Republic of The Gambia

Guidelines for Antiretroviral Therapy and Prevention for HIV in The Gambia

May 2025

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Foreword

The World Health Organization (WHO) has developed and updated guidelines for scaling up antiretroviral therapy in resource-limited settings. The treatment guidelines for a public health approach act as guidance for countries to facilitate the proper management and scale up of Antiretroviral Therapy (ART). This public health approach is geared towards universal access, standardization, and simplification of Antiretroviral (ARV) drug regimens to support the implementation of evidence-based treatment programmes in resource-limited settings. The goal is to avoid the use of substandard treatment protocols and to reduce the potential for the emergence of drug-resistant virus strains. The detailed national ART guidelines provide recommendations for managing toxicity or treatment failure and recommends formulations for weight and age that can help to standardize prescribing and dispensing practices and facilitate forecasting for ARV drugs.

The Gambia has made significant progress in the fight against HIV and AIDS. At the end of 2024, an estimated 26000 people were living with HIV and 17000 of them were receiving antiretroviral therapy (ART). In 2016, the National AIDS/STI Control Programme (NACP) adopted the new World Health Organization (WHO) recommendations to treat all people living with HIV with ART, regardless of immune status or clinical stage. The adoption of this recommendation sits alongside the ambitious 95-95-95 targets to ensure that 95% of people living with HIV (PLHIV) know their status, 95% of people who know their status are on ART, and 95% of those on treatment are virologically suppressed.

To achieve these targets, the Gambia's national strategic plan (2021-2026) has set the goal of testing approximately 25247 million people by 2026 and of increasing ART coverage from the current 44% to 95% by treating 23984 people with ART.

To achieve these targets, current programmatic approaches will have to be adapted. The Guidelines for Antiretroviral Therapy in Gambia (2025) describe the "What" of ART delivery, outlining the threshold and ART regimen that should be used and how clients on ART should be monitored.

It is my wish to encourage healthcare workers and patients to work together to achieve the 95-95-95 goals and to further learn from adapting our HIV services in the Gambia to provide quality, client-centred care that enhances the lives of those living with HIV while continuing to impact on the control of the epidemic.

This updated national HIV Care guidelines include newly recommended HIV testing and linkage strategies, ARV drug regimens, formulations and diagnostics that are appropriate to the local setting. This version provides an update to the previous consolidated guidelines. The national guideline review process included extensive consultations with various stakeholders through workshops and technical working group meetings. The purpose of reviewing the existing guideline is to ensure that the country is up to date with current trends and recommendations in HIV care.

This document remains the basis for planning and organisation of HIV service delivery at all levels of implementation in both government, non-governmental and private health institutions in the Gambia. To ensure a rational use of medicines, patients must receive medications appropriate for their clinical needs, in doses that meet their own individual requirements for an adequate period and at the lowest cost to the patient and the community. ART is a complex undertaking that involves a large variety and quantity of highly active drugs. It is a lifelong treatment that is regularly reviewed with the addition of new molecules. It is therefore very important for all HIV commodities procured in Gambia to be governed by these guidelines since inappropriate use may have unwanted consequences at both the individual and population levels. To promote an effective utilization of this guideline only trained and authorized persons in certified health care facilities are allowed to prescribe ARVs, and all HIV commodities are not to be sold to the public unless authorized by the Ministry of Health.

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Director of Health Services

Acknowledgement

The Ministry of Health wishes to acknowledge the continued support of the World Health Organization (WHO) towards the adaptation of WHO Consolidated Guidance for the review of the Guidelines for HIV care and Antiretroviral Therapy in the Gamb

The Gambia Ministry of Health, National AIDS/STI Control Programme (NACP) wishes to thank our development partners, led by Expertise France, for the funding assistance for the review of the HIV treatment guideline in the Gambia. Its utilization will facilitate the process for improved access to HIV services by all clients, particularly PLHIV, to whom we pay tribute for the partnership in the fight against HIV and AIDS. Special gratitude goes to all the healthcare providers whose selfless efforts across the cascade of care have enabled us to realize the successes achieved so far in antiretroviral therapy delivery and the comprehensive package of prevention, treatment, care and support services for PLHIV in the Gambia.

We are grateful to Dr. David Masson and Dr. Léon Salumu Luzinga, the consultants who led the review of this guideline, and the Director of Health Service, Director of National AIDS Secretariat, CCM Executive Secretary and other stakeholders. The review was based on global evidence and country experiences in the implementation of HIV prevention, treatment services. We wish to acknowledge the monumental role of all technical contributors, especially the DSD Technical Committee Group members. The National AIDS/STI Control Programme is also grateful for all the contributions made to this document by other stakeholders, particularly the CCM, AAITG, NPHL, NPS, EFSTH, NHCP, NLTP, National AIDS Secretariat and the Global Fund to fight AIDS, TB and Malaria.

The development of this updated edition of the consolidated HIV Treatment guidelines was made possible through the leadership of the Directorate of Health Service, Senior management of the National AIDS Secretariat, (NAS) Programme Manager, staff of the NACP and the entire cadre of service providers whose hard work has ensured the progress chalked in the prevention and control of HIV in Gambia till date.

We extend our heartfelt thanks to our colleagues, partners and stakeholders who took time from their busy schedules to review and validate the updated HIV treatment guidelines:

Table 1: List of Participants

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Finally, I wish to thank all those individuals and organizations (not listed here) who had contributed to the successful development of these guidelines.

Pa Ousman Bah
Program Manager
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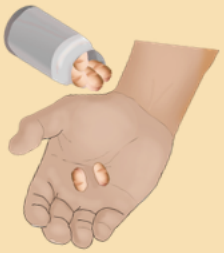
Giving Your Child Paediatric Dolutegravir 10 mg Dispersible, Scored Tablets (pDTG)

These are instructions on how to give your child pDTG alongside abacavir and lamivudine (ABC/3TC) 120/60 mg dispersible tablets. If your child is not taking ABC/3TC, there may be changes to these recommendations. Always follow the guidance of your healthcare provider.

1



Add the correct number of pDTG and ABC/3TC tablets to a clean, empty glass based on your child's weight. (See Dosing Table)

Weight	No. of pDTG Daily Tablets	No. of ABC/3TC 120/60 mg Daily Tablets
3 to < 6 kg	0.5	1
6 to < 10 kg	1.5	1.5
10 to < 14 kg	2	2
14 to < 20 kg	2.5	2.5

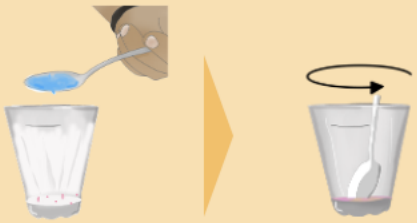
2

Add 2-4 teaspoons (10-20 mL) of clean water into the glass.

Stir until the tablets fully dissolve.

Give the medicine to your child to drink. Make sure they drink all the medicine right away or within 30 minutes.

3



If any medicine remains in the glass, add a little more water to the glass and give to your child. Repeat until no medicine remains in the glass.

Reminders

- *Remember to give your child their pDTG (and other ARVs) at the same time everyday*
- *Use other liquids or foods for mixing if your child is unable to take the tablets in water. Use the same amount of liquid or food as above to avoid spills and to ensure your child takes the full dose*
- *Only give your child another full dose of pDTG if they vomit within 30 minutes of taking their initial dose*

Ask your health provider if you have any questions about administering pDTG!

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Definition of Key Terms

Infant Child	One month to 1 year of age
Child	One year to 10 years of age
Adolescent	Aged 10 to 19 years inclusive
Early Adolescent	Age 10 to 14 years inclusive
Late Adolescent	Age 15 to 19 years inclusive
Adult	Older than 19 years of age
ART (Antiretroviral Therapy)	Refers to the use of combination of three or more ARV drugs to achieve viral suppression and is usually given for life
Antiretroviral drugs	Refer to the medicines themselves and not to their use
Child and adolescent born with HIV	Refer to paediatric patients who were infected with HIV by vertical transmission or during infancy and who have a grown up with the virus
Client Initiated Counselling & Testing	Testing process initiated by an individual who wants to learn his/her HIV Status
Continuum of care	Concept of an integrated system of care that guides and tracks clients over time, through a comprehensive array of health services spanning from screening for HIV, to diagnosis and management of HIV, to initiation into ART, retention in care and psychosocial support
Couple	Two people in an ongoing sexual relationship
Desensitization	Desensitization refers to a medically supervised process of gradually reintroducing cotrimoxazole to a patient who has previously experienced a **non-**severe hypersensitivity reaction (e.g., mild rash) to the drug. The goal is to build tolerance by increasing doses incrementally over a defined period, allowing the patient to continue prophylaxis or treatment safely.
Eligible for ART	Refers to people living with HIV for whom ART is indicated
Healthcare provider	Anyone who renders healthcare; includes doctors, nurses, counsellors
HIV symptomatic Infant	Any HIV-exposed infant displaying failure to thrive, haematological abnormality such as anaemia or thrombocytopenia, congenital pneumonia, pneumonia, hepato-splenomegaly, extensive oral candidiasis, significant lymphadenopathy & any opportunistic infections
HIV-exposed infant	Infant born to a woman who is HIV-positive or who becomes HIV positive anytime during pregnancy, labor and delivery or breastfeeding. The infant is at risk of acquiring HIV infection from the mother and that the infant/child may test HIV-positive" on antibody testing, reflecting the mother's antibody
Key populations	Both vulnerable and most-at-risk populations
Provider initiated counselling and testing	HIV counselling and testing recommended by healthcare provider in a clinical setting
Sero-discordance	Sexual partners where one partner is living with HIV and the other is HIV-Negative
Treatment failure in adults and children	is defined by a persistently detectable viral load exceeding 1000 copies/ml (i.e. 2 consecutive viral load measurements within a 3-month interval, with adherence support between measurements) after at least six months of using ARV drugs
Viral suppression	Refers to the aim of ART to maintain viral load below detectable levels of available assays (<1000 copies/ml)

List of Acronyms/Abbreviations

3TC: Lamivudine	NGO: Nongovernmental organization
ABC: Abacavir	NHL: Non-Hodgkin's Lymphoma
AIDS: Acquired immunodeficiency Syndrome	NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor
ALD: ABC + 3TC + DTG	NRTI: Nucleoside Reverse Transcriptase Inhibitor
ART: Antiretroviral therapy ARVs (Medicines for treating HIV)	NtRTI: Nucleotide reverse transcriptase inhibitor
AZT: Zidovudine	NVP: Nevirapine
ATV/r: Atazanavir/ritonavir	OGTT: Oral Glucose Tolerance Test
BCG: Bacille Calmette-Guérin	OI: Opportunistic infection
CHBC: Community- and home-based care	PJP: Pneumocystis Jirovecii Pneumonia
CD4: Cluster of differentiation 4	PCR: Polymerase chain reaction
CICT: Client Initiated Counselling &Testing	PEP: Post Exposure Prophylaxis
CMV: Cytomegalovirus	PrEP: Pre-Exposure Prophylaxis
CSF: Cerebrospinal fluid	PI: Protease inhibitor
DNA: Deoxyribonucleic acid	PICT: Provider-Initiated Counselling and Testing
DSD: differentiated service delivery	PLHIV: People Living with HIV
DTG: Dolutegravir	PMTCT: Prevention of Mother-To-Child Transmission (of HIV)
EID: Early infant diagnosis	PWID: People who inject drug
FDC: Fixed-dose combination	Q-TIB: fixed-dose combination of Isoniazid, cotrimoxazole, and pyridoxine
FP: Family planning	RNA: Ribonucleic Acid
GI: Gastrointestinal	RTV: Ritonavir
HBIG: Hepatitis B immune globulin	SEQAAAR: Safe, Efficacious, Quality, Affordable, Accessible, Available & Rationally used
HBV: Hepatitis B virus	SpO2: pulse oximetry (or pulse saturation in Oxygen)
HCT: HIV Counselling and Testing	STI: Sexually Transmitted Infection
HCW: Health Care Worker	TasP: Treatment as Prevention
HIV: Human immunodeficiency virus	TB: Tuberculosis
HIVST: HIV self-testing	TDF: Tenofovir
HL: Hodgkin's Lymphoma	TLD: Tenofovir Lamivudine Dolutegravir
HPV: Human papilloma virus	TMP: trimethoprim
ICP: Intracranial pressure	UNAIDS: The Joint United Nations Program on HIV and AIDS
IPT:	VCT: Voluntary Counselling and Testing
IRIS: Immune reconstitution inflammatory Syndrome	VL: Viral load
LA: Latex agglutination	WHO: World Health Organization
LFA: Lateral flow assay	ZDV: Zidovudine
MOH: Ministry of Health	
NADCs: Non-AIDS defining cancers	

Chapter One: Introduction

Antiretroviral therapy (ART) remains an essential component of the national response to the HIV epidemic in The Gambia. It forms a core part of the provision of comprehensive services for HIV prevention, testing, treatment, care and support. The primary goal of ART is to reduce HIV-related morbidity and mortality and to improve the quality of life of people living with HIV (PLHIV).

The Gambia is committed to achieving the global UNAIDS 95-95-95 targets, aiming that by 2030, 95% of people living with HIV (PLHIV) will know their status, 95% of those diagnosed will receive sustained antiretroviral therapy (ART) and 95% of those on ART will have suppressed viral loads. However, the country remains significantly behind these targets. According to the most recent Spectrum HIV testing and treatment cascade (2024), 64% of 25,247 estimated PLVIH knew their status, only 44% were receiving ART and 35% were virologically suppressed. The 95-95-95 indicators showed that 64% knew their status, 69% of known people were on ART and 79% of people on ART were virologically suppressed.

This level of treatment coverage remains well below global benchmarks and highlights persistent weaknesses in HIV case finding, linkage to care, and retention in treatment.

Despite these gaps, progress has been made in expanding ART services. As of December 2024, 11,187 people were on ART, reflecting a consistent increase from 3,997 in 2013. ART uptake has improved due to the adoption of the “test and treat” approach initiated in 2018, which allows all PLHIV to start ART regardless of CD4 count or clinical stage. The expansion has also been supported by the task-shifting initiative, enabling nurses and community health workers to provide ART, thereby enhancing accessibility in underserved areas. In addition, the introduction of HIV self-testing (HIVST), index testing and partner testing strategies has contributed to identifying individuals unaware of their HIV status.

However, several challenges persist. Linkage to care remains a critical bottleneck, with only 44.3% of those diagnosed successfully initiated on treatment. A disproportionate number of ART clients remain concentrated in urban health facilities, limiting equitable access for rural populations. This urban–rural disparity is shaped by multiple factors, including limited ART service availability in remote areas, travel barriers, stigma and fear of disclosure in close-knit communities. In response, The Gambia has introduced a national framework for Differentiated Service Delivery (DSD), including community ART refills, mobile outreach and fast-track refill models, to improve access and retention in rural and underserved areas.

Other disparities persist. Men remain underrepresented. In 2023, women accounted for 76% of ART clients (8,018 women compared to 2,487 men). Paediatric coverage remains low, with only 7% of PLHIV on ART being children. HIV prevalence also remains alarmingly high in key populations, including men who have sex with men (35.5%) and female sex workers (11%), underscoring the need for tailored, rights-based interventions.

To close the gap toward the 95-95-95 targets, The Gambia will intensify its efforts to strengthen HIV testing coverage and focus on DSD models that better meet the needs of diverse populations. It is equally important to prioritize linkage to care as a standard component of the HIV testing cascade, expand decentralized and community-based ART initiation and ensure stronger adherence support and retention strategies, particularly for men and young people.

With updated treatment guidelines, integrated services and intensified community engagement, The Gambia hopes to build a more resilient and equitable response and move closer to achieving HIV epidemic control.

1.1 HIV Prevention, Treatment, Care and Support Services in The Gambia

HIV treatment, care and support services in The Gambia began before the year 2000 on a small scale at the Medical Research Council (MRC). A major scale-up occurred in 2004 through the World Bank–funded Accelerated Results Implementation (ARI) initiative. Initial pilot sites included the Royal Victoria Teaching

Hospital (now EFSTH), MRC and Hands-On Care. In 2003, the Government of The Gambia secured a Global Fund Round 3 (GFATM Round3) grant to expand HIV care nationally, later followed by GFATM Round8 until 2014.

Since then, ART and PMTCT services have been decentralized and scaled up to 24 and 76 sites respectively, ensuring geographic coverage across all regions. Care is delivered through accredited treatment centres and ART is provided as part of a comprehensive HIV care package that includes clinical follow-up and counselling.

To meet growing service demands, The Gambia has implemented task-shifting and task-sharing, enabling trained nurses and physician assistants to initiate and manage ART. This has expanded access to treatment, especially in rural and underserved communities. Ongoing capacity building, clinical mentorship and standardized treatment protocols have supported scale-up and quality of care.

In 2018, The Gambia adopted the "Test and Treat" strategy, aligned with WHO guidelines, ensuring immediate ART initiation for all people living with HIV regardless of CD4 count or clinical stage. This marked a shift toward more patient-centered, universal treatment access.

The Gambia ART programme is now being further adapted through the rollout of DSD models to improve retention, reduce clinic burden and tailor care to the diverse needs of specific populations.

Effective HIV treatment management continues to rely on the rational use of medicines, adherence monitoring and routine follow-up to minimize resistance, support viral suppression and ensure long-term quality of life for people living with HIV.

1.2 Entry points into HIV Treatment, Care and Support services in The Gambia

The entry points into HIV treatment, care and support services in The Gambia include outpatient departments (ANC, EPI, STIs, FP) and inpatient wards as well as the following services: Client-Initiated counselling and Testing (CICT), Provider-Initiated counselling and Testing (PICT), e.g. index testing, self-testing, family testing, mobile testing.

As stipulated in the revised 2023 HTS Guidelines, these testing services must adhere to the "5Cs" principles—Consent, Confidentiality, Counselling, Correct test results and Connection to prevention, treatment, care and support. Importantly, HTS must be linked to timely initiation of ART and other HIV-related services. Providing HIV testing without effective linkage to care offers limited benefit and undermines national targets. The integration of these services into routine care is essential for epidemic control and for ensuring equitable access across all populations, especially key populations, adolescents and underserved communities.

1.3 Guiding Principles

1.3.1 Promoting Human Rights and Health Equity

Access to HIV prevention, treatment, care and support should be recognized as fundamental to realizing the universal right to health and these guidelines should be implemented based on core human rights and ethical principles.

The HIV programme needs to ensure that HIV services are accessible to all people living with or affected by HIV, including pregnant and breastfeeding women, children, adolescents, men and key populations. Particular attention must be paid to addressing gender, geographic, socio-economic barriers, and ensuring services are delivered in safe, confidential and stigma-free environments.

Informed and voluntary consent must always be obtained, especially for HIV testing. Clients must be given adequate information and support to make autonomous decisions and robust safeguards must be in place to uphold confidentiality.

The commitment to universal access with the “Treat All” strategy fully implemented in The Gambia since 2018, places human rights and health equity at the centre of the HIV response. This shift ensures that no one is left behind and that service delivery is not only available, but equitable, respectful and empowering.

1.3.2 Increasing Programme Effectiveness and Efficiency

Within the context of limited health system resources, it is essential to maximise the impact and efficiency of the HIV programmes. The Gambia’s adoption of the “Treat All” approach offering immediate ART initiation for all PLHIV has improved clinical outcomes and reduced HIV transmission, but also presents operational challenges as services expand.

To maintain high-quality care at scale, programmes must prioritize:

- Early diagnosis and prompt ART initiation
- Tailored services that respond to the needs of specific populations, including adolescents, key populations and rural communities
- Optimized resource use through effective service delivery models

In line with national policy and WHO recommendations, DSD should be further scaled up. Models such as multi-month dispensing, task-sharing, community-based ART delivery and fast-track refill improve access, reduce facility burden and align services with client preferences. These approaches enhance both programme efficiency and client satisfaction and are critical to accelerating progress toward epidemic control.

1.4 Summary of changes in 2025 The Gambia HIV Guidelines

The table 1.1 summarizes the key updates introduced in the 2025 revision of The Gambia's HIV Guidelines as compared to the 2019 version. The 2025 revision reflects alignment with WHO 2021 recommendations, expanded service delivery models and updated protocols for prevention, treatment and monitoring. The chapter follows the continuum of care as suggested by WHO.

Table 1.1: Summary of changes in 2025 HIV Guidelines

Chapter	Key 2025 Updates Compared to 2019
1. Introduction	- Emphasis on service delivery: task-shifting and differentiated service delivery (DSD) models as per New Guidelines
2. Prevention, Testing, Diagnosis & Linkage	- Integrated PrEP (oral and injectable); U=U messaging introduced - Updated PEP criteria and added PEP algorithm - integrated family testing strategy - include Community testing & follow-up tools (e.g., SMS, home visits) - updated and Structured linkage protocols from HIV testing to enrolment in care (intra-/inter-facility, community-based)
3. PMTCT (HIV, Syphilis, Hepatitis B)	- Updated maternal ART: TDF/3TC/DTG - Integrated HBV and syphilis screening; infant prophylaxis and family screening - VL monitoring before delivery and 6 monthly VL during pregnancy and breastfeeding introduced - Newborn management according to exposure (HIV, HBV and/or syphilis) - High-risk and low-risk HIV transmission and differentiated prophylaxis regimens - Confirmation of positive PCR by a second PCR on a second sample
4. ART in adults and sexually infected adolescents	- Introduction of PoC CD4 at baseline - Rapid initiation of ART, including same-day initiation (unless AHD) - People-centred care (DSD) - Updated 1st to 3rd line regimens
5.Monitoring Patients on Antiretroviral Therapy	- CD4 monitoring in case of suspicion of AHD - Added 6-monthly routine VL during pregnancy / breastfeeding - Introduced VL every 6 months for children and adolescents <20 yrs - Update of VL monitoring with modification of DBS threshold of 1000 copies/mL for virological failure
6. Advanced HIV Disease (AHD)	- WHO 2021-aligned AHD package - Introduction of TB LAM, CrAg & Toxo LFA diagnostics - Prevention, screening and clinical management of TB, CM and toxoplasmosis - Timing initiation of ART - Introduction of single-dose liposomal amphotericin B for Cryptococcal Meningitis - Updated TPT regimens (3HP, Q-TIB)
7. Co-infections	- PJP, STIs, screening, prevention and treatment of cervical cancer for women living with HIV and Kaposi's sarcoma treatment updated - Cotrimoxazole guidance based on new CD4 PoC thresholds (<200) - Testing and management of hepatitis B
8. NCDs & comorbidity	- New mental health section with PHQ-9 screening tools - Expanded management of hypertension and diabetes in PLHIV
9. Paediatric HIV Care	Reorganized paediatric ART into dedicated chapter - Updated 1st and 2nd line ART regimens (and updated weight-band dosing ART) - Emphasis on child-specific ART initiation and caregiver support - Child-centered monitoring approaches enhanced - Child and adolescent specific adherence support and disclosure management
10. Monitoring, Evaluation & Pharmacovigilance	Paragraphs added on mutation resistance

Chapter Two: HIV Prevention, Testing, Diagnosis and Linkage to Care

2.1 Prevention

2.1.1 Primary and Secondary HIV Prevention Strategies

Treatment, care and support of PLHIVs must now go hand in hand with prevention. Primary prevention focuses on remaining HIV-negative, whereas secondary prevention is directed to those who are already infected and aims to reduce the transmission of HIV to others, including unborn children. HIV infection remains incurable so far and thus control of the epidemic using primary prevention remains vital (see Table 2.1).

Services for HIV should be linked and integrated with other services in the health sector, including those for TB, sexual and reproductive health and social welfare and with those provided within homes and communities by families, international and national nongovernmental organizations (NGOs), community-based organizations (CBOs), faith-based organizations (FBOs) and groups or networks of people living with HIV. All such services should be provided as close to clients' homes as possible.

Table 2.1: Primary and Secondary HIV Prevention Strategies and Related Activities

Strategy	Activities
Public health Education	- Inform and educate the public about the nature of HIV and STIs, including modes of transmission and updated prevention tools such as PrEP and U=U (Undetectable = Untransmissible). - Promote human rights, gender equality and health literacy.
Promote safer sexual behaviour (behavioural change)	HIV prevention efforts should promote informed, safer sexual decision-making through a rights-based, age-appropriate and evidence-informed approach. Encourage the following: - Abstaining from unprotected sexual intercourse - Encouraging delayed initiation of sexual activity among adolescents - Supporting individuals to avoid situations that increase the likelihood of risky sexual behaviour, such as casual sexual liaisons or substance use - Reducing multiple and concurrent sexual partnerships - Promoting mutual monogamy or consistent condom use with every partner - Scaling up comprehensive sexuality education in schools and community platforms, aligned with national education and youth policies - Ensuring widespread availability of male and female condoms, lubricants, and correct usage information at all HIV service delivery points—including youth-friendly services, maternal and child health clinics and key population programmes
STI prevention and care	- Promote early STI-care-seeking behaviour - Make STI services accessible and acceptable - Improve syndromic and etiologic management and integrate STI services with HIV testing, family planning and PrEP delivery.
Promote testing and counselling for HIV	- Scale up HIV testing including self-testing (HIVST) as per The Gambia HIV Testing Guidelines

Prevent mother-to-child transmission of HIV, syphilis and hepatitis B	- Strengthen the triple elimination of mother-to-child transmission (eMTCT), with Option B+ (lifelong ART for all HIV-positive pregnant and breastfeeding women), early infant diagnosis and integrated maternal–child health services.
HIV care and adherence support	- Promote early initiation to ARVs - Promote ARVs in sero-discordant couples - Strengthen DSD, peer navigator, adolescent-friendly services and community ART delivery. - Support long-term retention and adherence to treatment.
Treatment as prevention (TasP)	- Promote immediate ART initiation upon diagnosis, including same-day ART initiation when appropriate. - Reinforce that maintaining viral suppression prevents HIV transmission (U=U).
PrEP (Pre-Exposure Prophylaxis)	- Promote and expand access to daily oral PrEP and long-acting PrEP options for individuals at substantial risk - Integrate PrEP into FP and ANC services. - Offer PrEP and HTS to partners of PLHIV and link sero-discordant couples to ongoing prevention and care.
Post-Exposure Prophylaxis (PEP)	- Ensure availability of PEP within 72 hours of potential HIV exposure, particularly for survivors of sexual violence, health care exposures and key populations.

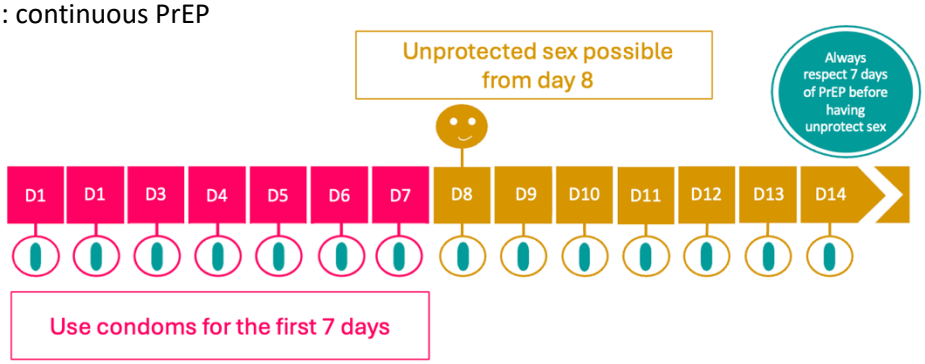
2.1.2. Pre-Exposure (PreP) and Post-Exposure Prophylaxis (PEP)

2.1.2.1 Oral Pre-exposure Prophylaxis (PrEP)

ART for Prevention among Sero-discordant Couples and other Key Populations.

When sero-discordant couples are identified and where additional HIV prevention choices for them are needed, daily oral pre-exposure prophylaxis (PrEP) with the combination of TDF + 3TC may be considered as a possible additional intervention for the uninfected partner(s).

Figure 2.1: continuous PrEP



- Oral pre-exposure prophylaxis (TDF+3TC) is provided to the HIV-negative partner in sero-discordant couples.
- Recent studies have shown that people living with HIV who maintain an undetectable viral load for at least 6 months do not transmit the virus to their sexual partners. This supports the concept of 'Undetectable = Untransmissible' (U=U).

