the client's body composition/fat distribution changed noticeably?
– Thinning of limbs and face?
– Fat distribution on limbs, breasts, stomach, back?
4. Has the client had:
– Nausea and vomiting?
– Persistent fatigue?
– Poor appetite?</td>
<td rowspan="4">Prevention
• Drink clean boiled water.
• Wash hands with water and soap before handling, preparing, serving, or storing food.
• Wash hands with water and soap after using a toilet or latrine or cleaning a child after defecation.
Treatment
• Drink more fluids to prevent dehydration. Prepare rehydration solutions using oral rehydration salt sachets or a homemade solution from cereals.
1. Go to a health facility if symptoms such as severe dehydration, fainting, dizziness, shortness of breath, bloody stools, high fever, vomiting, severe If the client has oedema on both legs or base of the spine:
– Rule out pre-eclampsia, kidney problems, elephantiasis, heart failure, and wet beriberi (vitamin B1 deficiency with oedema).
2. Measure the client's weight (kg) and height (cm).
3. Compute body mass index (BMI).
4. Measure mid-upper arm circumference (MUAC) for all pregnant women, all women up to 6 months post-partum, and adults who cannot stand straight.
5. Examine the client for conditions that cause secondary malnutrition (e.g., injuries, burns, surgical procedures, pregnancy, diarrhoea, or disease of the gastrointestinal tract, thyroid, kidney, liver, or pancreas).</td>
<td>Adults (non-pregnant and non-post-partum)
BMI < 16 kg/m^2 (If can't measure BMI, MUAC < 19 cm)
OR
Bilateral pitting oedema (both feet or legs are swollen, and the skin remains indented when pressed with a finger)
Pregnant women and women up to 6 months post-partum
MUAC < 19 cm</td>
<td>Severe acute malnutrition (SAM) with complication (fever, hypothermia, severe anaemia or dehydration, vomiting, bilateral oedema +++) or no appetite</td>
<td><u>Inpatient treatment</u>
Refer to therapeutic feeding programmes</td>
</tr>
<tr>
<td>SAM with appetite and no complication</td>
<td><u>Outpatient treatment</u>
Refer to therapeutic feeding programmes</td>
</tr>
<tr>
<td>Adults (non-pregnant and non-post-partum)
BMI ≥ 16.0–< 18.5 kg/m^2
(If can't measure BMI, MUAC ≥ 19–< 22 cm)
Pregnant women and women up to 6 months post-partum
Weight loss or no weight gain
MUAC ≥ 19–< 22 cm</td>
<td>Moderate/mild malnutrition
Significant weight loss</td>
<td rowspan="2">Refer to supplementary feeding programmes</td>
</tr>
<tr>
<td>Severe lung disease
Active TB (first 3 months of treatment)
Chronic diarrhoea
Difficulty swallowing</td>
<td>Signs of symptomatic disease</td>
</tr>
<tr>
<td>Adults (non-pregnant and non-post-partum)
BMI ≥ 18.5 kg/m^2
(If can't measure BMI,</td>
<td>Normal</td>
<td>Nutrition counselling</td>
</tr>
</table>

	6. Look for medical complications and danger signs (e.g., anaemia, severe dehydration, active TB, severe bilateral oedema). 7. If the client has no medical complications, give an appetite test using ready-to-use therapeutic food (RUTF).	MUAC ≥ 22 cm) **Pregnant and post-partum women** MUAC ≥ 23 cm		

Figure 12.3: Algorithm for Classification of Malnutrition in Children 6 months - 14 years old

ASK	LOOK,FEEL and MEASURE	CRITERIA	CLASSIFICATION	TREATMENT/CARE
Ask mother or caregiver or refer to records: 1. Has the child lost weight in the past month/since the last visit? 2. Has the child had: a. A cough for more than 21 days? (This may be a result of HIV-related chronic lung disease such as lymphocytic interstitial pneumonia [LIP] or bronchiectasis.) b. Active tuberculosis (TB) (on treatment)? c. Diarrhoea for more than 14 days? d. Another chronic opportunistic infection (OI) or malignancy?	**1. Look for severe visible wasting:** – Loss of muscle bulk on arms, shoulders, buttocks, and thighs, with visible rib outlines – Sagging skin on buttocks **2. Check for oedema** (swelling) in both feet or base of spine. **3. Measure child's weight (kg) and height (cm)** and find weight for height (WFH) using 2006 WHO child growth standards. **4. Measure mid-upper arm circumference (MUAC).** **5. Look at the shape of the curve on the growth chart.** – Has the child lost weight since the last visit? (Measure again to confirm current weight.) – Is the growth curve flattening? – Is the child gaining weight? Weight loss Growth curve flattening Weight gain	**Bilateral pitting oedema** +++ (both feet and/or legs are swollen, and the skin remains indented when pressed with the thumb) **OR** WFH < –3 z-scores (WHO 2006) **OR** BMI for age 10–14 years: ≤ –3 z-score **OR** MUAC 6–59 months: < 11.5 cm 5–9 years: < 13.5 cm 10–14 years: < 16.0 cm **AND** Does not pass an appetite test	**Severe acute malnutrition (SAM)**	
			With medical complication (WFH <–4 z-scores, shock, anorexia, intractable vomiting, convulsions, lethargy, lower respiratory tract infection, high fever, severe anaemia or dehydration, hypoglycaemia, hypothermia, pneumonia, TB)or **no appetite**	**Inpatient treatment** **Refer to therapeutic feeding programmes**
			Without medical complication and with appetite Clinical wellness Alertness Caregiver able/willing to manage SAM at home and return to clinic every 14 days	**Outpatient treatment** **Refer to therapeutic feeding programmes**
		6–59 months: WFH or BMI for age between –3 and –2 z-scores  MUAC 6–59 months: ≥ 11.5–< 12.5 cm 14.5 cm 10–14 years: ≥ 16.0–< 18.5 cm	**Moderate/mild malnutrition (MAM)** **Poor weight gain**	**Refer to supplementary feeding programmes**
		Weight gain parallel to or higher than median growth curve	**Normal** **Growing appropriately**	**Nutrition counselling**

		WFH ≥ −2 z-score **OR** MUAC ≥ 12.5 cm		
		Chronic lung disease, TB, persistent diarrhoea, or other chronic opportunistic infection or malignancy	**Condition with increased nutritional needs**	**Refer to supplementary feeding programmes**

Figure 12.4: List of contributors and reviewers of these guidelines

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