New treatments for PrEP (long-acting ART):

- CAB+RPV (cabotegravir + rilpivirine) injectable (one shot every 2 months) is an option for people with very high HIV transmission risk such as female sex workers. CAB+RPV has shown higher efficacy than daily oral PrEP.
- Lenacapavir (1 injection/6 months) is currently tested and preliminary results show good outcomes [1]

2.1.2.2 Post Exposure Prophylaxis (PEP)

Occupational exposure to potentially infectious material may occur through an injury with a sharp object that has been used on a patient or through the contamination of mucous surfaces with patients' blood or secretions.

In people who have been accidentally exposed to HIV through needle-stick inoculation or through contamination of mucous membranes by secretions, it has been shown that administration of ARVs within 72 hours of exposure reduces the likelihood of HIV infection being transmitted. In this situation, ART needs to be continued for one month.

Who Should Receive PEP?

According to the WHO Guidelines for HIV Post-Exposure Prophylaxis (2024, [3], p.5), PEP should be offered to any individual with a known or suspected exposure to HIV, regardless of whether the exposure occurred in an occupational (e.g., healthcare setting) or non-occupational (e.g., sexual assault, community, or household) context.

PEP is recommended for the following types of exposures:

- Percutaneous (needle-stick) injuries: For example, sharps injuries involving a potentially contaminated object previously used on another person.
- Mucosal exposure: Splashes of blood or other potentially infectious fluids to the eyes, nose, or mouth.
- Non-intact skin exposure: Contact between broken or abraded skin and blood or other potentially infectious fluids (e.g., during sexual violence or caregiving).
- Sexual exposure: Unprotected receptive anal, vaginal, or oral sex with a person of known or unknown HIV status, including in cases of rape or sexual assault.

PEP should also be considered when:

- The HIV status of the source is not known but the exposure involves a fluid with transmission potential and a route known to carry risk (e.g., blood to mucosa or sex).
- The fluid involved is one capable of HIV transmission: including blood, blood-stained saliva, semen, vaginal and rectal secretions, breast milk and cerebrospinal, peritoneal, pleural, pericardial, synovial, or amniotic fluids.

Risk to consider:

- Source individual has a high viral load or is not on ART.
- Presence of sexually transmitted infections (STIs).
- Deep percutaneous injury, particularly involving hollow-bore needles, visible blood, or puncture to a vein or artery.
- In cases of sexual exposure, lack of male circumcision in the exposed person may modestly increase risk.

Timing and Duration:

- PEP should be initiated as soon as possible, ideally within 24 hours and not later than 72 hours post-exposure.
- The recommended duration of PEP is 28 days using a three-drug regimen (preferably integrase inhibitor–based), following national protocols.

Exposures that do not require PEP include:

- when the exposed individual is already living with HIV,
- exposure to bodily fluids that do not pose a significant risk: tears, non-blood-stained saliva, urine, sweat, sputum and diarrhoea/faeces,
- when the source is established to be HIV-negative or if the exposure was sexual and the source has an undetectable viral load for at least 6 months (U=U).

NOTE: where exposure is suspected, provision of PEP should not be delayed by trying to identify or find out the HIV status or viral load of the source of exposure.

2.1.2.3 Prevention of Occupational Exposure in the Healthcare Setting

All health facilities (private and public) should adopt a policy for the prevention of occupational accidental exposure to blood-borne pathogens (BBPs).

- Universal precautions (i.e., the use of disposable latex gloves when handling bodily fluids, single-use equipment and proper management of sharp and hepatitis B virus (HBV) and other blood-borne pathogens when providing health care.
- Under universal precautions, the blood and certain body fluids of all patients are considered potentially infectious for HIV, HBV and other blood-borne pathogens.
- Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, which can reduce the risk of exposure of the health-care worker's skin or mucous membranes to potentially infectious materials.
- Health facilities should implement universal precautions for the prevention of exposure to potentially infectious material.

The programme should include:

a. The training of all employees in the handling and disposal of infectious material.
b. All personnel should be made aware of the risks involved in improper handling of such material and the steps necessary for preventing exposure should be clearly displayed in posters.
c. The greatest risk of accidental exposure is in the handling of sharp objects that have been used on patients.
d. All personnel should be taught how to safely handle and dispose of sharp objects.
    - Messages should promote the avoidance of recapping needles, using "sharps bins" for disposing of sharps and taking precaution in performing procedures.
    - Health personnel should also be conscious that blood and secretions from patients may be infectious and that simple contamination of unbroken skin does not comprise a significant risk, but contamination of intact mucous surfaces of the mouth and eyes does.
e. Facilities should ensure the availability and accessibility of medicines for PEP.

2.1.2.4 Procedure to be followed in the event of injury with a sharp object

In the event of an injury with a sharp object, such as a needle or scalpel, that has been used on a patient or in the event of a mucous surface being contaminated with blood or secretions from a patient, the following steps should be followed:

1. Wash the exposed area thoroughly with soap and running water.
2. Start the ARVs recommended for post-exposure prophylaxis immediately—these should be started within 2 hours if possible and at the latest within 72 hours of the exposure.
3. Ascertain the HIV status of the patient (source) and the injured health worker (recipient) after providing appropriate counselling:
    a. The standard rapid HIV antibody tests and hepatitis should be used and the results of tests obtained as quickly as possible. If the source is a child less than 18 months, test the mother (rapid HIV test) and, if the mother is not available, test the child (PCR on GeneXpert).
    b. Offer viral DNA or RNA testing, if the source is suspected to be in the window period (i.e., recently exposed or acutely infected and not yet detectable by standard HIV tests).
    c. Depending on the results of the HIV and Hepatitis tests, the following actions should be taken:
        a. If the source patient is HIV-negative, no further post-exposure prophylaxis is necessary for the exposed health worker. There will be a need to consider exposure to other infections such as hepatitis B.
        b. If the exposed health worker is HIV-positive, no further post- exposure prophylaxis is necessary. They should be referred for further counselling and the long-term management of their HIV infection, which would have occurred prior to the exposure.
        c. If the health worker is HIV-negative and the source patient is HIV- positive, continue ARVs for a period of one month; repeat the health worker's HIV and Hepatitis tests at three months and at six months after the initial test.
    d. If the health worker should seroconvert during this time, provide appropriate care and counselling and refer for expert opinion and long-term treatment.
    e. If the health worker declines to be tested for HIV and Hepatitis, reinforce counselling on the benefits of knowing his or her HIV status and inform them they may have no claim for possible future compensation.
    f. If it is not possible to determine the HIV status of the source patient, then assume that the source is positive and proceed according to the guidelines in the previous bullets.
    g. In the event of HIV infection exposure to the HCW, the greatest risk of transmission to other individuals is in the first six weeks.
4. The exposed Health Care Worker should be instructed to use measures to reduce the potential risk of HIV transmission to others, e.g. condom use, abstinence and refraining from blood transfusion and donation until the 6-month serologic test is negative.
5. Healthcare workers who are breastfeeding should consider discontinuing breastfeeding following exposure to HIV. This avoids infant exposure to ARVs and HIV in breast milk should the mother be infected. However, if the breastfed infant is aged less than 6 months and formula milk is not possible, take advice from a paediatrician and consider maintaining breastfeeding while administering ARV prophylaxis in the infant.

2.1.2.5 PEP with Hepatitis B immunoglobulin (HBIG) and/or hepatitis B vaccine:

a. Should be considered for occupational exposure (within 24 hours) after evaluating the hepatitis B status of the source patient and the vaccination status of the exposed person.
b. Hepatitis B vaccine and HBIG (if available) can be given at the same time but using different injection sites.
c. Routine pre-exposure hepatitis B vaccination should be offered to all health-care workers.

A detailed report of the injury (date, time, procedure, name of patient, name of HCW, testing procedures and PEP, etc.) must be compiled for the officer in charge (OIC), Hospital Administrator and regional health directorate (RHD).

2.1.2.6 PEP after Rape or Sexual Assault

It is recommended that a survivor of rape or sexual assault presenting within 72 hours of exposure be counselled and provided with the medicines recommended for post–occupational exposure prophylaxis.

It is important to determine the HIV and Hepatitis status of the perpetrator/suspect. If that is not possible, it may be assumed that the perpetrator/suspect is HIV-positive and HBV-positive and the survivor is provided with the treatment as listed in the preceding section including comprehensive STIs management, pregnancy test and emergency contraception. Refer the client to the nearest one stop centre for sexual assault survivors.

2.1.2.7 ARVs to be used in PEP

Immediately after exposure, all exposed adult individuals should take the following

- TDF/3TC /$DTG_{300mg/300mg/50mg}$ orally daily

The above regimen is given for one month. The dosage for children is as follows:

> 30 kg and > 10 yrs: TDF/3TC/DTG (same as adults)

< 30 kg and/ or < 10yrs: ABC/3TC + DTG (according to weigh, see appendix 1)

The exposed individuals should be counselled regarding side effects prior to receiving the medicines.

If the source is HIV-negative (including exclusion of recent infection (window period) by checking that DNA-PCR is negative, or RNA-VL undetectable), medicine administration should be discontinued.

If exclusion of recent infection is not possible (virologic tests are unavailable) and there are no side effects, even if the HIV rapid test is negative, consider continuing PEP (because during the window serologic period the source is highly infectious).

If recent HIV-infection in the source cannot be excluded, and severe ART side effects appear (such as allergy to ABC), take advice from your supervisor.

Fig 2.2 Steps for the Provision of Post-exposure

Post-exposure prophylaxis (PEP) should be offered to any individual with suspected(1) or known(2) exposure to HIV, and as soon as possible, ideally within 24 hours and not later than 72 hours.

Step 1 Clinical assessment and provision of First Aid

Conduct a rapid assessment to assess exposure

If a patient does not want to disclose details about exposure, this should not create a barrier to receiving PEP

Ask the following questions:

- Did the exposure involve a high-risk activity: needlestick injury, mucosal, unprotected sex, sexual assault, no-intact skin?
- Was there direct contact with blood, genital fluids, breast fluids or other potentially infectious body fluids?
- is status of source HIV-positive or unknown?

First Aid: wash immediately the site with soap and water (do not use strong, irritating antiseptics (like bleach or iodine), do not squeeze or rub the injury site.

Step 2 Assess eligibility for PEP

Ensure the client consents to receiving HIV Testing and PEP

- Assess when exposure occurred (exposure occurred within the past 72 hours?)
- Check if the exposed individual is known HIV positive or perform HIV test if unknown HIV status
- Check if the 'source' is HIV-infected, has unknown HIV status or is high risk

Do not provide PEP when: The exposed individual is already HIV-positive, the source is established to be HIV-negative(3), Individual was exposed to bodily fluids that do not pose a significant risk (e.g. tears, non-blood-stained saliva, urine, sweat)

Step 3 Information and support

Counsel on:

- The risk of HIV from the exposure
- Risks and benefits of PEP
- Side effects of ARVs (see Appendix 24)
- Provide Enhanced adherence if PEP will be prescribed
- Provide specific support in the case of sexual assault, including rape-linkage to the nearest one- stop centre for sexual assault survivors)

Step 4 ART prescription

Start PEP(3) immediately (do not wait for HIV test results) for 28-day

PEP should not be given if the exposed client is seen 72 hours after exposure

Recommended regimens include:

→For adults and adolescents of >30 Kg: TDF/3TC /$DTG_{300mg/300mg/50mg}$ orally daily

→For adolescents < 30 kg: ABC+3TC+DTG orally daily, according to weight (see ARV paediatric dosing table in Appendix 1)

Do not delay the first doses because of lack of baseline HIV test or any reason.

Document the event and patient management in the dedicated PEP register (ensure confidentiality of patient data).

Step 5 Follow up

Review client after one week for adherence support.

Discontinue PEP after 28 days.

Perform follow-up HIV testing at one month, three and 6 months after exposure.

Counsel and link to HIV clinic for care and treatment if HIV positive.

Provide prevention education and risk reduction counselling if HIV negative

(1) Suspected exposures are those where the HIV status of the source is not known.

(2) Known exposures are those where the source is a person confirmed to be living with HIV; the fluid involved in the exposure has potential for HIV transmission and the exposure event was parenteral or if sexual, the source has detectable levels of virus.

(3) PEP should not be initiated if the source is confirmed HIV-negative and there is no recent high-risk exposure in the previous 6 weeks. However, if there is a reason to suspect high risk behaviours, PEP should be initiated

2.1.3 Key Populations

Key populations that include men who have sex with men (MSM)**,** transgender people, sex workers and people who inject drugs (PWID) are disproportionately affected by HIV and continue to face significant barriers to accessing prevention, testing, and treatment services in The Gambia. These barriers include stigma, discrimination, legal constraints and lack of tailored services.

The use of antiretroviral therapy (ART) in key populations should follow the same clinical principles and recommendations as for the general adult population, including immediate initiation under the "Treat All" policy. However, specific service delivery adaptations are essential to ensure that key populations can access and remain engaged in care.

WHO recommends the integration of community-based HIV testing approaches for key populations, including:

- HIV self-testing (HIVST)
- Index testing with appropriate safeguards
- Peer-led outreach and mobile services.

These approaches should be delivered in safe, confidential and non-judgmental environments, supported by community structures and trained peer educators.

2.2 HIV Testing (See national HTS guideline for full protocol)

HIV Testing Services (HTS) are the critical entry point to HIV prevention, treatment, care and support. In The Gambia, HTS are delivered in alignment with the National HIV Testing Services Guidelines (April 2023, [4]) and guided by the core principles of human rights, client-centredness and public health equity.

2.2.1 Guiding Principles of HIV Testing

All HTS must be delivered in accordance with the "5 Cs":

- Consent: Testing must be voluntary and informed
- Confidentiality: All client information must be securely handled
- Counselling: Pre- and post-test counselling are mandatory
- Correct Results: Testing must follow national Quality Control procedures
- Connection to Care: All individuals must be actively linked to appropriate HIV prevention, treatment and support services.

In The Gambia, linkage to ART remains weak, with only 71% of diagnosed individuals enrolled in treatment (DHIS2 2024). According to WHO, HIV testing should never be offered in isolation. Programmes must implement proactive, client-focused linkage strategies that ensure timely ART initiation and retention in care.

These include specific strategies such as:

- Designated linkage focal persons or peer navigators
- Use of immediate referral and escort systems after testing
- Same-day ART initiation when clinically appropriate
- Active follow-up (phone, community health worker/social Worker visits) within 7 days post-diagnosis
- Clear documentation and monitoring of linkage outcomes.

These principles must be applied consistently across all service delivery points, including community-based and outreach settings, to ensure confidentiality, trust, autonomy and client safety.

2.2.2 HIV Testing Service Delivery Approaches in The Gambia

The national strategy promotes a mix of testing modalities, including:

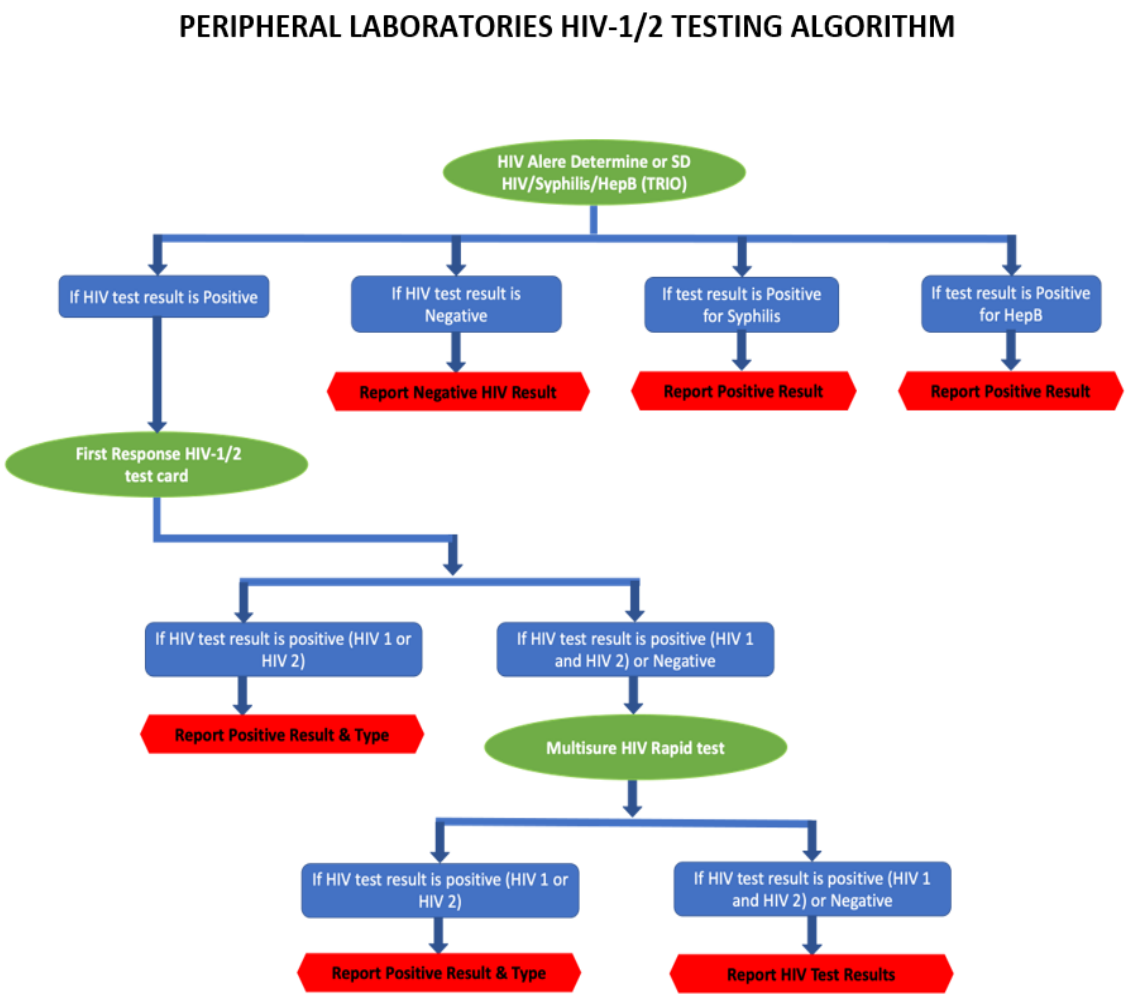
- Provider-Initiated Testing and Counselling (PITC) in healthcare settings
- Client-Initiated Testing (VCT) in both facility and community contexts
- Index Testing and Partner Notification Services (PNS) with appropriate safeguards
- HIV Self-Testing (HIVST), especially for key populations and men
- Couple and family testing, and testing during ANC and TB consultations

2.2.3 Counselling and Linkage

- Pre-test counselling must address the testing process, risks and benefits.
- Post-test counselling must include support for coping with results, referral to ART or prevention services and risk-reduction messaging.
- Counselling should be tailored to adolescents, key populations and others with specific needs.

2.2.4 National HIV Testing Algorithm

Figure 2.2: peripheral laboratories HIV testing algorithm



Note: For detailed guidance on implementation, supervision, and test kit protocols, refer to The Gambia National HIV Testing Services Guidelines (April 2023, [4]).

2.3 Linkage to HIV Care: Bridging Diagnosis and ART

2.3.1 Rational

Linkage to care is a critical step in the HIV continuum, ensuring that people diagnosed with HIV are promptly connected to treatment, prevention and support services. As part of the 95-95-95 UNAIDS targets, 95% of people diagnosed with HIV should be enrolled on ART. However, in The Gambia, only 44,3% of people living with HIV (PLHIV) are currently receiving ART, reflecting a major programmatic gap.

This low coverage highlights persistent weaknesses in the second "95," including delays in ART initiation after diagnosis, stigma and fear of disclosure and fragmented services between testing, clinical assessment and ART initiation. HIV Testing Services (HTS) must take primary responsibility for ensuring that individuals diagnosed with HIV are linked to treatment, support and prevention services. All facilities should emphasize the importance of post-test counselling and linkage must be part of an explicit facility strategy, integrated into every HTS programme.

Barriers to effective linkage can be grouped as follows:

- Client-level: lack of perceived illness, fear of lifelong treatment, depression, fear of stigma or disclosure;
- Socio-cultural: high levels of stigma and discrimination;
- Structural: poor referral system and transport-related challenges.

2.3.2 Strategic Interventions to Improve Linkage to Care

Linkage of HTS clients can be inter-facility, intra-facility or community facility.

2.3.2.1 Intra facility Linkage interventions

Intra-facility linkage refers to connecting a client from HTS to facilities accredited to provide HIV treatment within the same health facility. While intra-facility linkage should be prioritized to enable same-day service continuity, clients must be empowered to choose the facility that best meets their needs for care, treatment, or prevention. All intra-facility linkages shall be on the same day and where not possible, should be effected within 7 days.

2.3.2.2. Inter-facility Linkage

Inter-facility linkage involves referring and connecting clients from one health facility to another for access to HIV care, treatment and support services. The responsibility of the referring facility includes tracking all HIV-positive clients referred to other sites and ensuring that they are successfully enrolled in care and initiated on treatment within 14 days.

This process should follow the standard tracking schedule outlined in Table 2.2. below.

Table 2.2: Schedule for Tracking Inter-facility Linkages

Timeline	Action
Day 1 (referral day)	- A client diagnosed HIV positive must be referred to the facility of choice. - Linkage facilitator obtains client's consent and documents clients' contacts. - Linkage facilitator obtains client's consent for home visit.
Week 1	- Linkage facilitator calls a client or the contact in the health facility where the client was referred to. - If the client reached the new facility, document complete linkage. - If the client didn't reach the new facility by week 1, contact the client to remind them about the referral. Home visit to be organized if client consents.
Week 2	- Linkage facilitator calls client or the receiving facility to confirm whether the client has reached the facility effectively -If the client has reached the referral facility, the linkage facilitator documents the case as "linkage complete". - If the client did not reach the referral facility and if prior consent was given, the linkage facilitator either calls or conducts a home visit to explore reasons for the delay or non-linkage. - After follow-up, the facilitator again contacts the client or facility to confirm linkage. · If the client has now been linked → document as "complete". · If the client is still unlinked after 14 days → document as "lost to linkage"

2.3.2.3 Community-Facility Linkage

- Deploy CHWs, social workers, expert clients and peer supporters to trace clients diagnosed during outreach or who fail to initiate on ART.
- Introduce transport support for clients with access barriers.
- Schedule follow-up within 7–14 days for all unlinked clients, using SMS or phone contact.

2.3.3 Reducing Psychosocial and Stigma-Related Barriers

- Train providers in rights-based, non-judgmental counselling
- Promote peer-led disclosure support and safe spaces.
- Use community engagement strategies to normalize ART and reduce stigma.

2.3.4 Monitoring and Accountability

To ensure sustainable linkage performance:

- Track the proportion of newly diagnosed individuals initiated on ART within 7 days.
- Disaggregate linkage data by age, sex, district and point of diagnosis.
- Integrate linkage indicators into routine supervision and quarterly review meetings.
- Ensure referral outcomes are documented and followed up, particularly for inter-facility linkages.

Strengthening linkage to HIV care is essential to close the treatment gap in The Gambia. It requires proactive case management, client-centred delivery, community partnerships and institutional accountability. All linkage activities must align with the Gambia National DSD Guidelines (2023), emphasizing decentralized, community-delivered and stigma-free access to ART

2.4. HIV testing and diagnosis among infants and children

2.4.1 Introduction

More than 90% of HIV-infected children acquire their infection through mother -to -child transmission of HIV (vertical transmission). Eliminating new paediatric HIV infections through effective prevention of mother-to-child transmission (PMTCT) interventions must therefore remain a top national priority. Without timely diagnosis and treatment, HIV disease progression in infants is extremely rapid, particularly for those infected in utero, with many progressing to AIDS or death within the first few months of life.

The importance of Early Infant Diagnosis (EID) and prompt initiation of antiretroviral therapy (ART) in HIV-exposed infants cannot be overstated. The national EID algorithm for known HIV-exposed infants is presented in the PMTCT chapter and should be followed rigorously to ensure timely identification and enrolment into care.

However, a significant number of paediatric HIV infections still occur in children who were missed by PMTCT services either due to lack of maternal testing during pregnancy or delivery, refusal of treatment, late presentation, or loss to follow-up. These missed opportunities highlight the need for a robust catch-up testing strategy, including routine testing of children in clinical and community settings. Proactive identification and linkage of these children to ART services are critical to reduce child mortality and achieve epidemic control.

2.4.2 Early Infant Diagnosis (EID) or Antibody Testing

Antibody tests (rapid and laboratory-based ELISA) are the preferred methods of diagnosis for HIV infection for children over 18 months of age.

Before the age of 18 months, a positive antibody test proves that the infant was exposed to HIV but cannot conclude that he is HIV-infected, because transferred maternal antibodies can persist in the child's blood until the age of 18 months. DNA-PCR is the recommended test to be performed before the age of 18 months.

2.4.3. Screening for HIV exposure

All infants should have their HIV-exposure status established at their first contact with the health system, ideally by six weeks of age.

Check for HIV exposure status on the Infant welfare card (IWC), on the antenatal card or enquire from the mother or caregiver. Where the mother is available and was not tested during pregnancy, perform a rapid HIV test on the mother and if she is positive, then her infant is HIV exposed and needs to have a DBS collected for HIV DNA PCR.

If the mother is not available, the infant may be tested and if HIV antibody tests are positive at any age under 18 months, the child requires virological tests (i.e., the child is HIV exposed but needs a definitive test with HIV DNA PCR to confirm or exclude HIV infection).

Caution: if the mother was infected after delivery and the infant is breastfed, a rapid test performed in the child will be negative (no transferred antibodies) while he is exposed to HIV --> WHO (2021, [5], p 48) recommends that testing the mother is the priority to determine if a breastfed infant is exposed to HIV.

2.4.4 Clinical diagnosis of HIV infection in infants and children < 18 months

Prior to the age of 18 months, a DNA PCR test for HIV is more reliable. Where virological testing DNA PCR) is not available, for children less than 18 months, a presumptive diagnosis of severe HIV disease should be made if the infant is confirmed HIV antibody positive and:

1. Diagnosis of any AIDS-defining condition(s) can be made, or
2. The infant is symptomatic with two or more of the following clinical syndromes suggestive of severe HIV infection:

- Oral thrush
- Severe pneumonia
- Severe sepsis

Caution: the sensitivity of these clinical criteria for diagnosing HIV in infants is limited, estimated at less than 70%, meaning a substantial number of HIV-infected infants may be missed [6].

Other conditions could be considered to suspect HIV infection in an infant:

→ Poor growth, extra-inguinal lymphadenopathy, unexplained hepatomegaly or splenomegaly, and psychomotor milestones delay are frequent signs in HIV infected infants.

→ Recent HIV-related maternal death or advanced maternal HIV disease is considered as a risk factor of HIV infection in infants.

Infants under 18 months of age exposed to HIV, with clinically diagnosed presumptive severe HIV, should be started on ART. Confirmation of HIV diagnosis should be obtained as soon as possible.

2.4.5 When to consider that an infant is safe from HIV

In a child less than 18 months, who has never been breastfed (or if breastfeeding was stopped more than 8 weeks) and HIV antibody tests are negative, this child is uninfected and virological testing is indicated only if clinical signs or subsequent events suggest HIV infection.

In a child less than 18 months and still breastfed, if the DNA PCR test is negative, the infant probably does not have HIV infection but is exposed.

2.5 Diagnosis of HIV infection in children > 18 months

2.5.1 tests to use

Antibody tests (rapid and laboratory-based ELISA) are the preferred methods of diagnosis for HIV infection for children over 18 months of age. The algorithm is the same as for older children and adults.

2.5.2 Who to test among children?

2.5.2.1 Based on clinical conditions

According to the Gambia National Guideline for HIV testing service (2023), providers should be pro-active in efforts to detect children with HIV, especially the ones with:

- malnutrition (or low weight for age or losing weight or poor weight gain),
- tuberculosis,
- severe or recurrent pneumonia,
- chronic/persistent diarrhoea (>2 weeks) in the past 3 months,
- Unable to sit up by 6 months, to stand up by 12 months, or say one word by 15 months,
- enlarged lymph glands in 2 or more sites, parotid enlargement or enlarged liver with no evidence of malaria and/or any other cause of liver enlargement,
- oral thrush (white patches in mouth),
- who have ever had ear discharge. ([4], p. 42). See also Appendix 15

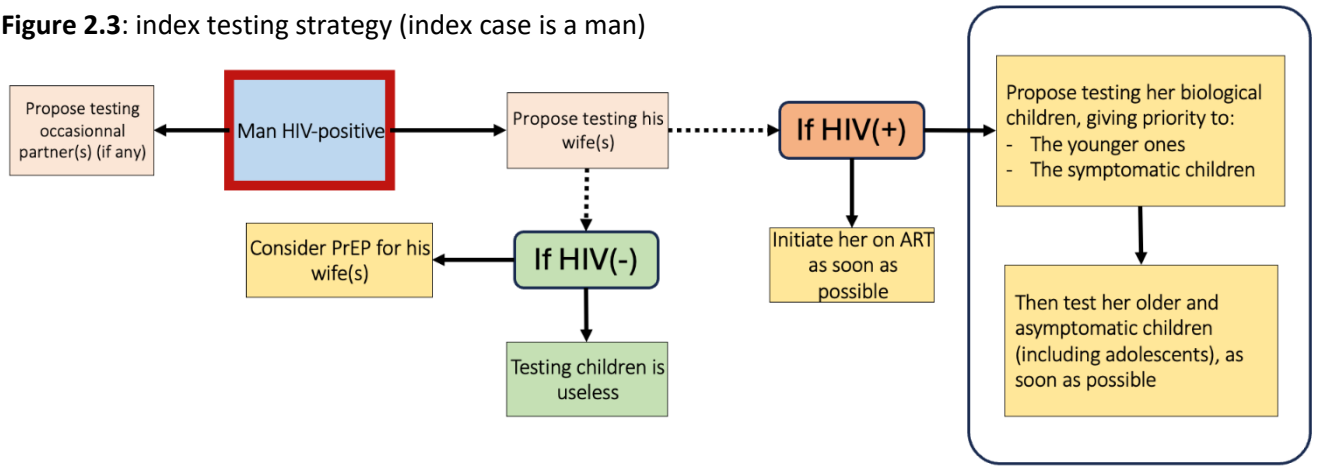
2.5.2.2 Based on family context

All adults living with HIV should be counselled to bring all children for testing. Likewise, parents and siblings of children diagnosed as HIV-positive should be tested (this is called index testing)

However, the risk of HIV infection depends on the HIV status of the mother of the biological children. The following figures show the strategy for testing the children according to who is the index case.

1/ If the index case is a man

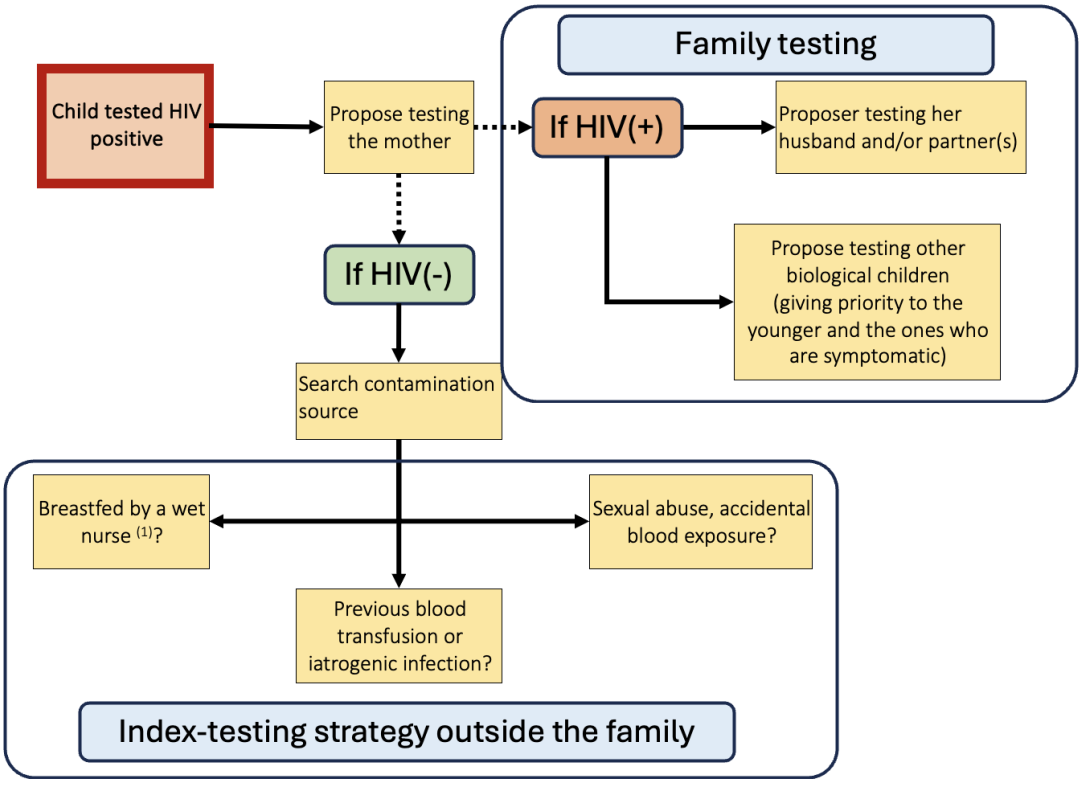
Figure 2.3: index testing strategy (index case is a man)



If the mother is not HIV infected, testing her children is useless, except if one is symptomatic (incest case).

2/ If index case is a child (and parental status is unknown)

Figure 2.4: index testing strategy (index case is a child)

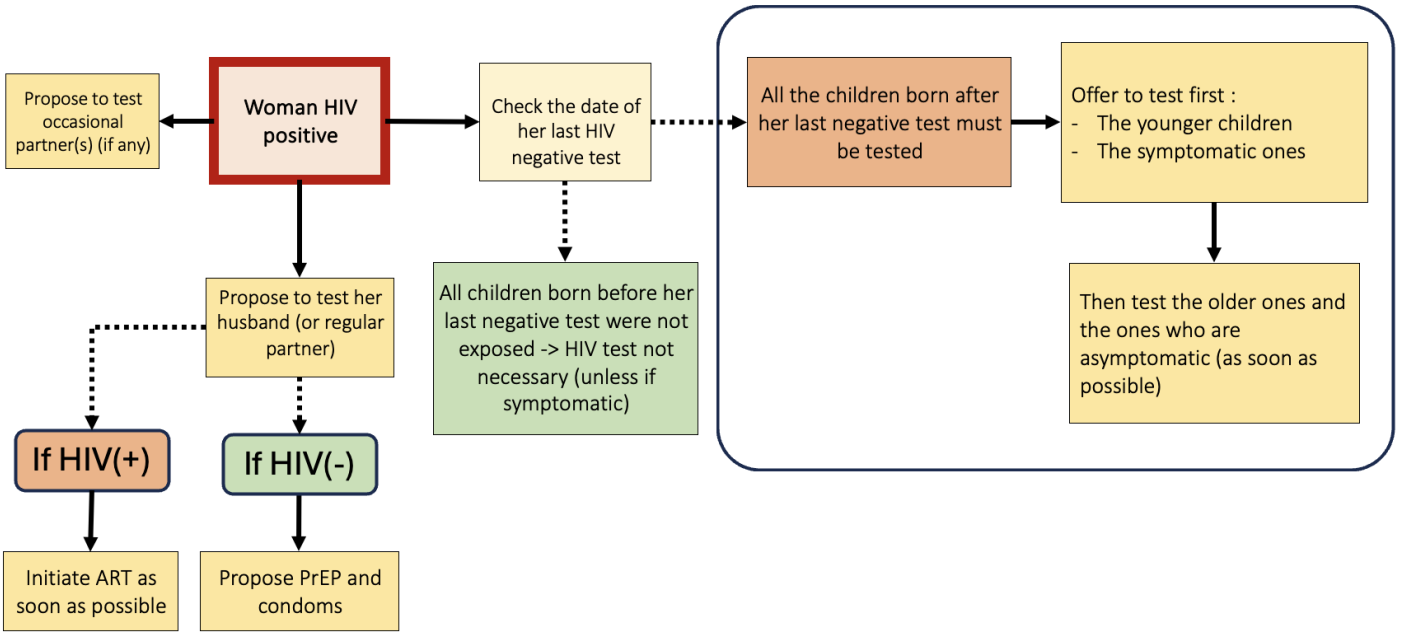


(1)A wet nurse is a woman who breastfeeds and cares for another's child.

If a child is tested HIV positive but the mother is HIV negative, testing the sibling is useless, except if one is symptomatic.

3/ If index case is a woman

Figure 2.5: index testing strategy (index case is a woman)



If a woman, who is tested HIV positive for the first time, was already tested and was negative (during previous pregnancies, for instance), all children born while she was HIV negative were not exposed to HIV. Except if one is symptomatic, they should not be tested for HIV.

4/ Finally, children who have been orphaned by AIDS should also be tested.

(See National Guideline for HIV testing service in The Gambia [4] for more information)

Chapter three: PMTCT of HIV syphilis and hepatitis B (triple elimination)

3.1 Introduction

Mother-to-child transmission is responsible for more than 90% of HIV infection in children and around half of such infections occur during pregnancy and delivery, whilst the rest during breastfeeding. It is therefore critical to identify HIV-positive pregnant and lactating women and manage them appropriately.

The PMTCT program is an entry point into care for the family. It is the beginning of a lifelong therapeutic relationship for the HIV or HBV-positive mother and her children and it is essential to reinforce the importance of HIV/HBV follow-up care for mother and her children, as well as screening her partner and other children.

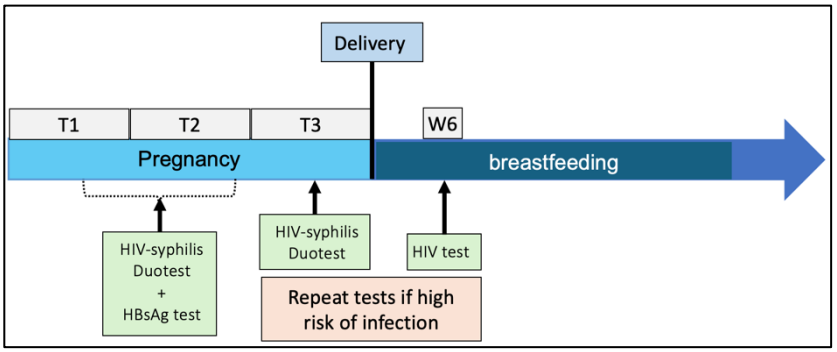
Untreated syphilis is responsible for 40% in utero fetal mortality and 20% perinatal mortality, as well as prematurity and congenital infection (with 20% of severe complications) [7], p.2)

Syphilis fetal contamination can occur during the second and third trimester of the pregnancy. Contamination is much more frequent during primary/ secondary syphilis (>60%) and the risk decreases (40% during early latent syphilis and 8% in late latent syphilis). [8]

Mother to child transmission of HBV rate depends on the viral replication level in the mother. When HBV viral is high (or HBeAg is positive), transmission risk is much higher than when HBV viral load is low (or HBe antigen is negative). Transmission occurs mainly at birth or after birth, even it is possible during pregnancy. The risk of developing chronic hepatitis B is around 90% in children who are infected at birth and 30% among children infected between one and four years old. (WHO, 2024, [9], p.66).

3.2 When to test pregnant women

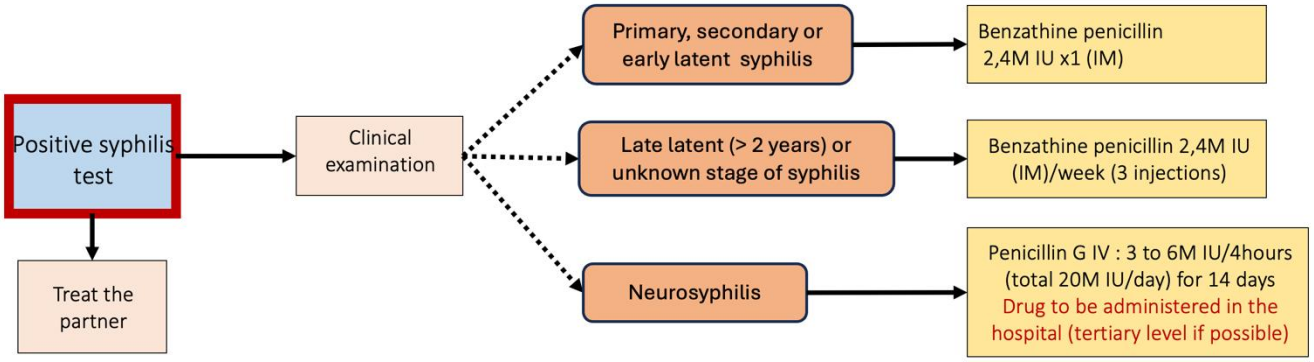
Figure 3.1: HIV testing for high-risk infection pregnant women



Pregnant women should be tested as early as possible during pregnancy. If the woman is at high risk of contamination (HIV-positive sexual partner, or unsafe sex with multiple partners, or drug user sharing needle). A follow-up testing will be offered at the end of pregnancy or in the labour room and/or 6 weeks after delivery.

3.3 Prevention of congenital syphilis

Figure 3.2: treatment of syphilis according to the phase of illness (adapted from WHO, 2016, [10])



See also Appendix 25 for more information on syphilis

When the syphilis test is positive:

- If the patient is allergic to penicillin: transfer to try a desensitization. (see appendix 26 and [11])
- If desensitization is not possible (or not successful): give ceftriaxone 1gr IM/day for 10 to 14 days.

Caution:

1/ Macrolides (erythromycin or azithromycin) are an alternative treatment for syphilis, but these drugs do not cross placental barrier and as a result the foetus is not treated.

2/ Tetracyclines are contraindicated during pregnancy

3/ Rapid tests could remain positive even if the treatment is successful --> repeating rapid test will not allow to detect new syphilis infection --> it is recommended to continue clinical STI screening at all prenatal consultation to detect if the pregnant woman has new syphilis infection.

The newborn should benefit from clinical examination to screen for congenital syphilis signs (see below for further information).

3.4. Prevention of hepatitis B

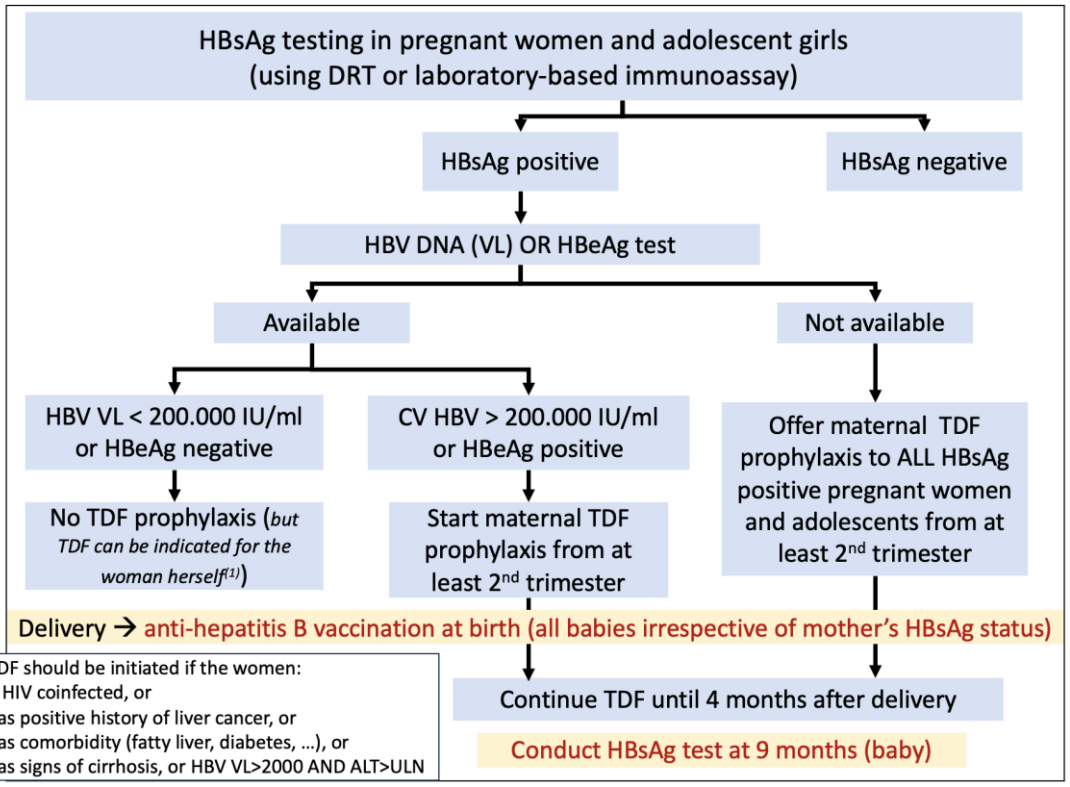
The management will not be the same in a pregnant woman mono-infected with HBV and a woman HIV-HBV co-infected.

Case one:

The pregnant woman is mono infected with hepatitis B:

--> start TDF monotherapy (or TDF-3TC if TDF alone is not available) from at least 2nd trimester of pregnancy. This treatment should continue for 12 weeks after delivery.

Figure 3.3: management of HBV infected pregnant women (adapted from WHO 2024, [9] , p. 48)



Case two:

The pregnant woman is co-infected with hepatitis B and HIV:

--> start TDF + 3TC + DTG as early as possible (see next paragraph).

3.5. When to start ART in HIV Positive Pregnant and Breastfeeding Women

All HIV infected pregnant and breastfeeding women should initiate lifelong antiretroviral treatment (ART), irrespective of their CD4 count or WHO clinical stage.

Table 3.1: Initiation of ART for Mother (PMTCT)

Population type	Preferred regimen	Alternative regimens
Pregnant and breastfeeding women	TDF + 3TC + DTG	[AZT or ABC] + 3TC + DTG[(1)] TDF + 3TC + ATV/r TDF + 3TC + LPV/r[(2)] TDF + 3TC + EFV[(3)]

[(1)] If renal failure, or proteinuria before initiation, ABC should be preferred to TDF. If unavailable, use AZT

[(2)] Only if no other option (because of frequent pill burden and side effects with LPV/r)

[(3)] Only for HIV1-infected women. Use if no other option (low genetic barrier of EFV, and cross resistance risk with NVP)

Being on lifelong ART will necessitate enhanced adherence counselling of HIV positive pregnant and breastfeeding women to support retention and minimize loss to follow-up.

3.6 Special Considerations when using ARVs in Pregnant Women

When using ARVs in pregnant women, the following precautions should be kept in mind as below:

1/ The preferred treatment (TDF + 3TC + DTG) is considered by WHO as safe for use even in the first trimester of pregnancy. However, for a known HIV positive woman who plan a pregnancy, a supplementation with folate (5mg/day) before conception can be considered to reduce the risk of foetal malformation.

2/ Although the treatment should be initiated as soon as possible, the woman must benefit from clinical examination to exclude advanced HIV disease and especially tuberculosis coinfection.

3/ Pregnancy tests can be used as pretherapeutic assessment: glycemia, creatinine and proteinuria results must be checked because:

- Drug-drug interactions exist between dolutegravir and some antidiabetic drug (metformin).
- TDF is contraindicated if renal function is altered.

In case of proteinuria, increased creatinine or hyperglycaemia before ART initiation, ask for medical advice.

4/ Special situations

The HIV infection is discovered during the last trimester (or last month) or during labour:

Initiate ARV as soon as possible and consider that the risk of transmission of HIV to the baby is high. The newborn should benefit from PCR at birth and enhanced ART prophylaxis (see paragraphs 3.12.3. and 3.13).

The woman is infected with HIV2:

Even if the transmission risk is much lower, the woman will be treated with the same ART regimen (the preferred regimen is active on HIV 1 and HIV 2).

3.7. Other treatments (CTX, TPT)

1/ Initiate Co-trimoxazole (CTX): 960mg/day and stop IPT.

Co-trimoxazole can be used during pregnancy, according to WHO, including during the first trimester and the last month of pregnancy.

2/ Give tuberculosis Preventive Treatment (TPT):

After excluding active TB, TPT can be initiated.

In pregnant and lactating women, the recommended treatment is Isoniazid 300mg daily and Vitamin B6 (Pyrimethamine): 15 to 40mg daily for six months.

Caution: Infants being breastfed by a mother who is on TPT should receive pyridoxine for the duration of the mother's treatment. (WHO, 2024, [12], p. 52)

3.8 Psychosocial support

Discovering HIV infection during pregnancy is often more traumatic than by a voluntary test because the woman is usually less prepared to receive such information.

To increase the probability of linkage to care and adherence to treatment, the health care provider should refer her to support societies or any community support association to help her accept her diagnosis.

Adherence is key to prevent mother to child transmission: adherence counselling must be provided at all antenatal visits.

Any woman who is late on appointment must benefit from enhanced adherence counselling sessions. Any woman who does not come for her appointment for refill must be rapidly traced.

3.9. Family (index) testing

Testing of pregnant women allows to discover new cases and is an entry point to test the partners and children to detect additional cases of HIV, HBV or syphilis infected people.

3.9.1. If the pregnant woman is positive for HIV

Check for the date of the last negative HIV test and propose testing her husband and all her children born after the last negative test. (See paragraph on family testing in chapter 2).

3.9.2 If the pregnant woman is positive for syphilis or hepatitis B

If the woman is positive for syphilis:

--> Her partner(s) must be treated and should use condoms until they are treated, to avoid reinfection.

If the period of maternal syphilis infection is not known, ask if other children have symptoms consistent with congenital syphilis, such as skin eruption, mucopurulent or blood-stained nasal discharge, poor growth, seizures which appeared in the first months of life. Or in older children (after 2 yrs of age), skin ulcers, walking difficulties, progressive deafness or vision disorders.

Box 3.1: signs of congenital syphilis

Signs and symptoms can be present at birth or in the first weeks of life (early congenital syphilis) or can appear after two years of life (late congenital syphilis).

Early congenital syphilis commonly manifests during the first 3 months of life. Clinical manifestations include:

- characteristic vesiculobullous eruptions or a macular, copper-coloured rash on the palms and soles
- papular lesions around the nose and, as well as petechial lesions.
- Generalized lymphadenopathy, thrombocytopenia, haemolytic anaemia and hepatosplenomegaly.
- growth and weight faltering
- characteristic mucopurulent or blood-stained nasal discharge causing snuffles.

A few infants develop meningitis, choroiditis, hydrocephalus, or seizures and others may be intellectually disabled. Within the first 8 months of life, osteochondritis (chondro-epiphysitis) may cause pseudo paralysis of the limbs.

Late congenital syphilis typically manifests after 2 years of life and causes:

- gummous ulcers that tend to involve the nose septum and hard palate
- leg deformation (periosteal lesions that result in sabre shins)
- Intellectual disability, difficulties to walk (juvenile paresis)
- Sensorial disorders: vision (optic atrophy, interstitial keratitis), audition (progressive sensorineural deafness) and dental abnormalities.

If she is positive for hepatitis B:

--> the partner must be tested and if he is HBsAg negative, he should be vaccinated.

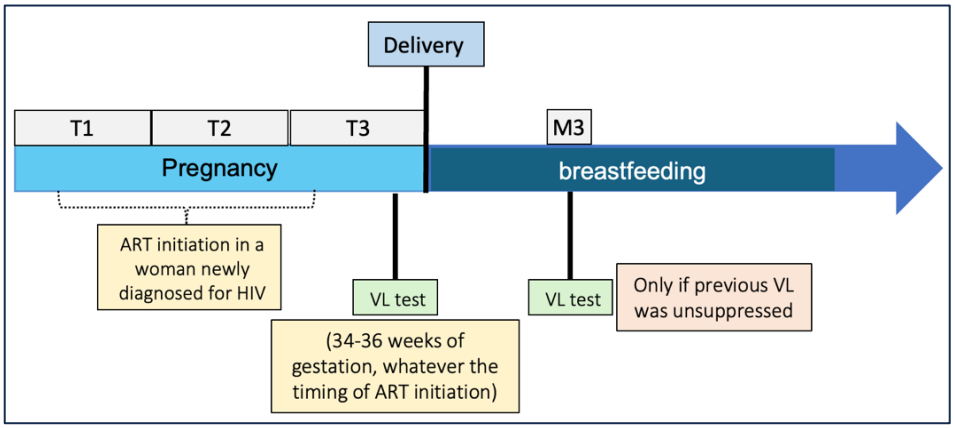
--> her biological children should also be tested and the health care provider must check their previous vaccinations for anti-hepatitis B vaccine. If any child was not completely vaccinated (or the information is not available), consider providing additional vaccination for children with negative test result.

3.10 Follow up of HIV-positive women until delivery

From the initiation on ART until the delivery, the woman will benefit from a monthly follow up.

Case 1: the woman is newly diagnosed with HIV

Figure 3.4: virologic follow up during pregnancy when HIV infection is newly diagnosed



For women diagnosed during pregnancy:

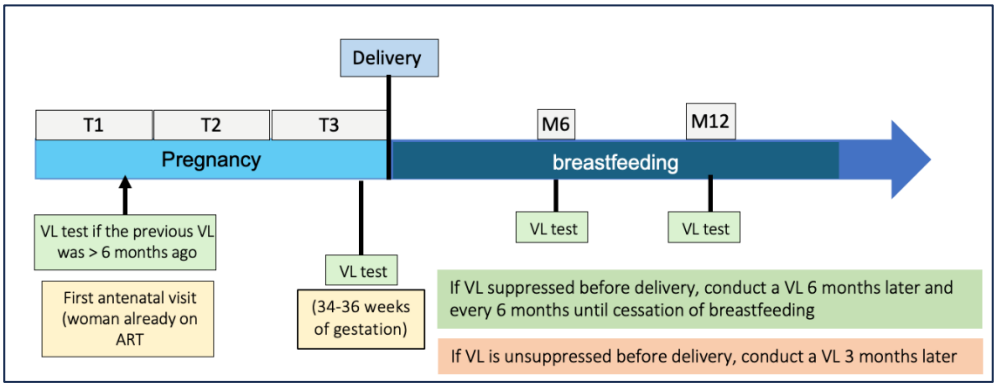
Conduct a VL test at 34-36 weeks of gestation, regardless of ART initiation timing.

If VL is unsuppressed, strengthen adherence and repeat VL 3 months later (around 12 weeks after delivery)

Case 2: the woman was already on ART

If the woman was already on ART, conduct a VL test at the first antenatal visit (if the previous one was done six months before or more).

Figure 3.5: virologic follow up when ART was initiated before pregnancy



If the VL is suppressed, conduct another VL test between 34 and 36 weeks of gestation.

If the VL is unsuppressed, conduct another VL test 3 months later after enhanced adherence counselling and before delivery.

In both cases, if VL is suppressed, conduct a VL test every 6 months until the end of breastfeeding.

Whenever possible, use point of care GeneXpert to get a same-day result.
According to the VL result before delivery (34 to 36 weeks of pregnancy), the child will be classified as high or low risk transmission (see further)

3.11 Management of the mother at delivery

3.11.1 Testing or retesting during labour or delivery

Pregnant women of unknown status who present in labour and delivery should be tested for:

- HIV: if test positive, start ART and consider the newborn as high transmission risk
- Hepatitis B: if positive, commence TDF and provide anti HBV vaccination at birth to the newborn
- Syphilis: if positive, treat the mother and refer the baby for treatment.

3.11.2 Avoid unnecessary invasive procedure

Encourage health facility delivery and the importance of skilled birth attendant, clean and safe delivery, avoiding episiotomy, invasive procedures or aspiration of the newborn unless strictly necessary.

These precautions are useful for the prevention of HIV and HBV transmission.

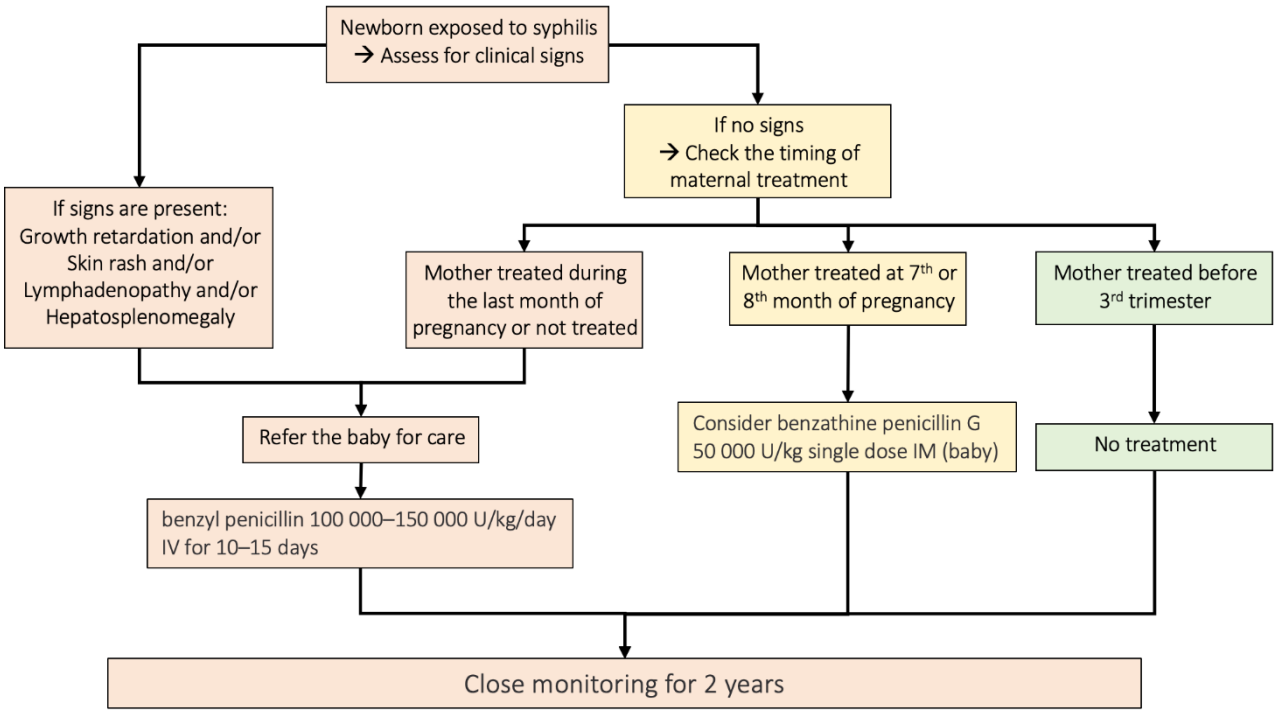
However, the best way to reduce the transmission is to obtain an undetectable VL for HIV (and as low as possible for HBV) before delivery.

3.12. Management of the newborn at birth

The management depends on the exposure

3.12.1 Exposure to syphilis

Figure 3.6: management of a newborn with syphilis antenatal exposure



3.12.2 Exposure to HBV

Most HBV transmissions occur at delivery.

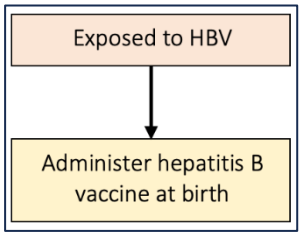


Figure 3.7: management of a newborn with HBV exposure.

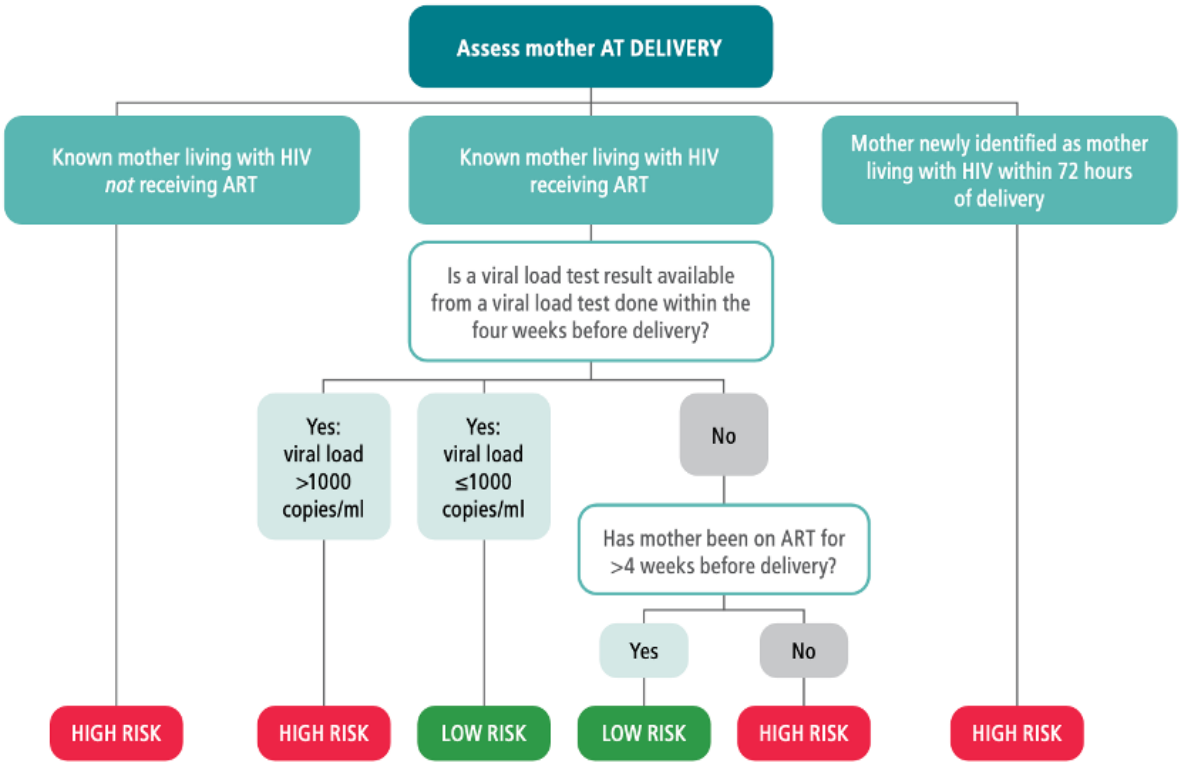
Vaccination anti-hepatitis B must be administered as soon as possible (within the first 24 hours and, if possible, in the first 6 hours) after birth.

Administration of immunoglobulin anti HBs would increase the prevention but this treatment is expensive and not readily available.

3.12.3 Exposure to HIV: first classify the risk of transmission

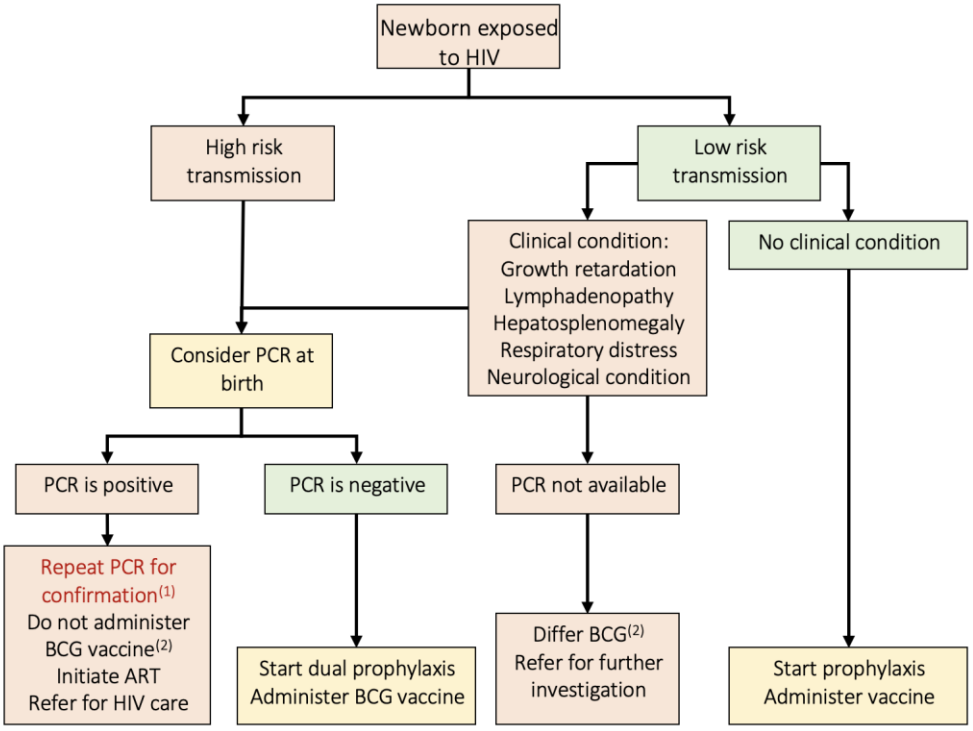
3.12.3.1 Classification of high risk and low risk of HIV transmission (WHO, 2021, [5], p.94)

Figure 3.8: Assessment of HIV risk of transmission



3.12.3.2 Management of the newborn, according to risk of transmission.

Figure 3.9: Management of HIV exposed newborns (at birth)



(1)PCR for confirmation must be done immediately, if possible on another sample

(2)If BCG is differed, it should be done after at least 6 months of ART, if the child is clinically well and VL is suppressed (WHO, 2022, [13], p. 28).

3.13 Dosage of ART prophylaxis in newborns and infants

This prophylaxis should be initiated as soon as possible after birth. If the delivery was not done in a health facility but the baby is exposed to HIV and breastfed, prophylaxis is still indicated whatever the time at first contact.

N.B: Always remember to change the dose when baby gains weight.

3.13.1. Low risk of transmission

Table 3.2: ART prophylaxis in HIV1 exposed infants (low risk of transmission)

Population type	Birth to 6 weeks	6 to 12 weeks
Exposed newborn to HIV1	Nevirapine	No prophylaxis
Birth weight < 2500g (1)	10 mg (1ml) OD	
Birth weight ≥ 2500g (1)	15 mg (1,5 ml) OD	

(1) For very low birth weight babies below 2000g dose of NVP is 2 mg/kg once daily. Increase dose when baby gains weight

Table 3.3: ART prophylaxis in HIV2 (or dual HIV1+HIV2) exposed infants (low risk of transmission)

Population type	Birth to 6 weeks	6 to 12 weeks
Exposed newborn to HIV2 or dual	Zidovudine (AZT)	No prophylaxis
Birth weight < 2500g	10 mg (1ml) BD	
Birth weight ≥ 2500g	15 mg (1,5 ml) BD	

(1) For very low birth weight babies below 2000g dose of AZT is 4 mg/kg BD. Increase dose when baby gains weight

3.13.2. High risk of transmission

Table 3.4: ART prophylaxis in HIV1 exposed infants (high risk of transmission)

Population type	Birth to 6 weeks		6 to 12 weeks
Exposed newborn to HIV1	Nevirapine	Zidovudine (AZT)	Nevirapine only
Birth weight < 2500g	10 mg (1ml) OD	10 mg (1ml) BD	20mg (2ml) OD
Birth weight ≥ 2500g	15 mg (1,5ml) OD	10 mg (1,5ml) BD	20mg (2ml) OD
Weight > 3000g	15 mg (1,5ml) OD	10 mg (1,5ml) BD	20mg (2ml) OD

If the child fails to gain weight from 6 to 12 weeks, maintain the dosage under 6 weeks

Table 3.5: ART prophylaxis in HIV2 (or dual HIV1+HIV2) exposed infants (high risk of transmission)

Population type	Birth to 6 weeks	6 to 12 weeks
Exposed newborn to HIV2 or dual	Zidovudine (AZT)	Zidovudine (AZT)
Birth weight < 2500g	10 mg (1ml) BD	20 mg (2ml) BD
Birth weight ≥ 2500g	15 mg (1,5ml) BD	20 mg (2ml) BD
Weight > 3000g	15 mg (1,5ml) BD	20 mg (2ml) BD*

* Expert opinion (no WHO recommendation for HIV2 neither for AZT prophylaxis doses after 6 weeks of age).

3.13.3. Formula fed infants

For non-breastfeeding infants:
HIV1: NVP as above for 6 weeks
HIV2: AZT as above for 6 weeks

For prophylaxis, no tests are recommended by WHO.
If suspicion of anaemia on AZT → Hb or FBC
If suspicion of hepatitis on NVP → transaminases

3.14 Vaccinations at birth: specificities

If the HIV exposed newborn is not symptomatic and PCR negative or not done

--> Administer BCG and oral anti-polio vaccine

If the HIV exposed newborn is symptomatic, perform PCR

If PCR is positive, then:

--> differ BCG and oral anti-polio vaccine for 6 months pending confirmed suppressed VL (WHO 2024, [13], p. 28 for BCG; and WHO 2022, [14], p. 298 for Polio) .

If PCR is negative, then:

--> Administer BCG and oral anti-polio vaccine

Anti hepatitis B vaccine can be administered in all cases.

Before the mother leaves the maternity

Verify the mother understood how to prepare the AZT or NVP solution and the dose to be administered.

Make an appointment for EID and family planning at six weeks postpartum for low-risk newborns.

Make an appointment at 2 weeks for high-risk newborns (check clinical conditions, adherence to ART (mother) and adherence to prophylaxis (newborn).

If any clinical conditions appear, the mother should consult immediately.

3.15. Follow up of HIV exposed newborn from 6 weeks to 18 months

3.15.1 the 6-weeks consultation

1. Make sure HIV-exposed infants are entered into the "PMTCT and Infant ARV register".

2. Evaluate ART adherence for the mother and the prophylaxis for the child

- With increasing antenatal coverage of ARV medicines for PMTCT, the relative proportion of infants infected with HIV in the post delivery period, may be increasing because of poor adherence to ARV during breastfeeding.
- The HIV infected mother who is breastfeeding and on lifelong ART should receive continued counselling and support for enhanced adherence on treatment to minimize the risk of HIV-transmission through breastfeeding.
- The need to emphasize the importance of testing breastfeeding women of unknown HIV status and re-testing women who were previously HIV negative in Antenatal Care (ANC), to pick up new HIV infections in breastfeeding women. Such women who test HIV positive during lactation should be started on lifelong ART.

3. Check for infant clinical conditions and assess nutritional status. The following clinical conditions could indicate HIV infection:

- Low weight gain
- Extra inguinal lymphadenopathy, hepatomegaly, splenomegaly
- Extensive oral thrush (oral thrush is not unusual in the first 8 weeks of life but extensive aspect is worrying)
- Developmental delay (see developmental assessment in appendix 13 and "red flags" in Appendix 14)

4. Initiate co-trimoxazole prophylaxis

Table 3.6: co-trimoxazole prophylaxis doses in infants and young children

Weight (Kg)	Suspension 5ml=240mg	Paediatric dispersible tablets 120mg	Adult tablets 480mg	Adult tablets 960mg
3 to 5.9 Kg	2,5ml=1/2 spoon	1 tab	-	-
6 to 14.9 Kg	5ml	2 tab	1/2 tab (1)	-

(1) this form should be avoided in young infants. If there is a shortage of paediatric forms, explain to the mother how to split and crush the tablet and mix it with expressed breast milk or clean water.

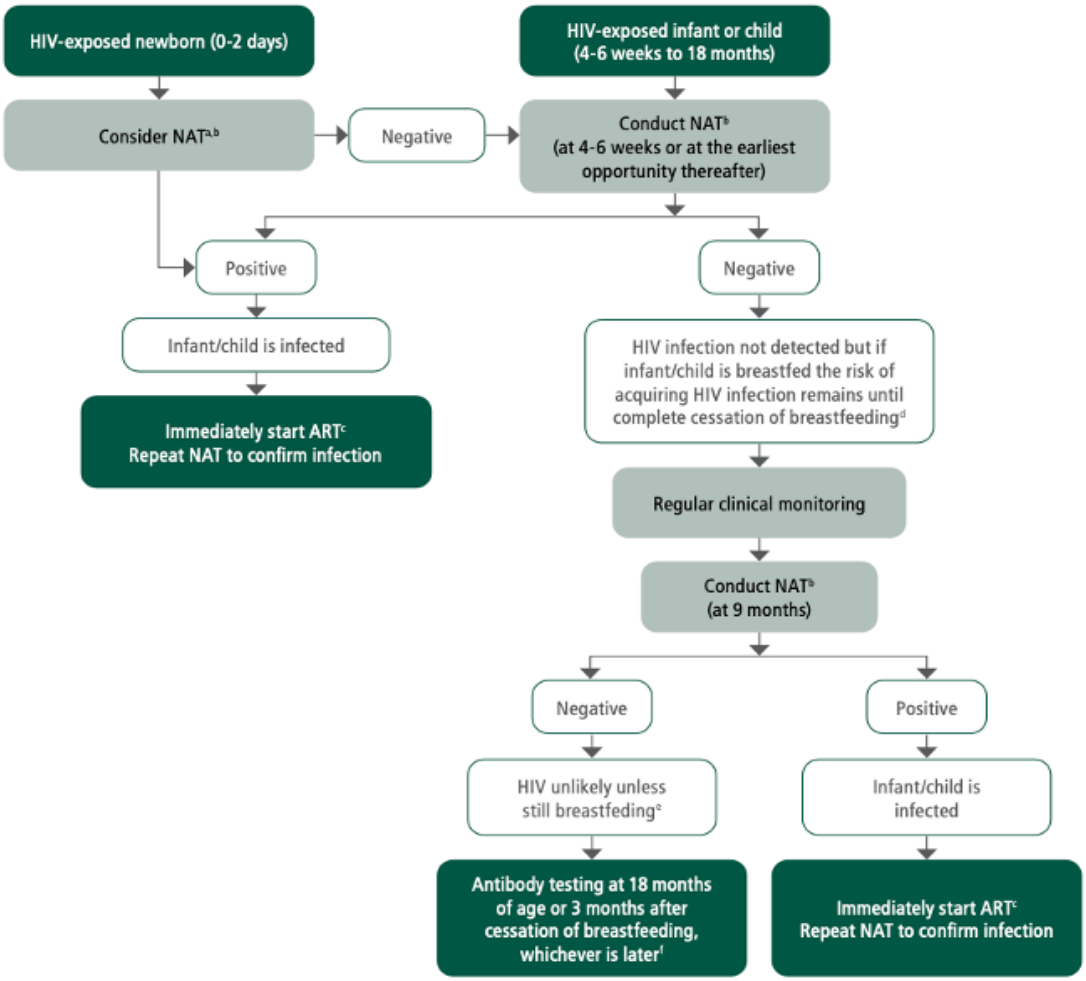
Co-trimoxazole prophylaxis should be given until the HIV status of the infant is known. It will be stopped only when HIV exposure is excluded. In HIV infected children, it will be continued lifelong.

5. Perform HIV PCR

If possible, perform PCR on GeneXpert and get the result on the same day. If the sample is sent to an external laboratory (hub), results must be received before the next consultation.

- If the PCR result is positive: both mother and child should be linked to ART site for continuum of care, ART initiation (see ART in children chapter 9) and PCR confirmation **(**see Appendix 28 for management of discordant results).
- If the PCR result is negative or unknown and transmission risk was low: stop prophylaxis
- If the PCR result is negative or unknown and transmission risk was high: prescribe adapted prophylaxis for 6 additional weeks.

Figure 3.10: algorithm of PCR and antibody testing in exposed infant (Source WHO 2021, [5]p. 41)



A DNA PCR test should be done to all exposed infants at six weeks of age. If the DNA PCR test is negative before the age of 18 months, the infant does not have HIV infection but is at risk of infection if breastfeeding is continued. A second systematic PCR must be done at 9 months (see “3.15.4-the nine-month consultation”).

In an infant, outside the window period (three months after last exposure - labour/delivery, or breastfeeding) and rapid HIV test is negative, then the infant has not been infected with HIV and can be considered definitively negative.

If an infant is still within the window period and rapid HIV test is negative, then the infant is still considered to be HIV exposed and may be infected and should be managed as an HIV-exposed infant.

6. Administer the EPI vaccinations (or verify the vaccines were administered)
There is no particularity for HIV-exposed infants regarding administration of vaccines usually provided at 6 weeks (pentavalent, anti-pneumococcal).

7. Infant feeding
Emphasize the importance of exclusive breastfeeding (no mixed feeding) for the first 6 months of the infant's life.

3.15.2 The 12-weeks consultation: stop or go on with prophylaxis?

1. Evaluate ART adherence for the mother and the prophylaxis for the child.

Check mother VL result:
If VL is suppressed, stop infant prophylaxis (if he was receiving the 12-weeks protocol).

If VL is NOT SUPPRESSED:
Provide adherence counselling to the mother and consider giving additional prophylaxis to the infant until maternal VL is suppressed.

If VL is not available: adherence should be assessed based on the respect of appointments and patient interview. If adherence is doubtful, consider go on with prophylaxis until performing a VL test (that should be suppressed).

Table 3.7: NVP prophylaxis beyond 12 weeks of life (WHO, 2010, p. 40 [15])

Population type	Nevirapine	Zidovudine (AZT)
12 weeks to 6 months	20mg (2ml) OD	No WHO recommendation Consider giving same doses as NVP (BD)
> 6 months until 9 months	30mg (3ml) OD	
> 9 months until VL suppression (1)	40mg (4ml) OD	

(1) or cessation of breastfeeding

2. Check for clinical conditions and nutritional assessment. Trace the growing weight curve and provide counselling on exclusive breastfeeding.

Search for presumptive signs (oral thrush, if present at 6 weeks, must have resolved). If weight gain is poor (flattening curve), explore the reason why (infectious process? HIV infection? TB?). Consider presumptive treatment if signs of HIV and PCR is not available.

3. Adapt doses of co-trimoxazole if weight is 6 kg or more.

4. Verify that the result of PCR1 was negative (if result was received since the previous consultation) or perform PCR1 if not yet done.

5. Verify that the vaccines were administered at 10 weeks, according to EPI.

3.15.3 the 6-months consultation

The steps are similar to the previous consultations.

Two peculiarities of this consultation:
1/ **Introduction of complementary food.**
Breastfeeding should be continued and complementary food progressively introduced, as for unexposed babies.

2/ Additional anti-measles vaccine:
Usually, the first anti-measles vaccine is provided at 9 months. However, when the mother is in an advanced stage during pregnancy, the antibodies transmitted to the foetus are reduced.

In this case, additional anti-measles vaccine can be considered. The injections at 9 and 15 months will be administered normally (unless the child is HIV-infected and immunosuppressed, see chapter 9).

3.15.4 The 9-months consultation: PCR2

The steps are similar to the previous consultations (adherence for ART in mother, co-trimoxazole in infant).

The main points are:

→ **Assess weight gain**: important to check, as complementary food was introduced 3 months earlier. If growth delay, explore the reason (dietetic errors, infectious process?).

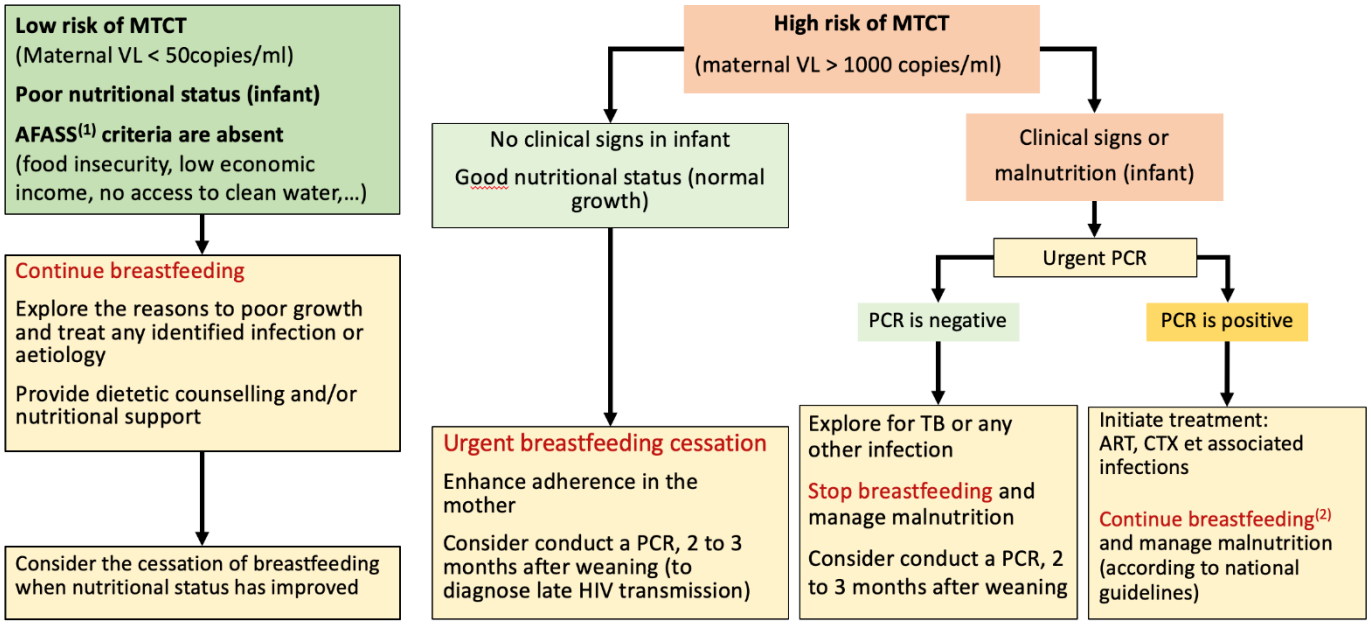
→ **Perform PCR2:** if positive, link the mother and the baby to care.

→ **Administer vaccines**: anti-measle and anti-yellow fever vaccines, unless severe immunosuppression is suspected.

3.15.5. When should breastfeeding be stopped?

The mother should be counselled on breastfeeding according to the risk of HIV transmission, the nutritional status of the child and the possibility of replacing maternal milk with a substitute.

Fig 3.11: Algorithm to decide when stopping breastfeeding in exposed children



(1) AFASS criteria are the following:

- **Acceptable:** The replacement feeding must be accepted by the mother, the family, and the close community.
- **Feasible:** The mother must have access to clean and safe water to wash bottles, nipples, and to prepare the formula if it is in powder form.
- **Affordable:** The family must be able to afford enough powdered formula or animal milk to adequately feed the baby.
- **Sustainable:** The mother must be able to prepare the infant's meals as frequently as recommended and in response to the baby's needs.
- **Safe:** The powdered formula must be safe and nutritious for the child's health.

(2) HIV infected infants diagnosed by virological testing should be breastfed for as long as possible.

Weaning should not be abrupt but rather should be gradual over a one-month period, except if maternal VL is unsuppressed and the weight of the child is normal.

3.15.6. When to consider the baby is safe from HIV infection?

Infants should be tested at 18 months if breastfeeding was stopped more than 2 months before.

If the mother is still breastfeeding at 18 months, the child must be tested **2 months** after the end of the breast-feeding period.

If a rapid test is negative, the child can be considered as not infected.

3.16 Reproductive Health and Family Planning

PLHIV have reproductive health rights and needs and should therefore receive access to the full range of reproductive health services available to the general population.

HIV positive women and couples living with HIV infection should be encouraged to discuss their reproductive options and those who wish to have children should be encouraged to discuss with their health care provider to ensure they go through a safe and successful pregnancy.

- Where pregnancy is not desired, effective contraception should be offered; if hormonal methods are chosen, dual contraception (use of both hormonal contraception and condoms) should always be encouraged and condoms provided.
- Effective use of contraception in HIV positive women plays an important role in the prevention of unplanned pregnancies and thus the prevention of mother-to-child transmission (PMTCT) of HIV infection.
- Where pregnancy is desired, a couple's status should be considered; if discordance exists, appropriate advice and support should be given:
  - If the woman is HIV infected, she should be suppressed before considering conception.
  - If the man is HIV infected, giving PrEP to the woman can be considered.
- If pregnancy has occurred in a HIV positive woman, ART should be used to optimize the mother's health and prevent mother-to-child transmission of HIV.
- The choice of contraceptive methods in HIV positive women is the same as in HIV uninfected women.

1/ Hormonal contraception may be used in HIV-infected women; however, choice of hormonal contraception should take into account ARV regimen:

- No drug-drug interactions exist between the preferred ART regimen (TLD) and hormonal contraception.
- EFV reduces the effectiveness of hormonal contraception, especially implant.

2/ Intra-uterine contraceptive device (IUCD) must not be implanted in severely immunocompromised women.

For additional information on interaction between ARV and contraception, refer to appendix 29, WHO 2019, p. 22 [16] and WHO, 2015, p. 5 [17].

Chapter Four: ART in Adults and Infected Adolescents

4.1 Guiding Principles and Goals of Antiretroviral Therapy (ART)

Antiretroviral therapy (ART) is a lifelong treatment aimed at achieving sustained viral suppression, reducing HIV-related morbidity and mortality, restoring immune function and preventing onward transmission, including mother-to-child transmission. Its success relies not only on the efficacy of antiretroviral drugs but also on timely initiation, adherence support and effective programme delivery.

Key principles guiding ART implementation include:

- Early initiation of ART for all people living with HIV, regardless of clinical stage
- Patient-centered care that supports lifelong adherence through counselling and psychosocial support
- Use of simplified, well-tolerated first-line regimens to improve adherence and reduce pill burden
- Regular monitoring of viral load to assess treatment response and detect treatment failure early
- Ongoing training of healthcare providers and quality-assured service delivery at all ART sites

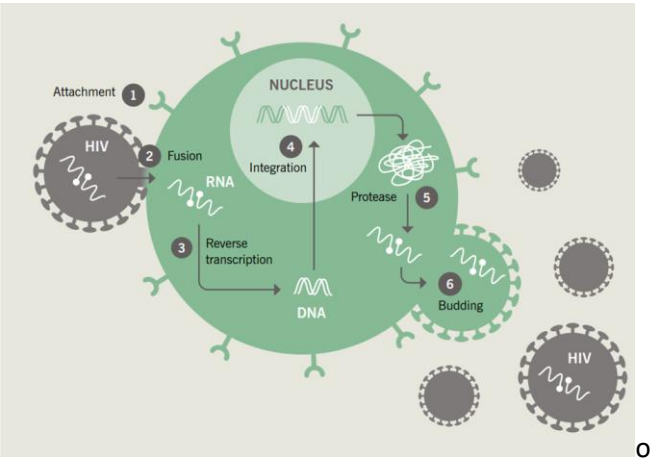
Before initiating ART, programmes should assess clinical eligibility, psychosocial readiness and potential barriers to adherence. Screening for tuberculosis symptoms and providing TB preventive therapy or treatment as appropriate should be integrated into routine care.

4.2 Characteristics of Available ARVS

Before detailing the characteristics of antiretroviral drugs, it is essential to understand the HIV replication cycle, as each class of antiretrovirals (ARVs) is designed to interrupt a specific stage in this process. HIV replicates by entering CD4 cells and hijacking the host's cellular machinery to produce new viruses.

This process involves several steps:

1. Attachment: HIV binds to the CD4 receptor on the surface of the host immune cell. This step can be inhibited by CCR5 inhibitors, which block a co-receptor (CCR5) required for the virus to attach and enter certain cells.
2. Fusion: The viral envelope fuses with the host cell membrane, allowing HIV RNA to enter the cell.
3. Reverse Transcription: The viral RNA is converted into DNA by the enzyme reverse transcriptase.
4. Integration: The newly formed viral DNA is integrated into the host cell's genome with the help of the integrase enzyme.
5. Replication and Assembly: The host cell produces viral proteins and RNA, which are assembled into new HIV particles using the enzyme protease.



6. Budding: Fully formed HIV particles exit the host cell to infect new cells, continuing the replication cycle.

Figure 4.1: Illustration of the six stages of HIV replication (source MSF 2021 Guidelines).

The main classes of ARVs act by targeting one or more of these stages:

- Reverse Transcriptase Inhibitors (NRTIs, NtRTIs, NNRTIs) act on the reverse transcription phase.
- Integrase Inhibitors (INSTIs) prevent integration of viral DNA into the host genome.
- Protease Inhibitors (PIs) block the assembly and maturation of viral particles.
- Fusion and Entry Inhibitors act at the early stages of viral entry into CD4 cells.
- CCR5 Inhibitors. These block the CCR5 co-receptor that HIV uses to enter and infect the cell

Understanding these mechanisms helps guide rational selection and combination of ARVs, aiming to suppress viral replication, prevent resistance and preserve immune function.

Table 4.1: Classes of ARVs

Nucleoside reverse Transcriptase Inhibitors (NRTIs)	Non-Nucleoside reverse Transcriptase Inhibitors (NNRTIs)	Integrase Strand Transfer Inhibitors (INSTIs)	Protease Inhibitors (PIs)	Fusion Inhibitors	Entry/CCR 5 Inhibitors
Tenofovir disoproxil fumarate (TDF)	Nevirapine (NVP)	Dolutegravir (DTG)	Lopinavir/ritonavir (LPV/r)	Enfuvirtide (T-20)	Maraviroc
Tenofovir alafenamide (TAF)	Efavirenz (EFV)	Raltegravir (RAL)	Atazanavir/ritonavir (ATV/r)		
Zidovudine (AZT)	Etravirine (ETR)	Bictegravir (BIC)	Darunavir/ritonavir (DRV/r)		
Lamivudine (3TC)	Rilpivirine (RPV) [(1)]	Cabotegravir (CAB) [(1)]			
Emtricitabine (FTC)					
Abacavir (ABC)					

[(1)] available in oral and injectable formulations

Note: fusion inhibitors and CCR5 inhibitors have low genetic barriers and are difficult to administrate. They are not currently recommended in The Gambian protocol.

New drugs and classes of ARV on development or recently approved:

1/ Lenacapavir is a capsid inhibitor that needs only one injection every 6 months (see PreP section)

For people living with HIV, preliminary results showed good outcomes for people treated by lenacapavir + 2 Broadly Neutralizing Antibodies (2 injections yearly), with 96% of undetectable VL at week 26.

2/ Islatravir is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) that could be used in PrEP (implants are in development and could prevent HIV infection for more than 1 year) or for treatment of patients with multi-resistant viruses (in association with other ARV drugs).

4.3 Considerations for Regimen Efficacy and Safety

Preferred first-line ART regimens in The Gambia are aligned with WHO 2021 recommendations and are based on a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) and one integrase inhibitor (DTG). These regimens are highly efficacious, widely available in fixed-dose combinations (FDCs) and generally well-tolerated.

- Tenofovir (TDF) + Lamivudine (3TC) + Dolutegravir (DTG) is the recommended first-line regimen for adults and adolescents.
- Abacavir (ABC) + 3TC + DTG is recommended for children.
- Dolutegravir is preferred due to its potency, high genetic barrier to resistance and favorable safety profile.

While most ARVs are safe and effective, individual and class-specific adverse effects can occur, as well as clinically significant drug interactions, especially with anti-TB, anti-cryptococcal and anticonvulsant therapies.

Note: For detailed information on regimen selection, toxicity profiles, and drug to drug interactions, refer to the dedicated section (and appendix 12)

4.4. When to start ART (Guiding Principles for ART Initiation in The Gambia)

ART should be initiated at the earliest opportunity in all people with confirmed HIV infection, regardless of clinical stage or CD4 cell count. Since 2013, evidence and programmatic experience have continued to favor early initiation of ART because it results in reduced mortality, morbidity and HIV transmission outcomes.

In the context of The Gambia with persistently low ART initiation and linkage-to-care rates, these updated principles are designed to strengthen early client-centered ART initiation and close the critical gap between HIV testing and treatment:

4.4.1. Promote Same-Day or Rapid ART Initiation

ART should be offered and initiated as early as possible, ideally on the same day as HIV diagnosis or first clinical contact, unless contraindicated (e.g., cryptococcal meningitis, CNS tuberculosis, CNS Toxoplasmosis). This is particularly urgent for pregnant women in late gestation or in labour, infants and young children diagnosed with HIV and individuals with severe immunosuppression where delays increase mortality risk.

Table 4.1: Approaches supporting same-day ART initiation at the level of the client, provider and health system

Phase	Strategies targeting clients	Strategies targeting health-care providers	Strategies targeting the health system
Pre-ART initiation	Improve pre-ART counselling content and delivery Promote shared decision-making	Provider training on rapid ART initiation Provider training on counselling Provider supervision, coaching and mentorship support Provider performance feedback Use the SoP 'HIV readiness assessment checklist (*Appendix 16*) to determine a client's readiness and appropriateness for immediate ART initiation.	Promote First ART counselling on the day of HIV testing Reduce the number of pre-ART sessions Increase the duration of pre-ART sessions Provide ART first starter pack immediately with no pharmacy waiting time Point-of-care CD4, TB screening
Post-ART initiation	Promote Appointment reminders Intensified post-ART counselling Increased duration post-ART initiation clinical visit Incentive to attend post-ART initiation visits		

(adapted from WHO HIV Guidelines 2021, [5])

4.4.2. Ensure informed and shared decision-making

ART initiation must be based on the voluntary and informed decision of the client.

Health workers should:

- Explain the benefits of ART, its lifelong nature and the expected outcomes
- Address fears and misconceptions
- Allow adequate time for the client to make a decision
- Reassure clients that treatment can begin even before all laboratory results are returned, except where advanced HIV disease is suspected.

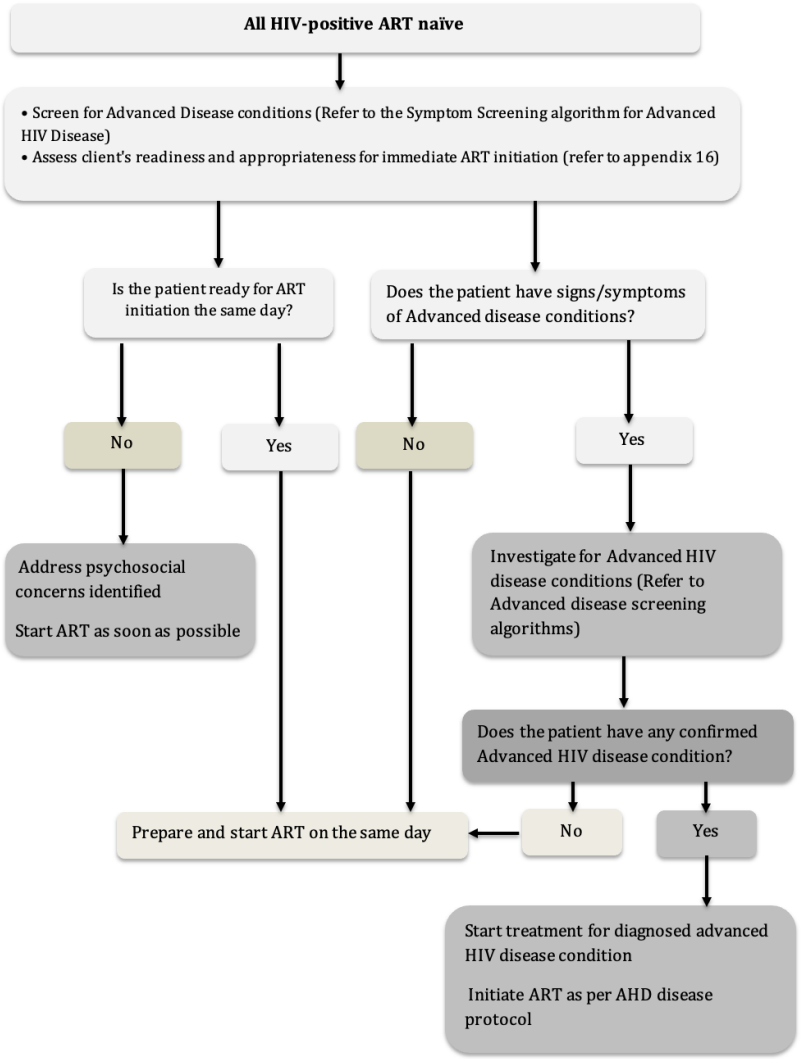
4.4.3. Implement treatment literacy and psychosocial Support

Support all clients with clear, accessible treatment information and assess psychosocial concerns (Appendix 16) before initiation. One pre-initiation session is often enough; follow-up counselling should be delivered during the first two weeks after ART initiation. Where possible, involve a treatment supporter (partner, peer, family member).

4.4.4. Exclude Advanced HIV Disease (AHD)

Before ART initiation, screen all individuals for AHD using symptom-based algorithms. When conditions like cryptococcal meningitis or CNS TB, CNS toxoplasmosis are suspected, defer ART and manage the condition first, as per AHD recommendations (see chapter 6).

Figure 4.2: How to Evaluate Patients for ART Initiation ((adapted from WHO.2021, [5)



4.5 Timing of ART Initiation

4.5.1 General situation

Key message

ART should be initiated as soon as the individual is ready, ideally on the same day of diagnosis or first clinical contact. Same-day or rapid ART initiation reduces delays, prevents loss to follow-up, and improves clinical outcomes. This is especially important in The Gambia, where linkage to care remains a major challenge.

4.5.2 Timing in special clinical situations

Table 4.2: timing of ART initiation (special conditions)

Clinical Condition	Recommended Timing of ART
Adults and adolescents living with HIV (not yet on ART) and suspected TB	TB investigations should be urgently initiated. If TB cannot be confirmed the same day, *initiate ART without delay*, especially in individuals with AHD. If TB is confirmed the same day, initiate TB treatment first and begin ART within the first 2 weeks.
Adults and adolescents being diagnosed with TB before ART initiation	Start TB treatment immediately. ART should be initiated as soon as possible within 2 weeks
Adults and adolescents living with HIV who is already on ART and diagnosed with TB	Initiate TB treatment and adjust the ART regimen if needed (e.g. RIF and DTG interaction)
Adults and adolescents on TB treatment diagnosed with HIV	Initiate ART within the first 2 weeks after the commencement of TB treatment
HIV with TB meningitis	Delay ART for at least 4–8 weeks to reduce risk of IRIS and mortality
HIV and Cryptococcal meningitis (CM)	Delay ART for 4–6 weeks after starting antifungal therapy
Other AHD (non-meningitis TB, cryptococcal or Toxoplasmosis)	Initiate ART once stabilized

4.6 What to expect in the first months of ART

During the first months of ART, clinical and immunological improvement and viral suppression are expected particularly when individuals adhere to ART. However, opportunistic infections (OIs) and/or immune reconstitution inflammatory syndrome (IRIS) may develop, as well as early adverse drug reactions, such as drug hypersensitivity, especially in the first three months of treatment. These complications are most common when the people starting ART already have advanced HIV disease. Poor adherence in this period is also associated with the risk of early treatment failure and rapid development of drug resistance.

4.7 Adherence to ART

Adherence to ART refers to the degree to which a person's behavior in taking medication and following care recommendations aligns with the treatment plan agreed upon with a healthcare provider. It is a key determinant of treatment success as it ensures sustained viral suppression, reduces the risk of drug resistance and improves overall health outcomes.

Support for adherence should begin before ART initiation and continues throughout treatment. Clients should receive clear client-centered education about HIV, the benefits of ART, possible side effects and the importance of long-term adherence. Several factors can affect adherence including forgetfulness, fear of stigma, disclosure, mental health challenges and structural barriers such as distance to health facilities and transport costs. Medication-related side effects and health system issues like drug stock-outs may also undermine adherence.

To address these barriers, the WHO and Gambia's DSD guidelines recommend a combination of support strategies, including routine adherence counselling, peer-led support mechanisms and the use of digital tools such as SMS reminders or pill boxes. DSD models like multi-month dispensing and fast-track refill services have also proven effective in improving adherence by reducing the burden of frequent clinic visits.

Throughout follow-up, clients should be assessed regularly in a non-judgmental and supportive manner to explore any missed doses or treatment interruptions. This ongoing dialogue helps identify and resolve barriers early, ensuring that adherence support remains responsive to each client's unique needs and circumstances.

4.8 What to start

The choice of antiretroviral (ARV) regimens in The Gambia is guided by the latest WHO 2021 recommendations, which emphasize the use of potent, safe, well-tolerable and scalable treatment regime. With the national transition to DTG-based regimens now completed, this guideline consolidates the latest evidence and programmatic experience to support long-term treatment success.

Before initiating Dolutegravir (DTG), ensure the following:

- Assess for pre-existing diabetes or symptoms of hyperglycemia
- Review any other medications the client is currently taking to identify potential drug interactions.

Note**:** Routine baseline blood glucose testing is not required by WHO but may be performed based on national or programmatic priorities.

Clinical considerations when using TDF:

1. Laboratory monitoring is recommended before initiating treatment with TDF.
2. Routine blood pressure monitoring may be used to assess hypertension.
3. Urine dipsticks may be used to detect glycosuria or severe TDF nephrotoxicity in individuals without diabetes using TDF-containing regimens.
4. If the creatinine test is routinely available, use the estimated Glomerular Filtration rate (GFR) at baseline before initiating TDF regimens as below.

Box 4.1: Calculation of GFR or Creatinine clearance in ml/min using Cockcroft Gault Equation

Male: 1.23 X (140-age) **X** weight in Kg/ Creatinine (in micromoles/L)

Female: 1.04 X (140-age) **X** weight in kg/ Creatinine (in micromoles/L)

Do not initiate TDF when the estimated GFR is <60 ml/min, or in long term diabetes, uncontrolled hypertension and renal failure.
Refer to your supervisor or hospital, client with GFR< 60 ml/min for further assessment.

4.9 First-line ARV Regimens for Adults and Adolescents (≥30 kg)

Preferred and alternative 1st line regimens

Table 4.3: First-line regimen for Adults and Adolescents (≥30 kg)

Population Type	Preferred Regimens	Alternative Regimens
Adults and adolescents (≥ 30kg), including TB/HIV [1], HBV/HIV	TDF + 3TC + DTG	TDF + 3TC + EFV 400 [2] TDF + 3TC + LPV/r (if HIV2)[3] AZT + 3TC + DTG [4] ABC + 3TC + EFV400 [5]

[1] *For HIV-TB coinfected patients, dose adjustment of DTG is needed,*

[2] *Do not use EFV if HIV2 (or dual HIV1 + HIV2) infection. Use only when DTG cannot be uses due to documented diabetes mellitus or increased metabolic risk such as overweight (BMI ≥30 kg/m²) hypertension or family history of diabetes or TB co-treatment, when complementary plain DTG 50 mg is not available*

[3] *Recommended as an alternative when DTG is not available or contraindicated and EFV is not suitable due to intolerance or psychiatric side effects, or client with HIV2 or when resistance to EFV is suspected.*

[4] *Use when TDF is contraindicated especially in clients with renal impairment (eGFR <60 ml/min) or clients with history of TDF-associated toxicity*

[5] *Use if both TDF and DTG are contraindicated, such as history of TDF-related renal or bone toxicity or DTG is contraindicated due to metabolic concerns or TB-related dosing*

NOTES:

The regimens above are effective for both HIV 1 and 2 (except EFV).

Rationale for Using EFV_{400mg} instead of EFV_{600mg}: studies have shown that efavirenz at a dose of 400 mg is not only virologically non-inferior to Efavirenz 600mg but also has fewer adverse events which is the major limiting factor of Efavirenz use. Fewer adverse events lower the risk of treatment discontinuation. EFV 400 mg can be co-administered with Rifampicin-containing anti-TB treatment, with co-administration well tolerated and plasma concentrations maintained above the levels considered to be effective. EFV_{400mg} is recommended for use as an alternative first line anchor ARV when DTG is contraindicated.

4.10 Second-line Treatment Regimens

Ideally, patients who fail to respond to first-line treatment should be treated with a different regimen that contains medicines that were not included in the first line regimen.

The second-line regimen should be initiated in consultation with a specialist in HIV and AIDS treatment, immediate supervisors, or the clinical mentorship team. Clinical mentors should be consulted where there is doubt about what to do. More adherence counseling will be required in preparation for the planned new therapy.

The current second line regimen recommends a boosted PI-containing regimen for those taking a first-line regimen containing DTG that has failed. For those taking a non-DTG-based first-line regimen that has failed, DTG is the preferred option.

Table 4.4: Preferred second line regimens

Population Group	Failed First-Line Regimen	Preferred Second-Line Regimen	Alternative Second-Line Regimen
Adults and Adolescents (≥ 30kg)	TDF + 3TC + DTG	AZT [(1)] + 3TC + ATV/r	AZT [(1)] + 3TC + DRV/r [(2)]
	TDF + 3TC + EFV_{400}	AZT [(1)] +3TC + DTG	AZT [(1)] + 3TC + ATV/r or DRV/r[(2)])
	TDF + 3TC + RAL	AZT [(1)] + 3TC + ATV/r	AZT [(1)] + 3TC + DRV/r
	AZT + 3TC + DTG	TDF + 3TC + ATV/r	TDF + 3TC + DRV/r
	AZT + 3TC + EFV_{400}	TDF + 3TC + DTG	TDF + 3TC + ATV/r *(or DRV/r[(2)])*
	ABC + 3TC + EFV_{400}	TDF + 3TC + DTG	AZT + 3TC + RAL

[(1)] If there is a contraindication to AZT, maintaining TDF could be considered

[(2)] If the patient previously failed on an LPV/r or ATV/r-containing regimen, after specialist review

4.11 Third-line Treatment Recommendation for Adults and Adolescents

Patients who fail second-line ART should be:

- Referred for specialist review (National HIV committee, pediatricians or clinical mentors)
- Undergo adherence re-assessment and support
- Have viral load and resistance testing performed prior to starting third-line ART

In The Gambia, genotyping samples will be referred abroad until in-country capacity is developed.

If a genotyping test can be performed, 3rd line regimen will be adapted to resistance profile.

If mutations are suspected but genotyping is not available, the regimen will be decided by the National HIV committee, considering that if the patient has failed on DTG-based regimen and LPV/r (or ATV/r)-based regimen:

- ⇨ DRV/r is usually still sensitive but low-level cross resistance is possible and it should be prescribed twice a day (DRV_{600mg} + RTV_{100mg} BD).
- ⇨ DTG may be used if low-level resistance was selected (poor interest if hi-level resistance): DTG_{50mg} BD can be tried.
- ⇨ Maintaining NRTI backbone can improve virological outcomes, by acting on non-muted viruses.

After prescribing a third line regimen, strong adherence support must be provided and a VL test must be planned after 3 months.

Chapter Five: Monitoring Patients on Antiretroviral Therapy

5.1 Introduction

Patients on ART need close monitoring to assess adherence to the treatment regimen, tolerance, the side effects of the medications and the efficacy of the treatment. Give the patient an Appointment Card to document his or her follow-up visits. Adolescents have special needs that go beyond just delivery of ART. Counsellors will need to be aware of the need for specialized counselling.

5.2. Initial Clinical and Laboratory Evaluation (Before ART Initiation)

Table 5.1: Initial evaluation

Test	Indication
Confirmatory HIV test	All patients
WHO Clinical staging	All patients
Full blood count (or at least Hb)	All patients to detect anemia or if AZT is planned
Serum creatinine	If TDF is planned
Liver function tests (LFTs):	In case of TB or Hepatitis B/C coinfection,
CD4 count (Visitect®)	All HIV naïve patients to assess Advanced HIV Disease
Blood glucose and lipid profile	Patients with comorbidities or patients aged >45 years
Syphilis, Hep B, Hep C serology	Pregnant women, all sexually active adolescent and adults, key populations (sex workers, PWID, MSM, prisoners)
Pregnancy test	Women of reproductive age (based on date of last menstruation)
GeneXpert / CXR / TB LAM	As per TB screening and CD4 count

5.3. Clinical Monitoring at Follow-up Visits

Components of a comprehensive clinical assessment:

1. Review demographic information, medical history, ART history
2. Symptom screen (including TB, STIs, hepatitis, mental health)
3. Nutritional assessment (MUAC, weight and height)
4. Physical examination (skin, oral cavity, lymph nodes, lungs, heart, abdomen, genital tract, neurological assessment-motor function, reflexes, coordination and signs of peripheral neuropathy)
5. WHO staging update
6. Assessment of side effects and adverse drug reactions (refer table of side effect, Appendix 24)
7. Psychosocial review (disclosure, adherence, family planning, school attendance for children)

Patients in DSD models may receive a simplified assessment based on stability.

5.4. Laboratory Monitoring

Table 5.2: Indication of initial laboratory tests

Test	When to Perform	Indication
Viral Load (VL)	6, 12 months after ART, then annually	Monitor ART efficacy
CD4 count	Baseline (ART initiation)	Opportunistic infection risk
CrAg	If CD4 <200 or WHO stage 3 or 4	Cryptococcal screening
TB LAM	If CD4 <200	TB diagnosis
Full Blood Count	Client on AZT or suspicion of anaemia	Monitor anaemia
Serum Creatinine	Before TDF or in case of comorbidities	Nephrotoxicity risk
Liver Function Tests	Hepatotoxic ART, hepatitis symptoms	Monitor liver toxicity
Lipid/Glucose	Baseline, yearly if >45 or comorbid	Metabolic issues
TB tests (Gen Exp)	If TB is suspected	TB diagnosis

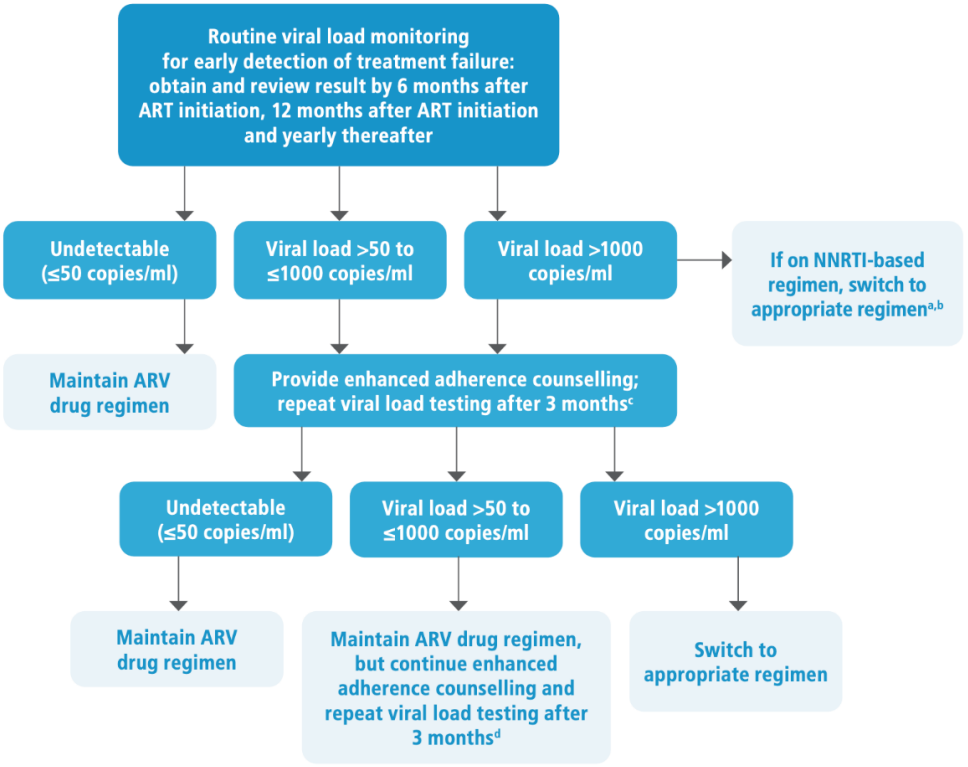
5.5 Viral Load Monitoring and Failure Detection

The HIV viral load decreases to undetectable levels within 6 months of successful ART. However, this response also depends on the initial, pre-treatment viral load; where the pre-treatment viral load is very high it may take longer than 6 months for full suppression to be attained

Table 5.3: Schedule for VL Monitoring

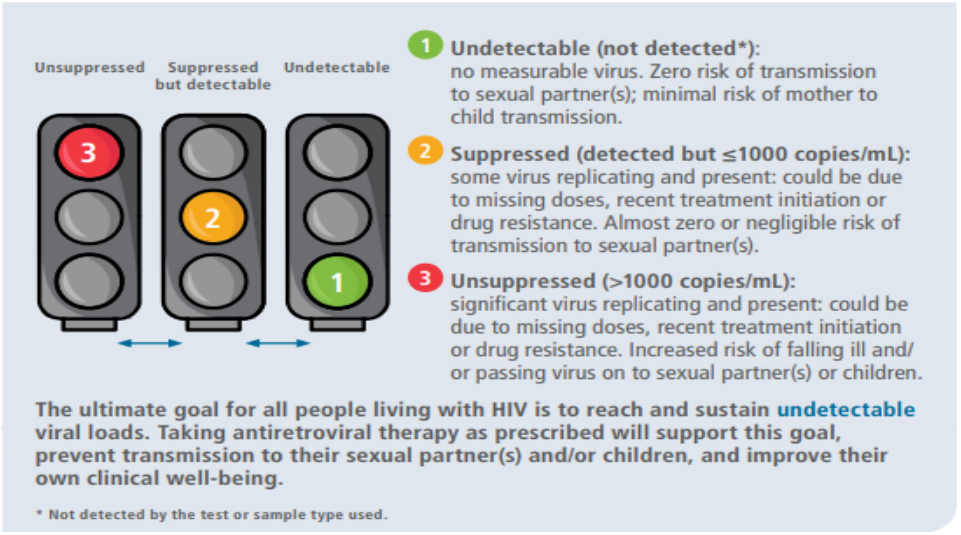
Population Group	VL Testing Schedule
Adults and stable adolescents horizontally infected	6 and 12 months after ART, then annually
Children and adolescents born with HIV	Every 6 months
Pregnant/breastfeeding women (newly started)	At 34-36 weeks of pregnancy and every 6 months if suppressed and after 3 months if unsuppressed
Post-switch to 2nd	At 6 months then yearly
3rd-line ART patients	Every 6 months

Fig 5.1: VL testing algorithm for adolescents >30 Kg and adults using plasma samples



WHO 2021, p.148 [5]

Fig 5.2: Classification of VL result



WHO 2023, p. 5 [18]

5.6 Genotype Testing and Link with specialized laboratory

Genotyping is recommended after confirmed virologic failure and 3 intensive adherence sessions with ≥95% adherence. In The Gambia:

- Samples will be referred abroad for resistance testing
- Results must inform optimized 2nd- or 3rd-line regimens (e.g., DRV/r-based)
- Genotyping prioritized for clients on DTG failing with high VL, complex prior ART history and Children failing PI-based regimens (after DTG-based regimen failure).

Note: genotyping is still not done by the National laboratory but could be done in the future.

5.7 Monitoring Adherence to ART

Strict adherence (which is at least 95% adherence) to recommended treatment regimens is important for treatment to be effective. Counselling and the provision of accurate information to all patients (treatment literacy) is an important determinant of treatment adherence. Information on side effects should be provided, and patients should be told what to expect from the treatment.

An adherence to treatment tool (e.g. pill count, self-reporting) should be provided and patients/carers instructed on how to fill out the form. Counselling should be provided at each visit. Patients should be encouraged to seek help between visits as needed.

Patients should be instructed to bring all medications and containers at each visit. Providers should carry out an adherence assessment to determine whether the medications have been taken as per schedules agreed upon.

5.8 Monitoring Adverse Medicine Events or Medicine Side Effects

A patient on ART may develop new symptoms whilst on treatment. Such symptoms may be indicative of inter-current illnesses, adverse medicine events or immune reconstitution inflammatory syndrome (IRIS). All patients should be examined carefully at each visit especially in the first 6 months of ART. Any inter-current illness should be treated appropriately. If in doubt, refer the patient to your clinical mentor or higher-level ART clinic.

Table 5.4: Main symptoms related to ARV

Adverse Effect	Suggested Monitoring / Action
Anaemia	Check Hb at initiation and after 2 weeks (esp. if on AZT). Deworm and give iron if needed. Switch drug if persistent.
Lactic Acidosis	Suspect if fatigue, abdominal pain, tachypnoea. Stop all ARVs and rehydrate. Restart with TDF-based regimen after stabilization. Referral to a higher level of care or a specialist is encouraged where available.
Lipodystrophy	Monitor body changes. If on AZT, consider switching to TDF. Counsel patient on cosmetic implications.
CNS toxicity (esp. DTG and EFV)	Inform patient at ART initiation. Usually transient. If severe or persistent, switch as per guideline recommendation
Metabolic (diabetes, dyslipidaemia)	Monitor blood sugar and lipid profile periodically (yearly)
Other mild symptoms	GI upset, headache, mild rash → symptom management. Usually, self-limiting.

Major types of toxicity associated with first-, second-and third-line ARV drugs are presented in Appendix 24

5.9 Visit Schedule:

- 2 weeks after ART initiation,
- Then monthly for 3 months,
- Thereafter every 3 months.
- In patients established on treatment, DSD can be proposed and 6-monthly dispensation initiated.

5.10 Immune Reconstitution Inflammatory Syndrome (IRIS)

Immune reconstitution inflammatory syndrome (IRIS) is linked to an overactivation of the immune system when CD4 cells begin to be functional again. It usually occurs in the first few days or weeks (2 to 12) after initiation of ARV therapy.

5.10.1 Frequency and risk factors of IRIS

Depending on the criteria used to qualify IRIS, its frequency varies in the studies. On average, 18% of adult patients co-infected with HIV and TB develop paradoxical IRIS-TB. However, in adult patients with a very low CD4 count (< 50 cells/mm3) or extrapulmonary tuberculosis, the frequency may exceed 50%.

5.10.2 Most frequent germs involved in IRIS

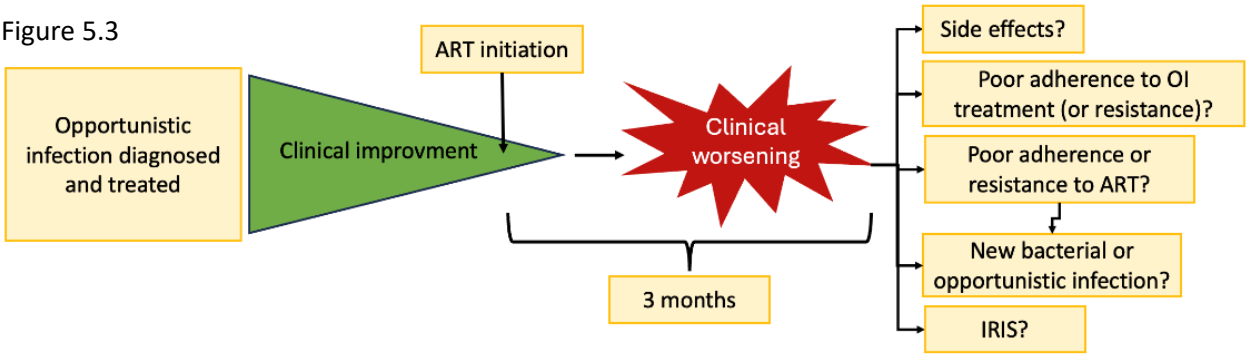
Many opportunistic germs can be associated with immune reconstitution syndrome, but TB (Koch's bacillus) is the most common, involved in about half of cases. Other germs are fungi including the cryptococcus (with the meningeal location), atypical mycobacteria, viruses (especially HSV, CMV, HHV8 responsible for Kaposi's sarcoma, JK virus).

5.10.3 Clinical manifestation of IRIS

Clinical manifestation may change according to the germ and the localization. However, two sequences can be described: paradoxical and unmasking IRIS.

1/ Paradoxical IRIS

Figure 5.3



In this situation, an infection was diagnosed before initiating ART (TB for example) and treatment of OI was initiated. Initial evolution was good, ART was initiated and clinical situation continued to improve. Then the patient deteriorates.

2/ Unmasking IRIS

Figure 5.4

In this situation, no infection was diagnosed before initiating ART. Initial evolution on ART was good (clinical situation improved). Then the patient deteriorates.

5.10.4 Diagnosis of IRIS

Before considering an IRIS, the clinician should rule out:

1/ Medicine side effects (both IRIS)

2/ Poor adherence (or resistance) to OI treatment (in paradoxical IRIS)

3/ Poor adherence or resistance to ART → persistent immunosuppression → new OI or bacterial infection (both IRIS)

After excluding these causes, arguments of IRIS are:

- Chronology of symptomatology (improvement before deterioration)
- Acute local and general manifestations. For instance, in case of TB-IRIS: fever, cough, shortness of breath, night sweats, weight loss, lymph nodes, new or worsening Xray findings.
- Increased CD4 and decreased VL (demonstrating adherence and effectiveness of ART)

5.10.5 Treatment of IRIS

Usually, ART and opportunistic infection treatment should be maintained in case of paradoxical IRIS. In unmasking IRIS, treatment of opportunistic infection should be initiated.

If inflammatory symptoms are important, corticosteroids should be added. No consensus exists on the dose and duration, but a randomized, double-blind, placebo-controlled trial of prednisone (1,5 mg/kg once daily for 14 days, followed by 0,75mg/kg once daily for 14 days) showed that Prednisone reduced the need for hospitalization and therapeutic procedures; and hastened improvements in symptoms, performance and quality of life. [19]

In most cases, the clinical situation improves and corticosteroids can be decreased progressively.

Note: in most severe presentations, when IRIS is localized in CNS (neuro-TB or cryptococcal meningitis) or vital danger signs are present, stopping ART can be considered.

5.10.6 Prevention of IRIS

The best way to prevent IRIS is to diagnose and treat the patients before they are severely immunosuppressed.

Corticosteroid may be considered at ART initiation, in patients with TB and severely immunosuppressed. A study showed a reduction by 30% of IRIS manifestation in patients who received 4 weeks cortico-therapy at ART initiation (Prednisone: 40mg once daily for 2 weeks, followed by 20mg once daily for 2 weeks. Prednisone was initiated the same day than ART). [20]

All patients presenting clinical worsening in the first weeks/months of ART should be referred to hospital level for comprehensive assessment and therapeutic decision.

Chapter Six: Management of Advanced HIV Disease (AHD)

According to the WHO 2021 guidelines, Advanced HIV Disease (AHD) is defined for adults, adolescents and children aged five years and older as having a CD4 cell count below 200 cells/mm³ or a current WHO clinical stage 3 or 4 condition. In children under five years of age, AHD is assumed irrespective of CD4 count due to high viremia, rapid disease progression and elevated mortality risk. However, children in this age group who have been on antiretroviral therapy (ART) for more than one year, clinically stable and have achieved viral suppression are not considered to have AHD.

6.1. Background

Despite major progress in expanding access to ART, AHD remains a significant cause of morbidity and mortality, especially in sub-Sharan Africa. In 2021, AIDS-related illnesses claimed approximately 650,000 lives globally, with a large proportion attributed to AHD. Individuals with AHD—characterized by severe immunosuppression—are highly vulnerable to preventable and treatable opportunistic infections such as tuberculosis, cryptococcal meningitis and severe bacterial infections. Studies from sub-Saharan Africa have shown that around 10% of people living with HIV (PLHIV) continue to present with CD4 counts below 200 cells/mm³ and in some settings, over half of newly diagnosed individuals have advanced disease. Furthermore, a significant proportion of PLHIV in care experience treatment failure to ART regimens and approximately 25% return to care with advanced HIV disease following treatment interruption. To address these persistent gaps, the WHO released its 2017 and updated 2021 guidelines, promoting a simplified, standardized package of care that includes timely screening, prophylaxis and management of common OI. In The Gambia and similar West African settings, where HIV-related data on AHD remain limited, strengthening early identification and tailored care for AHD remains essential to reduce preventable deaths and achieve global targets to end AIDS as a public health threat by 2030.

6.2. Identifying Individuals with Advanced HIV Disease in The Gambia

Early identification of individuals with advanced HIV disease (AHD) is essential to initiate timely, life-saving interventions.

In The Gambia, AHD screening will be systematically performed for all individuals who:

- Are newly initiating ART,
- Are re-engaging in care after more than 90 days,
- Are not virally suppressed, or
- Present with symptoms suggestive of WHO stage 3 or 4 conditions.

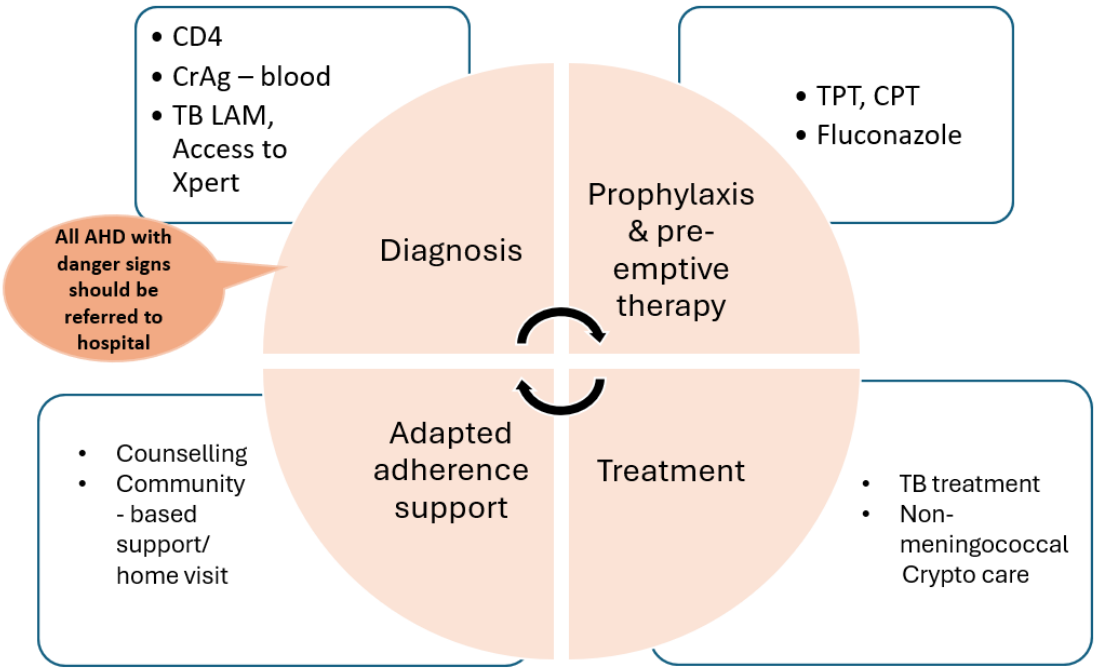
In alignment with WHO recommendations, AHD will be identified using either WHO clinical staging (stage 3 or 4) or a CD4 cell count below 200 cells/mm³. Both criteria are independently sufficient to define AHD in individuals aged 5 years and older.

To ensure effective and consistent identification, The Gambia will scale up the VISITECT® CD4 Advanced Disease Rapid Test across both primary and hospital-level facilities. This point-of-care test enables rapid identification of individuals with severe immunosuppression, complementing clinical staging.

The VISITECT test will serve as the national standard for CD4-based AHD screening. It is not suitable for children under five years of age.

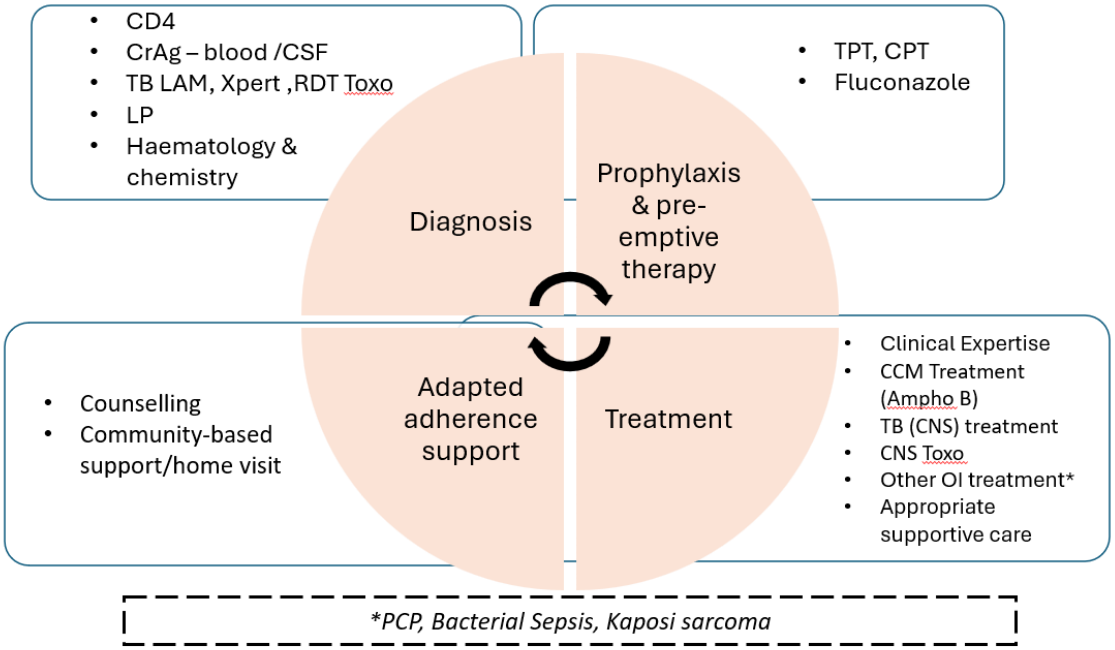
6.3. Package of Care for AHD

Figure 6.1: AHD Package for outpatients



(Adapted from the global Advanced HIV Disease Toolkit, UNAID/CHAI), [21]

Figure 6.2: AHD Package for hospitalized



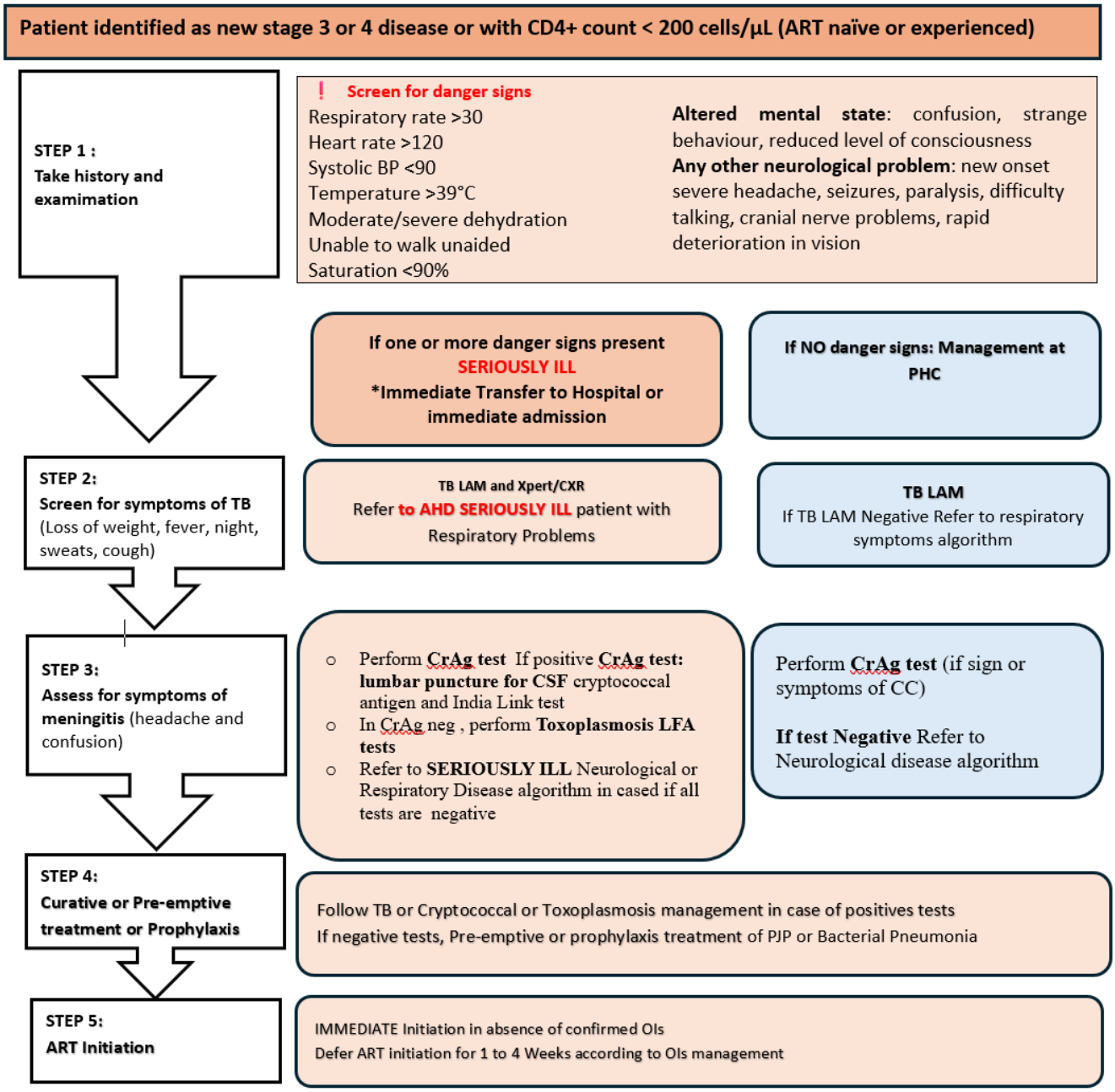
(Source: The global Advanced HIV Disease Toolkit,UNAID/CHAI)

6.4. The components of AHD care

- Integrated routine AHD screening into HIV care services
- Timely patient identification for AHD care including diagnostics and supporting labs
- Initiation of essential, recommended treatment and prophylaxis
- Patient monitoring
- Established referral systems for access to comprehensive AHD package
-

6.5. Clinical approach to patients with advanced disease

Figure 6.3: Symptoms Screen and Advanced Disease Management Pathway



Adapted from WHO, 2021, p. 225. [5]

6.6 Tuberculosis Prevention and Treatment among PLHIVs

6.6.1. Background

HIV remains the major risk factor for developing tuberculosis (TB) disease. People living with HIV (PLHIV) are approximately 10 to 37 times more likely to progress to active TB than individuals without HIV. TB continues to be a leading cause of hospitalization and death among PLHIV. Co-infection with TB and HIV is associated with poorer treatment outcomes, including a significantly higher risk of mortality, compared to TB infection alone.

According to a recent analysis of National TB data reported in DHIS2 between 2017 and 2021, only 36.1% of HIV-TB co-infected individuals were receiving antiretroviral therapy [22]. The mean number of adult patients identified with HIV TB coinfection was 330 [248-456] in the 2014-2023 period. There is a trend to the decrease of number of HIV-TB patients from 2014 to 2023 (-29%), while the number of PLHIV adults increased by more

than 130%. Thus, the percentage of HIV-TB coinfection decreased from 11% to 3% from 2014 to 2023. These figures could reflect improvement in TB management in The Gambia and a reduction of TB prevalence but could also highlight critical gaps in the delivery of integrated TB/HIV services and point to an urgent need for enhanced case finding, early ART initiation and strengthened adherence support.

Given this burden, all patients with presumptive or confirmed TB should be routinely screened for HIV, and all PLHIV must be systematically screened for TB symptoms at every clinical encounter. Wherever feasible, TB and HIV services should be co-located and delivered by the same healthcare team to optimize efficiency, patient-centered care and treatment outcomes. Since PLHIV are at increased risk of rapid clinical deterioration when TB is present, clinicians should avoid unnecessary delays in both diagnosis and the initiation of appropriate TB treatment.

HIV/TB care settings should implement the three I's strategy:

- Intensified TB case- finding
- Isoniazid + Rifapentine Preventive Therapy
- Infection control at all clinical encounters.

6.6.2. Clinical presentation of TB in PLHIV

Box 6.1: clinical presentation of PTB and extra pulmonary TB

Pulmonary TB

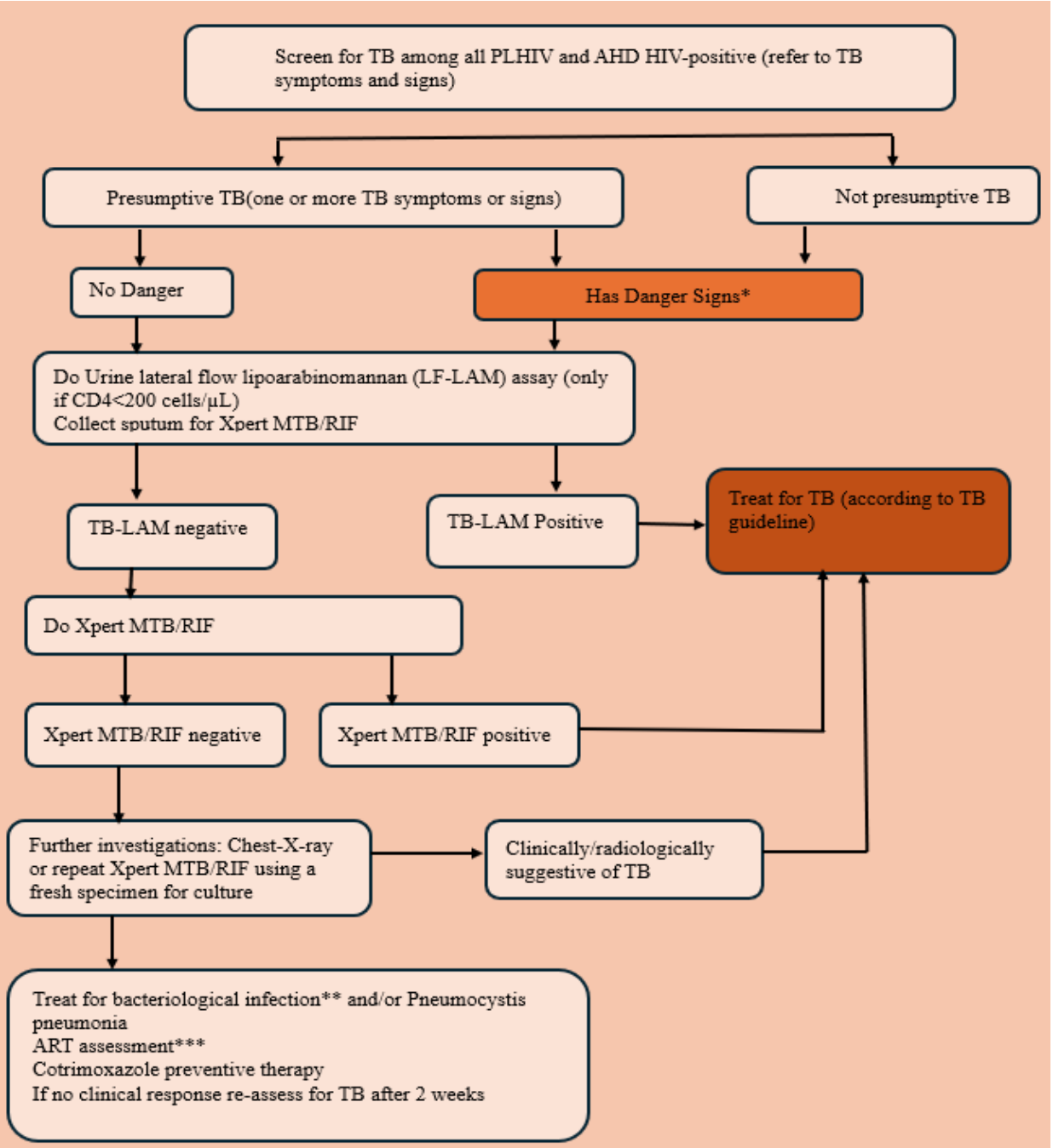
- General malaise, weakness, tiredness
- Chronic cough (≥2 weeks)
- Loss of appetite and weight loss (>10% of previous body weight)
- Night sweats
- Fever
- Chest pain
- Sometimes haemoptysis (blood in sputum when coughing)

Extra-Pulmonary TB (EPTB)

- Headache/confusion, fever, vomiting, stiff neck, sometimes loss of consciousness
- Enlarged lymph nodes (>2 cm), often painless, in neck, axillae, or inguinal areas
- Chest pain (usually unilateral), shortness of breath, peripheral oedema, abdominal swelling
- Genito-urinary TB: dysuria, nocturia, abdominal pain, haematuria
- TB spine (Pott's disease): localised pain, followed by deformity

6.6.3. Diagnostic investigations

Figure 6.4: Algorithm for screening, diagnosis and management of TB among PLHIV



*Danger signs for adults refer to signs of a seriously sick person and they include respiratory rate > 30/min, temperature >39 °C, heart rate 120/min and unable to walk unaided. All PLHIV with danger signs **MUST BE REFERRED TO HOSPITAL FOR BETTER MANAGEMENT**

** Antibiotics with broad-spectrum antibacterial activity (except fluoroquinolones) should be used.

*** ART should be recommended for all adults, regardless of CD4 cell count or clinical stage. In ART-naïve patients, ART should be started as soon as possible following start of TB treatment (see details in TB guidelines on p. 70). Patients already on ART should be assessed for ART failure through VL

Adapted from MSF 2021, [23]

6.6.4 TB treatment and ARVs

6.6.4.1 General Guidance

1. Person Living with HIV (Not Yet on ART) and Suspected TB

- TB investigations should be urgently initiated.
- If TB cannot be confirmed the same day, initiate ART without delay, especially in individuals with advanced HIV disease (CD4 <200 or WHO stage 3 or 4).
- If TB is confirmed the same day, initiate TB treatment first and begin ART within the first 2 weeks.

2. Person Diagnosed with TB Before ART Initiation

- Start TB treatment immediately.
- ART should be initiated as soon as possible within 2 weeks

3. Person Already on ART or Diagnosed with HIV During TB Treatment

- If already on ART and diagnosed with TB, initiate TB treatment and adjust the ART regimen if needed due to drug interactions (e.g., rifampicin).
- If HIV is diagnosed during the TB treatment, initiate ART within the first 2 weeks after the commencement of TB treatment

6.6.4.2 ART Regimen Adjustments in TB Treatment

Table 6.1: Impact of Rifampicin on ART drugs and recommended adjustments

ART Drug/Regimen	**Interaction with Rifampicin**	**Recommended Adjustment**
Dolutegravir (DTG)	Rifampicin reduces DTG levels significantly.	Increase DTG dose to 50 mg twice daily during TB treatment.
Efavirenz (EFV)	Compatible with rifampicin.	No dose adjustment needed. Continue standard EFV-based regimen.
Lopinavir/ritonavir (LPV/r)	Rifampicin greatly reduces LPV levels even with ritonavir boosting.	Use rifabutin instead of rifampicin if LPV/r must be maintained. Alternatively, switch to EFV-based regimen.
Atazanavir/ritonavir (ATV/r)	Rifampicin reduces ATV levels significantly.	Avoid co-administration with rifampicin. Consider switching to EFV or use rifabutin instead.
Darunavir/ritonavir (DRV/r)	Rifampicin reduces DRV levels despite ritonavir boosting.	Not recommended with rifampicin. Use rifabutin or consider alternative ART regimen.
Rifabutin as TB treatment	Fewer interactions with ART.	May be used in place of rifampicin when PIs need to be maintained.

6.6.5. TB Preventive Treatment (TPT)

6.6.5.1 general strategy

Tuberculosis (TB) prevention is a cornerstone of HIV care and public health. Effective TB prevention includes a combination of biomedical, clinical and infection control measures to reduce the risk of infection and disease progression.

Key strategies include:

- Bacille Calmette-Guérin (BCG) vaccination at birth to prevent severe forms of TB in children (see precautions if the newborn is symptomatic, chapter 3).
- Early identification and prompt treatment of individuals with active TB disease.
- Provision of TB preventive treatment (TPT) to individuals at high risk of progression from TB infection to disease.
- Implementation of TB infection prevention and control (IPC) measures in healthcare settings and households.

6.6.5.2. TB Preventive Treatment (TPT)

TPT aims to reduce the risk of latent TB infection progressing to active disease, particularly among people living with HIV (PLHIV), young children (less than 5 years) and household contacts of TB patients. PLHIV with no symptoms of active TB (current cough, fever, weight loss, night sweats) should be offered TPT after TB disease has been clinically ruled out. TPT may be initiated regardless of ART status.

TPT is currently not recommended for contacts of patients with confirmed or suspected multidrug-resistant TB (MDR-TB) pending further evidence. However, in children under 5 years and HIV-positive individuals who are contacts of drug-sensitive TB cases, TPT should be strongly considered.

The following regimens are recommended for TB preventive treatment:

Preferred regimen:

- 3HP: Isoniazid and Rifapentine weekly for 12 weeks (3 months), recommended for individuals aged 2 years excluding pregnant women.

Alternatives regimen:

- 6H: Isoniazid 300 mg daily for 6 months (safe for pregnant women)
- Q-TIB: A fixed-dose combination of Isoniazid, cotrimoxazole and pyridoxine, taken daily for 6 months (considered safe for pregnant women)
- 3HR: Isoniazid +Rifampicin daily for 3 months (safe for pregnant mothers.) (adjust ART TLD regimen)

TPT should always be paired with pyridoxine supplementation to reduce the risk of isoniazid-induced peripheral neuropathy, particularly in adults and adolescents.

NB: Refer to the National TB and TPT guidelines for details and MDR-TB.

6.7. Cryptococcal Disease Among Adults Living with HIV

6.7.1. Background

Cryptococcal disease is a major opportunistic infection affecting people with advanced HIV disease. It remains a significant contributor to morbidity, disability and mortality in this population. Among its manifestations, *cryptococcal meningitis* is by far the most common and severe clinical presentation. Healthcare professionals should remain highly vigilant for cryptococcal meningitis in patients with advanced HIV disease.

Box 6.2: Signs and Symptoms of Cryptococcal Meningitis

Early Signs and Symptoms of Cryptococcal Meningitis

- Headache (persistent, often worsening)
- Nausea ± Vomiting
- Dizziness or Light-headedness
- Cognitive delay (e.g., acting unusual to friends, family, or providers)
- Changes in vision or hearing (blurry vision, double vision (diplopia], decreased hearing)
- Mild confusion or altered behaviour
- Photophobia, neck stiffness, and a positive Kernig's or Brudzinski's sign

Late Signs and Symptoms of CM:

- Change in mental status (Lethargy, Confusion, Stupor or coma)
- Seizures, photophobia
- Papilledema (optic disc swelling)
- Cranial nerve palsies → horizontal diplopia
- Focal neurological deficits (weak arms or legs, difficulty walking)
- Complete or partial blindness or deafness

6.7.2 Diagnosis of Cryptococcal Meningitis

Early diagnosis of cryptococcal meningitis is critical to reduce mortality among PLHIV with advanced HIV disease. A definitive diagnosis requires the detection of *Cryptococcus* antigen (CrAg) in cerebrospinal fluid (CSF) or a positive CSF culture confirming the presence of *Cryptococcus*. The CrAg Lateral Flow Assay (CrAg LFA) is the preferred diagnostic tool due to its high sensitivity, ease of use, and suitability for point-of-care testing. The process of screening patients for Cryptococcal Meningitis must be guided by the algorithm shown in Appendix 10.

In Gambia, the diagnostic approach varies by level of care:

- At peripheral health centres, the recommended method is the CrAg LFA performed on serum, plasma, or whole blood or finger-prick blood. This test enables early detection and referral of positive cases with danger signs to hospital for further management.
- At the hospital level, patients with suspected meningitis should undergo lumbar puncture followed by CSF CrAg LFA testing. Where resources allow, India ink staining of CSF may be performed for confirmation.

6.7.3 Treatment of cryptococcal infection

Table 6.2: Treatment of Cryptococcal infection for Adults

	Non-meningeal Cryptococcal disease	Meningeal Cryptococcal disease
Induction Phase	Fluconazole 800 mg for 2 weeks *Note*: For patients on rifampicin, increase Fluconazole dose by 50% across all phases	Preferred regimen: Amphotericin B liposomal single high dose (10mg/kg) + 2 weeks of *Flucytosine* (100mg/kg/day in four divided doses) and *Fluconazole* 1200mg/day Alternative induction regimens: 2 weeks of Fluconazole (1200 mg daily for adults + Flucytosine (100 mg/kg/day, divided into four doses per day).
Consolidation phase	Fluconazole 400 mg for 8 weeks	Fluconazole 800mg/day for 8 weeks
Maintenance phase	Fluconazole 200 mg for 14 weeks to complete 6 months of treatment	Fluconazole 200mg/day for a minimum of 12 to 18 months of maintenance phase. Condition to stop maintenance phase: Adults: VL<1,000 copies/mm^3 & CD4 ≥ 200 or CD4 ≥200 (if viral load not available) after 12 and 18 months

6.7.4 Monitoring and Management of Amphotericin B Liposomal and supportive care

Several formulations of amphotericin B are commercially available, including liposomal, deoxycholate and lipid complex preparations. These formulations are not interchangeable due to differences in pharmacokinetics, toxicity profiles and dosing.

In Gambia, we use liposomal amphotericin B (50 mg lyophilized powder for injection), which is associated with lower toxicity and reduced need for intensive monitoring and supportive care compared to amphotericin B deoxycholate.

Table 6.3: Managing amphotericin B–related toxicity

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Single high-dose liposomal amphotericin B														
Pre-emptive hydration and electrolyte supplementation (adults and adolescents)														
1 litre of normal saline solution with 20 mEq KCl over two hours before infusion	X													
8-mEq KCl tablets orally (twice daily)	X	X	X											
Magnesium supplementation if available[a]	X	X	X											
Monitoring (adults, adolescents and children)														
Serum potassium	X		X											
Serum creatinine	X		X											
Haemoglobin	X						X[b]							

[a] 250-mg tablets of magnesium trisilicate or glycerophosphate twice daily or magnesium chloride 4 mEq twice daily.
[b] If still in hospital.

Source: WHO, 2022, p. 11 [24]

Table 6.3: Managing amphotericin B–related toxicity for Single 10 mg/kg liposomal amphotericin B protocol

Elevated creatinine	Ensure adequate hydration and discontinue concurrent nephrotoxic drugs if possible. Adjust fluconazole and flucytosine doses appropriately if renal impairment is significant. Note that renal function often improves initially following rehydration.
Severe anaemia	Transfusion if possible,
Hypokalaemia	If hypokalaemia is significant (K<3.3 mmol/l), increase potassium supplementation. Monitor potassium daily if possible

Table 6.4: Monitoring and managing people with cryptococcal meningitis

Control of elevated CSF pressure (refer to Box 6.3 for symptoms and signs of raised intracranial pressure)	Control of increased intracranial pressure improves survival by 25% in persons with Cryptococcal Meningitis. All patients with a CSF Pressure >250mm of water will need a therapeutic LP the following day to reduce the CSF pressure to<200 mm using a manometer. Removing 20-30mL of CSF (even in the absence of a manometer) may be adequate to decrease CSF pressure. Most patients will need 2-3LPs during the induction phase Failure to adequately manage ICP can result in persistent headache, cranial nerve abnormalities which include hearing loss, vision loss and death.
Routine use of adjunctive corticosteroid therapy during the induction phase is not recommended in treating HIV-associated cryptococcal meningitis.	
Immediate ART initiation is not recommended among adults, adolescents and children living with HIV who have cryptococcal meningitis because of the risk of increased mortality and should be deferred 4–6 weeks from the initiation of antifungal treatment and based on ART history and experience. For patients already on ART, see figure 6.5 for the management of antiretroviral therapy.	

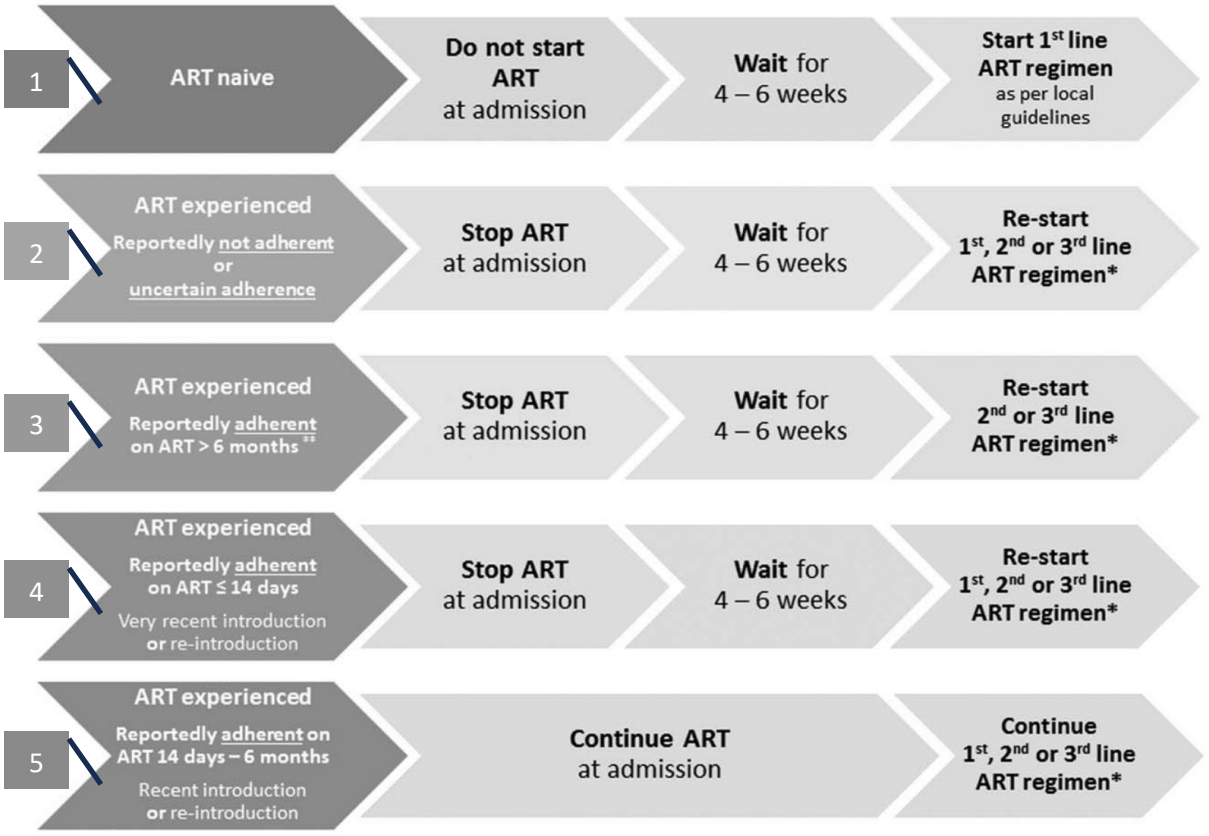
Box 6.3: Common symptoms and signs of raised intracranial pressure

Symptoms
- Headache
- Nausea with or without vomiting
- Changes in vision or hearing (such as double vision, blindness or deafness)

Signs
- Change in mental status (ranging from confusion to lethargy to coma)
- Papilloedema
- Seizures
- Cranial nerve palsies (such as eye movement problems, especially cranial nerve VI)
- Other focal nervous system deficits

WHO, 2022, p. 17, [24]

Figure 6.5: ART Timing with CCM [25]



* Decision on which ART regimen to re-start should be made according to patient's history, local guidelines, HIV viral load and genotypic resistance testing if possible. If it is considered likely that the patient has developed resistance to 1st line (e.g. NNRTI resistance), then restart with 2nd line containing boosted PI or DTG if possible. ** Unless documented to have a suppressed viral load at time of admission or within the month prior to admission, in which case continue ART

1 CCM was diagnosed before initiation. Treat first CCM and initiate on 1st line after 4-6 weeks

2 Patient developed CCM while on ART but adherence was uncertain. Stop ART and restart with the same regimen after 4-6 weeks. Enhanced adherence and perform VL 3 months after re-initiation.

3 Patient developed CCM while on ART and adherence was good. Resistance to ART is likely. Stop ART and restart after 4-6 weeks on second (or third) line ART regimen.

4 Patient was very recently initiated and develop CCM. Cryptococcoses was probably not diagnosed but was present before initiation. Stop ART for 4-6 weeks and restart with the same ART regimen.

5 Patient developed CCM symptoms while on ART and adherent. Cryptococcal infection (due to incomplete immune recovery) or unmasking cryptococcal-IRIS are possible. In both cases, ART should be continued while treating CCM.

If a patient is ART experienced for more than one month, and is diagnosed with CCM, perform a VL test:
If VL < 1000 copies/ml, consider an IRIS.

Chapter Seven: Prevention, Screening and Management of Common Co-infections

7.1 Co-trimoxazole Preventive Therapy (CPT)

7.1.1. Background

While antiretroviral therapy (ART) has significantly reduced HIV-related morbidity and mortality, PLHIV remain vulnerable to opportunistic infections (OIs) and other comorbidities. In The Gambia, where malaria and severe bacterial infections are prevalent, co-trimoxazole prophylaxis remains a critical component of HIV care. It is particularly effective in preventing several common and potentially life-threatening infections in immunosuppressed individuals, including *Pneumocystis jirovecii* pneumonia (PJP), *Streptococcus pneumoniae*, cerebral toxoplasmosis and non-typhoidal salmonellosis. CPT is a simple, well-tolerated and cost-effective intervention for PLHIV and can be administered concomitantly with ART. This has shown reduction in morbidity, mortality and hospitalization.

By reducing the incidence of these infections, co-trimoxazole contributes significantly to improving survival and quality of life among PLHIV, especially those with advanced HIV disease or delayed initiation of ART.

7.1.2. Co-trimoxazole indication, discontinuation, side effect management

Table 7.1: Co-trimoxazole prophylaxis indications, doses and complications

Recommendations		
Criteria for initiating co-trimoxazole prophylaxis	**Criteria for discontinuing co-trimoxazole prophylaxis**	**Recommended dose/management of allergy and intolerance**
All PLHIV newly initiating on ART As a priority: Adults with AHD (WHO stage 3 or 4 and/ or with CD4 cell count ≤200 cells/µL)	Stop for those who are clinically stable with evidence of immune recovery CD4 cell count >200 cells/µL) and/or viral loads on ART suppression.	Recommended dose Adults: CTX 960 mg od. Non-severe side effects (grades 1 and 2): -> Desensitise adults (see Appendix 6). Grade 3 toxicity to CTX or desensitisation not successful: -> Dapsone 100 mg daily -> Add pyrimethamine 50 mg + folinic acid** 25 mg weekly. In case of severe reactions to CTX (grade 4 skin, liver, kidney or bone marrow toxicity), dapsone should not be used, as there may be cross-reactivity. Dapsone is safe in pregnancy ** Note that folinic acid is not the same as folic acid.
PLHIV with active TB regardless of CD4 cell count	Refer to TB Guideline	

Dapsone should be discontinued once the CD4 has been greater than the subsequent values for at least 6 months: 200 cells/mm^3 for adults.

7.1.3. Co-trimoxazole toxicity

Adverse effects of Co-trimoxazole are rare but include skin rash, Stevens Johnson syndrome, anaemia, neutropenia, jaundice and renal failure. In the event of skin reaction to Cotrimoxazole, see guidance on management (table 7.2)

Table 7.2: Management of adverse effects of co-trimoxazole

Severity	Description	Management
Mild Grade 1	Dry skin, erythema +/- fine papules or itching affecting <50% of body surface area	Continue CTX, monitor closely, consider symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids)
Moderate Grade 2	Dry skin, erythema +/- fine papules, or itching affecting >50% of body surface area	Stop CTX, consider symptomatic treatment with antihistamines +/-topical steroids (NOT oral steroids), consider trial of desensitization after symptoms completely resolved
Severe Grade 3 and 4	Mucosal involvement or blistering with associated fever affecting any % of body surface area or Steven Johnsons syndrome (SJS)[1]	Stop CTX, admit to hospital for supportive management (IV fluids, wound care, pain control, infection control, monitoring for superinfection), patient should NEVER be re-challenged with CTX or other sulfa-containing drugs

(1) The term SJS is used when the body surface area involved is <10%, TEN if it is >30%, and SJS/TEN overlap when it ranges from 10% to 30%.

7.2. Pneumocystis Jiroveci Pneumonia (PJP): Symptoms, diagnosis, treatment and prevention

Pneumocystis Jiroveci Pneumonia (PJP), formerly known as Pneumocystis carinii pneumonia (PCP), is a common opportunistic infection in individuals with advanced HIV disease. The incidence has declined with the implementation of cotrimoxazole prophylaxis and antiretroviral therapy (ART).

Table 7.3: Symptoms, diagnosis, treatment and prevention of PCP

Signs and Symptoms	Symptoms: Progressive exertional dyspnea, fever and chills, non-productive cough, chest discomfort, difficult breathing, fast breathing and weight loss. Signs: Pulmonary symptoms: tachypnea, pulmonary examination may reveal mild crackles and rhonchi but may yield normal findings in up to half of the patients.
Diagnosis	Chest X-Ray is the main diagnostic tool: - bilateral interstitial infiltrates - Pneumatoceles and pneumothorax are possible but not common. - Pleural effusions and intrathoracic adenopathy are rare. However, the chest X-Ray may also be normal
Management and Treatment	Admit client Give supportive care: oxygen therapy, fluids **Preferred therapy:** Cotrimoxazole (10-20mg/kg/day IV) (based on TMP component) for 14- 21 days **Alternative therapy:** Oral Cotrimoxazole for 21 days: Total daily dose: 1 tablet of 960mg orally for every 8kg of body weight; divide total dose into 3-4 individual doses. Maximum 8 tablets per day. **Adjunctive therapy**: Use corticosteroids only in hypoxic patients with severe PJP (PaO2 <70 mmHg or SpO2<90%): Prednisone (oral): • Day 1–5: 40 mg twice daily • Day 6–10: 40 mg once daily • Day 11–21: 20 mg once daily
Prevention	Daily Cotrimoxazole prophylaxis for: • CD4 <200 cells/mm³ • WHO clinical stage 3 or 4 - Ensure ART adherence - Monitor for side effects and adherence Refer to point 7.1.2 for condition of discontinuation

7.3. Toxoplasmosis: symptoms, diagnosis, treatment and prevention

Toxoplasmosis, caused by the protozoan parasite Toxoplasma gondii, is a major opportunistic infection in PLHIV, especially those with advanced immunosuppression (CD4 <200 cells/mm³). In The Gambia, the implementation of rapid diagnostic tests for Toxoplasma (lateral flow assays) will support earlier detection and management.

Table 7.4: Symptoms, diagnosis, treatment and prevention of toxoplasmosis

Signs and Symptoms	*Symptoms:* Headache, confusion, fever, seizures, focal neurological symptoms deficits *Signs*: Neurological abnormalities; may include visual impairment if ocular toxoplasmosis is present. Common in patients with CD4 <200 cells/mm³.
Diagnosis	Diagnostic tools available in The Gambia: - Rapid Toxoplasma antibody detection tests - Serology: • Toxoplasma IgG positive indicates prior infection • Toxoplasma IgM positive suggests recent or acute infection - Imaging (CT or MRI) shows ring-enhancing lesions in CNS
Management and Treatment	Admit (or refer) client with neurological symptoms et signs **(**toxoplasmic encephalitis**).** **Acute Treatment:** [26] *Dosage:* Trimethoprim 5 mg/kg and sulfamethoxazole 25 mg/kg administered orally or intravenously twice daily. Duration: At least 6 weeks, with extension if clinical or radiologic response is incomplete. **Chronic Maintenance Therapy (Secondary Prophylaxis):** *Dosage***:** One double-strength tablet (800 mg SMX/160 mg TMP) twice daily. *Criteria for Discontinuing Chronic Maintenance Therapy* • Successfully completed initial therapy, *and* • Asymptomatic of signs and symptoms of TE, *and* • CD4 count >200 cells/mm³ for >6 months in response to ARVs **Alternative treatment if cotrimoxazole is contraindicated** Give all 3 drugs for 6 weeks: • Pyrimethamine 200mg orally as loading dose, then 50mg orally daily if weight less than 60kg, or 75mg orally daily if weight 60kg or above Plus: • Folinic acid 15mg orally daily Plus: • Clindamycin 600mg 3 times a day orally. If the patient is severely unwell or unable to swallow and IV formulation is available, give 600mg IV 3 times daily for the first 3-5 days If gastrointestinal side effects (nausea, epigastric pain, abdominal pain – can occur with high dose oral treatment) reduce oral dose to 450mg 3 times daily Clinical improvement is expected after one-two weeks. Consider other diagnosis if no improvement after 2 weeks.
Prevention	Primary prophylaxis: - Co-trimoxazole for PLHIV with CD4 <200 cells/mm³ and Toxoplasma IgG positive. Secondary prophylaxis: - Continue until CD4 >200 cells/mm³ for at least 6 months on ART.

	- Educate clients on safe food handling and hygiene to avoid exposure.

Rem: sulfadiazine + pyrimethamine can also be prescribed, if available

7.4 Sexually Transmissible Infections and Other Reproductive Tract Infections

Ulcerative and inflammatory diseases of the reproductive tract often co-exist with HIV infection, increased HIV infectiousness and shedding. Some may cause serious complications like peritonitis due to pelvic inflammatory disease.

At the initial assessment, a thorough history should be obtained including information on:

- Previous STIs
- Symptoms of current STIs (discharge, pain on micturition, genital sores, dyspareunia, itching)
- Risky sexual practices:
    - ✓ Multiple partners
    - ✓ Anonymous partners
    - ✓ Drug and alcohol abuse
    - ✓ Report of unprotected sex outside of a mutually monogamous relationship
    - ✓ Exchange of sex for drugs or money, or sex with a partner who reports these behaviours
- Contraceptive and condom use.

The history should be accompanied by a thorough physical examination, including examination of the external genitalia for ulcers and discharge. All PLHIVs should receive a serological test for syphilis.

PLHIV diagnosed with an STI should be managed with their sexual partner (s) according to standard STI treatment protocols.

At initial diagnosis of HIV infection, all sex workers should be assessed for STIs and if present offered syndromic therapy.

Patients who have persistent signs and symptoms of STIs in spite of syndromic treatment should undergo diagnostic evaluation for definitive diagnosis and aetiologic therapy

All PLHIVs should be evaluated for continued risky sexual practices and symptoms of STIs through sensitive and non-judgmental interviewing. Those with on-going risk should receive intensive counselling to reduce risky behaviour and be provided with easy access to condoms. Sex workers should be evaluated for STIs at every visit.

(Refer to appendix 7 and national protocol)

7.5 Prevention and treatment of Malaria

7.5.1 Malaria in people living with HIV

Children and adults with HIV infection suffer more frequent and more severe malaria than HIV uninfected individuals. Furthermore, people with advanced immunosuppression are at risk of failure of anti-malarial treatment. In pregnancy, there is increased risk of placental malaria, severe anaemia, premature delivery and perinatal mortality.

7.5.2 Strategies to prevent malaria

The following are recommended strategies to prevent and control Malaria:

Co-trimoxazole preventive therapy, as recommended for all HIV-infected patients, provides effective protection against malaria infection. PLHIV should have access to insecticide treated mosquito nets or indoor residual spraying to reduce exposure to mosquito bites and malaria transmission.

HIV-positive pregnant women who are taking Co-trimoxazole prophylaxis **should not be given Sulfadoxine-Pyrimethamine (SP) for intermittent preventive treatment.**

Children should be vaccinated against malaria according to EPI (no specificity for HIV exposed or infected children).

7.5.3. Management of malaria in PLHIV

PLHIV with fever and on CPT should not be treated for a presumptive diagnosis of malaria. As far as possible, laboratory confirmation of malaria using rapid diagnostic test (RDT) or blood film should be obtained prior to initiation of anti-malarial therapy. Other causes of fever should be considered.

PLHIV with malaria should receive standard anti-malarial therapy according to National guidelines. However, patients on ART receiving anti-malarial therapy should be monitored closely for adverse drug reactions.

Some drugs used to treat malaria and ARV drugs may share toxicities (particularly sulfa-based drugs).

Table X.1: shared toxicity between ARV and anti-malarial drugs.

Drugs	amodiaquine	Primaquine
EFV	**liver toxicity**	*hematotoxicity*
AZT	*hematotoxicity*	*hematotoxicity*

BOLD: do not administer

Italic: use with caution

Pharmacokinetic interactions exist. Some increase plasmatic anti-malarial drug concentration (increasing the risks of side effects), others decrease anti-malarial drug concentration (reducing effectivity of the treatment).

Table X.2: pharmacokinetic interactions between ARV and anti-malarial drugs

Drugs	Quinine	Primaquine	Artemisinin	Lumefantrine
EFV	*QT interval prolongation*	*QT interval prolongation*	↘ *anti-malarial activity*	↘ *anti-malarial activity*
ATV/r	↗ *plasmatic quinine* *QT interval prolongation**		↗ *plasmatic artemisinin*	↗ *plasmatic lumefantrine* *QT interval prolongation**
LPV/r	↘ *plasmatic quinine*		↘ *plasmatic artemisinin*	↗ *plasmatic lumefantrine* *QT interval prolongation**
DRV/r	↗ *plasmatic quinine* *QT interval prolongation**			↗ *plasmatic lumefantrine*

*Clinical monitoring including ECG is recommended if coadministration

No drug interactions are expected between anti malaria medicines and the preferred first line ART regimens (TLD in adults and adolescents and ALD in children).

7.6 Cervical Cancer

Cervical cancer, caused by persistent infection with high-risk serotypes of the human papillomavirus (HPV), particularly types 16 and 18, is the most common cancer among women in The Gambia. It is significantly more prevalent and progresses more rapidly in women living with HIV due to immune suppression. Cervical cancer is classified as an AIDS-defining condition and thus qualifies as an indication for immediate ART initiation.

Prevention and early detection are central to reducing morbidity and mortality associated with cervical cancer. HPV is primarily sexually transmitted and infection can lead to cervical intraepithelial neoplasia (CIN), which progresses through stages (CIN 1 to CIN 3) before evolving into invasive carcinoma, particularly in immunocompromised individuals.

7.6.1 Screening Recommendations

All women living with HIV should be screened for cervical cancer at the time of HIV diagnosis and at regular intervals thereafter. Screening should begin at the age of sexual debut or by age 25, whichever comes first. Recommended screening intervals for HIV-positive women are every 12 to 36 months, depending on results of prior screenings.

7.6.2. Available screening methods

- Visual Inspection with Acetic Acid (VIA): practical and allows for immediate detection and treatment.
- PAP smear: cytological analysis of cervical cells classified by CIN grade.
- HPV DNA testing: effective for identifying high-risk HPV infections.

7.6.3. Treatment and Follow-Up

Women with positive screening results should be referred promptly for evaluation and management. Pre-cancerous lesions may be treated with cryotherapy or loop electrosurgical excision procedures (LEEP). Suspected or confirmed invasive cancer should be referred for oncology care. ART should be optimized to achieve and maintain viral suppression, which supports immune recovery and slows disease progression.

7.6.4. HPV Vaccination

HPV vaccination is a key preventive measure and should be offered to all eligible adolescent girls, including those living with HIV.

- Girls under 15 years should receive two doses;
- Girls aged 15 years or older, or who are immunocompromised, should receive three doses.

7.7 Kaposi Sarcoma

Kaposi Sarcoma (KS) is a low-grade vascular tumor associated with Human Herpesvirus-8 (HHV-8) and is one of the most common AIDS-defining cancers. It can occur at any CD4 count but is more common with CD4 <200 cells/mm^3. KS may be indolent or aggressive, affecting the skin, oral mucosa, lymph nodes, or internal organs.

Table 7.5: Symptoms, diagnosis, treatment and prevention of Kaposi Sarcoma

Category	Information
Signs and Symptoms	Multifocal violaceous or purplish-red macules, plaques or nodules, commonly on the skin of the nose, ears, thighs and feet. Oral involvement on the palate or oropharynx may indicate visceral disease. Lymph node involvement or lymphoedema may also be present. May be associated with systemic symptoms such as weight loss, fever, or night sweats.
Diagnosis	Primarily clinical. Biopsy confirmation is ideal. Investigations include chest X-ray for pulmonary disease, endoscopy for GI lesions. Staging can be clinical or according to AIDS Clinical Trials Group (ACTG) Tumor-Immune-System (TIS) staging system.
Treatment	Patients with Kaposi's sarcoma should initiate ART immediately, regardless of CD4 count and be referred for further evaluation for potential chemotherapy Chemotherapy is indicated for extensive or symptomatic disease. **Preferable First line:** Paclitaxel (if available). Regimen 1: 100 mg/m^2 over 3 hrs (6–8 cycles). Regimen 2: 25 mg/m^2 weekly x8 weeks for poor condition. Monitor FBC and LFT at baseline and before every paclitaxel infusion. Transfuse before paclitaxel dose if Hb<8g/dl Give chlorphenamine tablets 4mg + paracetamol 1gr + dexamethasone 12mg IV/PO + cimetidine 400mg or ranitidine 50mg IV/PO 30-60 min before paclitaxel. Monitor for allergy / anaphylaxis (rare) Dosing and administration dose is based on body surface area m^2 (see Appendix 22)- round the dose to the nearest 5mg. Dilute in 500ml normal saline solution, slow IV infusion (1-3 hours) **Alternative treatment:** • Liposomal Doxorubicin (if paclitaxel contraindicated). • Bleomycin/Vincristine (if other options unavailable).
Prevention	No specific primary prevention. Early HIV diagnosis and prompt ART initiation is key. Integration of cancer screening and palliative care support in HIV services is recommended.

7.8 Viral Hepatitis

HIV-hepatitis B (HBV) co-infection is a common problem and presents specific clinical challenges.
In the African context, most people living with hepatitis B chronic infection were infected during early childhood. The mother to child transmission occurs mainly at the time of birth, but it can also occur in the first years of life. Early transmission increases the risk of developing a chronic form of viral hepatitis B (up to 90% for children infected at birth, while in adults sexually infected, the risk of transitioning to a chronic form is much lower, estimated around 10%).
In the absence of treatment, HIV coinfection profoundly affects almost every aspect of the natural history of HBV infection:

- more rapid progression to cirrhosis and hepatocarcinoma,
- higher liver-related mortality,
- higher rates of chronicity after acute HBV infection, higher rates of reactivation and rates of occult HBV (HBV DNA positivity in the absence of HBsAg-positivity)
- reduced treatment response compared with people without HIV coinfection.

(Source: WHO, 2024, p.180 [9])

7.8.1 Diagnosis and care for adults and adolescents

All people living with HIV should be tested for hepatitis B and all HBs antigen positive adults and adolescents should be treated with TDF. As TDF is included in the preferred ART first line regimen, the screening for hepatitis B is recommended, if not done before, in the following situations:

1/ Before switching a patient to a second line regimen that does not contain TDF (i.e AZT or ABC)

--> people living with HBV-HIV coinfection should receive an additional TDF treatment for HVB infection (i.e. TDF + [AZT+3TC+3rd drug])

2/ During pregnancy (as early as possible)

--> additional monitoring and actions will be provided (specific follow up of the mother, vaccination of the newborn at birth, HBs antigen test of the infant at 9 months), see PMTCT chapter.

7.8.2 Treatment for children and adolescent (<30 kg)

The recommended treatment for HBV infected children (2 to 11 years) is Entecavir (not yet widely available). Continue with the standard HIV ART regimen.

Note: Lamivudine (3TC) is active against HBV, but resistance mutations are rapidly selected by HBV and cross-resistance are possible between Entecavir and 3TC.

For non-HIV children, consult The Gambian National Hepatitis guidelines or WHO Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection (2024)

Chapter Eight: Co-morbidities and Common Non-communicable Diseases (NCDs) among PLHIVs

With improved access to antiretroviral therapy (ART), HIV infection is now a chronic, manageable condition in The Gambia. As a result, mortality has significantly declined. However, this success is now accompanied by an increasing burden of non-communicable diseases (NCDs), such as cardiovascular disease, diabetes, chronic liver and kidney disease and mental health disorders. These may result from ageing, HIV-induced chronic inflammation, or long-term adverse effects of ART especially with some older regimens like protease inhibitors. PLHIV now face the dual challenge of managing HIV alongside multiple chronic comorbidities. This calls for a proactive and integrated approach to screening, prevention and management of NCDs within HIV care.

Currently, HIV and NCD services are often delivered in separate clinics, leading to fragmentation of care. This limits access for patients with multiple chronic conditions.

Evidence from other sub-Saharan countries shows that integrating HIV and NCD services is feasible, cost-effective and acceptable to patients. The Gambia should explore integrated care models, particularly in high-volume urban and regional health facilities.

8.1. Assessment and Management of Mental Disorders Amongst PLHIV

People living with HIV (PLHIV) face lifelong challenges associated with chronic illness not only physically, but also mentally. Mental health disorders, particularly depression, anxiety and substance use, are common among PLHIV and are driven by a wide range of factors. These conditions are often present from the time of HIV diagnosis or ART initiation either as potential side effects of antiretroviral therapy (ART) or due to the emotional burden of living with a chronic, stigmatized illness.

Mental health conditions cause significant distress and add complexity to the management of HIV. They not only affect the individual but also have a wider impact on families and communities. Critically, mental illness is strongly associated with poor adherence to treatment, increased engagement in risk behaviors and higher morbidity and mortality among PLHIV. Despite this, mental health issues often remain undetected and untreated, especially in low-resource settings where trained mental health professionals may be unavailable.

In The Gambia, while national data on mental health disorders among PLHIV is limited, evidence from similar settings in sub-Saharan Africa demonstrates a high burden of depression, anxiety and substance use disorders among this population. Mental health conditions are a key barrier to achieving positive HIV outcomes, including viral suppression and retention in care.

Healthcare providers especially those in primary care settings play a critical role in identifying and addressing mental health concerns. It is essential that all PLHIV are routinely screened for mental health symptoms.

The PHQ-9 tool (Patient Health Questionnaire-9) should be used during routine clinical visits to identify individuals with depressive symptoms. Where mental health concerns are identified, providers should initiate appropriate management, including psychosocial support, basic counseling and referral to specialized services when necessary.

This section aims to support clinicians in the diagnosis, management and follow-up of the most common mental health disorders among PLHIV, the depression. A stepped-care approach, integrated into existing HIV services, is essential for improving outcomes and promoting the overall wellbeing of PLHIV.

It is important to consider that HIV itself, opportunistic infections, ART and other unrelated medical conditions may contribute to the development of mental health disorders. A thorough assessment of these potential causes should be conducted before establishing a definitive diagnosis.

Table 8.1: Patient Heath Questionnaire (PHQ9)

Name: _____ Date: _____

Over the last 2 weeks, How often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
If one of the above symptoms are present more than half of the time, go on with the following questions:				
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating (on things linked with patient's usual activities)	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Throughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Add columns :				
TOTAL:				

10: If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all: _____
Somewhat difficult: _____
Very difficult: _____
Extremely difficult: _____
If you faced any difficulty, did it occur for two years or more? _____

A patient is considered as having signs of depression if:

PHQ9 score	Provisional diagnosis	Recommendation
5–9	Minimal symptoms	Adherence support and educate to contact clinic if worse
10-14	Mild depression or Chronic depression	Refer to clinical supervisor or psychological support Reassess in one/two weeks
15-19	Moderate depression	Refer to clinical supervisor or Psychologist for assessment and treatment
>20	Severe depression	Major impairs and need for immediate medical treatment and counselling

8.2. Hypertension

Hypertension is a significant non-communicable disease (NCD) affecting PLHIV, with implications for both cardiovascular and renal health. Poorly controlled hypertension in HIV-positive individuals increases the risk of heart disease and accelerates progression to renal failure disease. PLHIV should be assessed regularly for hypertension risk factors, including tobacco use, overweight or obesity, physical inactivity, dyslipidemia and a history of adverse cardiovascular events such as stroke or myocardial infarction. In addition to lifestyle factors, certain antiretroviral drugs, particularly protease inhibitors (PIs) are known to exacerbate cardiovascular risk and interact with antihypertensive agents such as amlodipine, potentially leading to elevated drug levels and toxicity. Smoking remains a major modifiable risk factor.

Table 8.2: Risk factors, diagnostic criteria, management and monitoring of HTA

Aspect	Details
Risk Factors	Smoking, obesity, inactivity, ART (especially PIs), unhealthy diet, age > 40, family history.
Screening	BP measurement at every clinic visit Assess risk factors. Follow-up frequency based on BP level.
Diagnosis Criteria	BP ≥ 140/90 mmHg on two separate occasions with patient seated (see appendix 23)
Management	- Initial steps include lifestyle counselling - Refer to your supervisor or hospital for initiation of the treatment and in case of uncontrolled BP after initiation. -Preferred drugs: Amlodipine 5 -10 mg
Monitoring	Every 6–12 months: FBC, Urine protein, K+/Na+, Creatinine, ECG if available
Drug Interactions	Amlodipine levels elevated with PIs

8.3. Diabetes Mellitus

Diabetes Mellitus (DM) is a growing non-communicable disease that poses a significant burden among PLHIV. The HIV-positive population is at a higher risk of developing diabetes due to chronic inflammation, side effects of antiretroviral therapy (especially protease inhibitors and dolutegravir) and metabolic disturbances such as dyslipidemia and lipodystrophy. In addition, diabetes has direct clinical implications for HIV care, including increased susceptibility to opportunistic infections such as tuberculosis (TB) and worsened outcomes in TB treatment. PLHIV with diabetes face challenges in glycemic control, adherence to multiple medications and increased risk of complications such as nephropathy, neuropathy and retinopathy. Routine screening, lifestyle interventions and careful selection of antiretroviral regimens are key to mitigating the burden of diabetes in this population. Annual screening using fasting blood glucose is advised, in high-risk individuals.

Table 8.3: Risk factors, diagnostic criteria, management and monitoring of diabetes

Aspect	Details
Risk Factors	Obesity, inactivity, smoking, family history, HIV-related factors (e.g., inflammation, dyslipidemia, lipodystrophy), ART (especially PIs, DTG).
Screening	Annual fasting glucose & urine dipstick for all PLHIV, or targeted screening every 6 months if at high risk.
Diagnosis	Fasting glucose levels, HBA1C
Management	- Lifestyle: diet, physical activity, smoking/alcohol cessation - Refer to your supervisor or hospital for better management - Metformin (start low, monitor for lactic acidosis especially with TDF, liver/kidney issues). - Avoid Glibenclamide in elderly or risk of hypoglycemia. - Avoid DTG if diabetic; use metabolically neutral ARVs such as EFV.
Complications	Increased risk of nephropathy, neuropathy, retinopathy, cardiovascular disease.
Monitoring	Monitor blood glucose, screen for complications (renal, neurological, visual).

Chapter Nine: Management of an HIV-Infected Child using ARVs

9.1. Introduction

Infants and young children have an exceptionally high risk of poor outcomes from HIV infection. Up to 52% of children die before the age of two years in the absence of any intervention. By five years of age as much as 75% of HIV positive children will be dead if they are not initiated on ART [27].

The goal of ART for children is to increase survival and decrease HIV-related morbidity and mortality.

9.2 Criteria to Initiate ART in Children and Adolescents Born With HIV

All children and adolescents diagnosed with HIV should be initiated on ART, regardless of age, clinical stage, or immunological status.

9.3 ART regimens in children

9.3.1 Preferred and alternative regimens

Table 9.1: Choice of ARV for Children and Neonates

Population type	Preferred 1st line regimens	Alternative 1st line regimens
Children >30kg	TDF(1) + 3TC + DTG	TDF + 3TC + EFV_{400mg}(6) [ABC or AZT(2)] + 3TC + DTG [ABC or AZT] + 3TC + [ATV/r or LPV/r](3)
Children 25-30 kg	ABC + $3TC_{(600+300mg)}$ + $DTG_{(50mg)}$	AZT(2) + 3TC + DTG [ABC or AZT] + 3TC + [ATV/r or LPV/r](3)
Children 20 - < 25 kg	ABC + $3TC_{(120+60mg)}$ + $DTG_{(50mg)}$	ABC + $3TC_{(120-60mg)}$ + $LPV/r_{(100mg+25mg)}$
Children 10 - < 20 kg	ABC + $3TC_{(120+60mg)}$ + $DTG_{(10mg)}$	ABC + $3TC_{(120-60mg)}$ + $LPV/r_{(40mg+10mg)}$ or (100+25mg)
Children 3 - < 10 kg	ABC + $3TC_{(120+60mg)}$ + $DTG_{(10mg)}$	AZT+$3TC_{(30+60mg)}$ + LPV/r (40mg+10mg)
Neonates and infants < 3kg	AZT + $3TC_{(60+30mg)}$(5) + $NVP_{(10mg/ml)}$	

(1) TDF is contraindicated in patients with kidney disease. If there is kidney disease, use ABC.

(2) If there are severe side effects on ABC (allergy) and kidney disease, use AZT.

(3) ATV/r is easier to take, better tolerated than LPV/r and should be preferred in children weighing > 25kg

(4) LPV/r 40-10 mg formulation is adapted to children unable to swallow the tablets

(5) ABC is difficult to use in newborns (except if syrup is available). If AZT-$3TC_{60mg+30mg}$ can be used (see appendix). If not available --> ABC+3TC+DTG must be initiated when the infant is 4 weeks old and weighing 3 kg or more.

(6) EFV_{400mg} should only be used if severe side effects on DTG-based regimen

Note: with the current preferred regimens, the probability of cross mutations between prophylaxis treatment and preferred curative treatment is reduced.

9.3.2 Issues to Consider when Initiating ART in Children and Adolescents

ART regimens and formulations: refer to the dosing table (Appendix 1).
Keep the following factors in mind with regard to dosing:

→ Weight of the child

- Doses are defined by weight bands. Weight must always be checked before prescribing ART and medicine doses must be adjusted as the child grows.
- The change from ABC to TDF is possible from the weight of 30kg. However, we recommend waiting till 35kg, to reduce the risk of renal and bone side effects.

→ Availability of paediatric formulations of the medicines:

- Using split or crushed adult formulations should be avoided when possible: the bioavailability of crushed adult tablets was not tested so the real dose that the child is receiving is unknown. For instance, giving a half crushed adult tablet of AZT-3TC to a child is not recommended.
- Scored tablets (tablets marked with breakable lines) may be divided into two equal halves
- Dispersible tablets (ABC-3TCped, DTG10mg) must be dissolved with a small amount of water and administered within 30 minutes. They can be mixed with food and administered immediately.
- ABC-3TC (adult) should be swallowed whole. However, it can be crushed, dissolved in water and mixed with food and taken immediately.
- Other tablets (DTG_{50mg}, TDF, LPV/r) should not be crushed. If the child is not able to swallow the tablet, choose another formulation.

→ Palatability of the medicines:

- ABC+3TC and DTG_{10mg} are both dispersible and the taste is child friendly.
- $LPV/r_{100/25mg}$ pills must be swallowed whole, which is difficult for children less than 5 years old. The use of LPV/r must be reserved to very specific conditions (see treatment failure)

→ Effect of food on the absorption of the medicines

- Most ARV medicines can be given with or without food (ABC, 3TC, DTG, LPV/r and AZT).
- TDF may be taken with or without food, although taking it with food can improve absorption. ATV/r must be taken with food to ensure adequate drug levels

→ General considerations

- Give clear explanations to the caregiver and to the child, if he/she is more than 7 years old.
- Use pillboxes if available.
- Standardization is important to safely dispense correct doses.

9.3.3. Psychosocial factors

It is important to identify and counsel at least one dedicated caregiver who can supervise and/or give medicines. Disclosure to another adult in the same household (secondary caregiver) is encouraged to assist with medication.

Box 9.1: key questions when initiating ARV treatment in children

1/ Who will administer the medication or supervise its intake?

2/ Who knows the child's diagnosis (or who will be informed in the family)?

3/ When (time) will the medicines be administered?

4/ What strategy will be put in place so as not to forget the treatment?

5/ How will the medicines be stored and where will they be stored?

(For more details, see appendix 17)

9.3.4. Disclosure and communication with the child: what to say to the child while initiating ART?

The process of disclosure to the child should be initiated as early as possible, usually from 6 – 7 years of age. Adherence is good in children who know their status and are supported to adhere to medicines.

At initiation, some information can be provided to the child (see table 9.2). The disclosure process will continue until the end of adolescence.

Table 9.2: Messages that can be delivered to a child when initiating ART

Age	Symptoms?	Proposition of sentence
< 6-7 yrs	Yes	Your mom is going to give you medicine to drink. They have a great strawberry taste. It's to treat your disease (your pimples, your stomach, your cough, ...).
	No	Your mom is going to give you medicine to drink. They have a great strawberry taste. That way you'll stay strong, you'll grow up well and not get sick.
7 - 9 yrs	Yes	There's a **little germ** in your body. That's why you're sick (whether you cough, or have a stomach pain, or pimples, ...). The drugs will make the germ sleep and you will heal. They taste good, you will have to take them every day.
	No	There's a **little germ** in your body. If we don't do anything, you're going to get sick. With the medication that mom will give you, the microbe will fall asleep and it won't be able to give you diseases. You will stay strong and you will grow well. But you will have to take them every day.
> 10 yrs	Yes	There are germs in your blood that make your defences very weak. That's why you often get sick. We don't know how to kill these germs but we know how to put them to sleep with the drugs you take every day. In a few weeks, your defences will become strong again and will fight diseases, you will feel better. You should not stop the medication, otherwise the germs will wake up and weaken your defences again.
	No	There are germs in your blood that are weakening your body's defences against disease. If we don't do anything, you may get sick soon. But if you take these drugs every day, these germs will fall asleep and your defences will be strong and you will stay healthy. But even if you feel fine, you should never stop taking these medications.

9.4. Initial assessment

9.4.1. Clinical and nutritional assessment

Clinical conditions must be carefully assessed.

As in adults, the clinician should:
→ Look for opportunistic infection (oral and oesophageal candidiasis, lymphadenopathy, skin rash, pulmonary disease, hepatomegaly, splenomegaly and any neurological signs).
→ Screening for pulmonary TB and extrapulmonary TB (lymphadenopathy and CNS localization)

Note: Cryptococcal meningitis is rare in children and should not be systematically screened in children. For adolescents born with HIV and diagnosed after the age of 10 years old, follow the adult protocol.

Nutritional status

Malnutrition is very frequent in children before initiation. Indexes used to define malnutrition change according to the age of the child. The table 9.3 indicates the indexes and cut-off that should be used.

All children and adolescents must benefit from measurements of their mid-upper arm circumference (MUAC), weight and height.

→ Weight for height index is used until the age of 5 (see appendix 31)

→ BMI for Age is used from 5 years and beyond (see appendix 32)

Table 9.3: Anthropometric threshold to define malnutrition according to age range

Age of the child	Index	SAM	MAM
< 6 months	Weight/Height	< -3 SD	> -3 SD and < -2 SD
	Pitting oedemas	Present	Absent

6-59 months	Weight/Height	< -3 SD	> -3 SD and < -2 SD
	MUAC	< 115 mm	>= 115mm and < 125mm
	Pitting oedemas	Present	Absent
5 years to less than 10	BMI/A	< -3 SD	> -3 SD and < -2 SD
	MUAC	< 129mm	
10 years to less than 14	BMI/A	< -3 SD	> -3 SD and < -2 SD
	MUAC	< 160mm	

MUAC: middle upper arm circumference; BMI/A: body mass index for age

(1) Source of the cut-off for MUAC 5 yrs and beyond: WHO 2009, p. 9, [28]

Children with severe acute malnutrition should be hospitalized in HIV clinic for comprehensive assessment.

9.4.2 Classification (WHO Advanced HIV Disease criteria)

In children less than five years old, qualitative CD4 tests cannot be used and before ART initiation, rapid evolution and death-risk are high. So, all children less than 5 yrs not on ART are classified as advanced HIV at initiation (WHO, 2017, p. 3 [29]). However, children from 2 to 5 yrs, established on ART, should not be considered to have advanced disease and are eligible to multi-month dispensing (WHO, 2021, p.218 [5]).

In children older than 5 yrs, advanced HIV is defined by:

- CD4 < 200 cells/mm^3
- WHO clinical stage III or IV (see appendix 3)

Children classified as advanced HIV patients will benefit from close follow up during the first months after ART initiation (see further).

9.4.3 Biological initial assessment

There is no need for biological tests before initiating ABC or 3TC.

For Tenofovir: perform urine dipsticks for glycosuria and proteinuria and estimated Glomerular Filtration Rate (eGFR) based on serum creatinine (revised Schwartz equation):

Box 9.2: Schwartz equation to estimate Glomerular Filtration Rate in children [30]

Revised bedside pediatric eGFR (Schwartz, 2009)

$$eGFR = \frac{0{,}413 \times \text{height (cm)}}{\text{creatinine (in mg)}/10}$$

$$eGFR = \frac{36{,}5 \times \text{height (cm)}}{\text{creatinine (in µmol/l)}}$$

If urine dipstick is positive (protein(+) or glucose(+)) or if eGFR is < 60ml/mn → refer for further investigation

9.4.4 Check routine vaccination status and consider catch-up vaccination

Children with severe immunosuppression may be at higher risk of complications with some live attenuated vaccines, and the response to inactivated vaccines may be less effective if they are immunocompromised. Additional doses or revaccination after immune reconstitution on ART may therefore be required. (WHO, 2021, p. 223, [5]).

→ if the child is suspected of severe immunosuppression and is supposed to receive a live attenuated vaccination (measles, yellow fever or rubella): differ the vaccination until clinical recovery (at least 6 months on ART and a proof of VL suppression).

→ if the child was vaccinated while immunosuppressed, an additional vaccination should be planned, after at least 6 months of ART and one undetectable VL test.

The most important vaccine to catch up are:

- Pneumococcal conjugate vaccine

- Measles vaccine

Pentavalent could also be considered.

9.5 How to initiate treatment in children?

9.5.1 Start co-trimoxazole prophylaxis in all children and adolescents

Table 9.4: Co-trimoxazole doses according to weight bands

Weight (Kg)	Suspension 5ml=240mg	Paediatric dispersible tablets 120mg	Adult tablets 480mg	Adult tablet 960mg
3-5,9 Kg	2,5ml=1/2 teaspoon	1 tab	-	-
6-14,9Kg	5ml	2 tab	1/2 tab (1)	-
15-24,9Kg	10ml	4 tab	1 tab	½ tab
> 25Kg	-	-	2 tab	1 tab

Co-trimoxazole prophylaxis must be initiated in all children and adolescents, even in those who are not in advanced HIV disease. Co-trimoxazole prophylaxis should be continued as long as tolerance is good. It prevents several common and potentially life-threatening infections in children living with HIV, including *Pneumocystis jirovecii* pneumonia (PJP), *Streptococcus pneumoniae* pneumonia, cerebral toxoplasmosis, non-typhoidal salmonellosis, malaria and some diarrhoea (ciclo-isospora).

9.5.2 Initiate TB preventive treatment (TPT) after exclusion of active TB

For infants (less than 12 months) living with HIV, TPT will only be prescribed if there is history of contact with a person infected with TB, after exclusion of active TB (WHO, 2024, p. 12 [12]).

For children aged more than one year and adolescents, TPT should be prescribed to all patients, including those previously treated for tuberculosis.

TPT protocol according to the age of the patient.

1/ Fix dose of rifapentine/isoniazid (RFP/INH) is the preferred TPT regimen of children older than 2 years.

For low weight children (less than 10 kg), young children unable to swallow RFP/INH tablets and patients on Protease inhibitors, the 6H protocol should be used.

2/ Single tablet of dispersible INH100mg is the preferred regimen for infants and children less than 2 years old or less than 10 kg.

In both cases, pyridoxine must be prescribed.

No ART regimen change is needed when adding TPT to ART preferred 1st line regimens.

Table 9.5: Simplified TPT regimens and doses in children

Medicine frequency and duration	Formulation	Dose of TPT medicine	Recommended number of tablets per body weight in kilograms						
Weight band			3-5.9kg	6-9.9kg	10-15kg	16-23kg	24-30kg	31-34kg	>34kg
3HP (once weekly rifapentine + isoniazid for 3 months	FDC tablet	RFP_{300}/INH_{300}			1	1.5	2	2.5	3
	Single tablet	Pyridoxine $_{25mg}$			1	1	1	1	1
Weight band			3-5.9kg	6-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg	>25kg	
6H (daily isoniazid for 6 months	Single tablet	INH $_{100mg}$	0.5	1	1.5	2	2.5	Use adult dose	
	Single tablet	Pyridoxine $_{25mg}$	0.5	0.5	1	1	1		

The use of rifapentine in infants is now possible (WHO 2024) and the protocol in The Gambia may change. Refer to National guidelines on the management of tuberculosis in children and adolescents (2023) for more details.

Note: if nutritional assessment is suggestive of malnutrition (that can be associated with TB), postponing TPT initiation could be considered until clear exclusion of TB.

9.5.3 Initiate ART

ART should be initiated as soon as possible in children living with HIV (same day or within the first week), after education of the caregiver (and of the child if he is 7 years old or beyond). However, as in adults, ART should be delayed in some specific conditions.

9.5.3.1. Patients with neurologic conditions

Initiation of these children must be managed at hospital level.

Many opportunistic infections and common paediatric infections may be accompanied by neurological signs. Some require specific treatment (antibiotics for bacterial meningitis, antimalarial treatment for cerebral malaria, for example), but in most neurological symptoms related to an opportunistic infection, ARV treatment and immune restoration are the only treatments available. However, the following infections must be investigated and treated if present:

Cerebral toxoplasmosis

Cerebral toxoplasmosis related to the reactivation of toxoplasmosis (acquired in utero or earlier in childhood) is possible in older children severely immunocompromised.

Neurological symptoms are similar to adults: moderate fever, headache, altered mental status, (focal) seizures, focal neurologic deficits (such as motor or sensory loss, cranial nerve palsies), visual abnormalities.

Other presentations are possible in children: congenital toxoplasmosis and acute toxoplasmosis. These presentations are not specific of HIV infected children, but the transmission in utero is more frequent if the pregnant woman is immunocompromised; and acute infection syndrome (cervical or axillary lymphadenopathy, flu-like syndrome, fever, myalgia, hepatosplenomegaly) can persist for weeks or months in moderate immunocompromised children.

ART and treatment of toxoplasmosis can be initiated at the same time (see paediatric protocol, appendix 27)

TB meningitis

If TB meningitis is diagnosed, TB treatment must be initiated first. ART will be initiated after 4 weeks of TB treatment (and within the first 8 weeks of TB treatment). Corticosteroids are an adjuvant treatment in TB meningitis (see National guidelines).

This presentation is frequent in infant and (even if the prevalence is declining) in children less than 5 years.

Note: Cryptococcal meningitis is very rare in children. Only immunocompromised adolescents (aged 10 years or more) should be systematically screened for cryptococcoses. However, if a child younger than 10 years presents with signs and symptoms of meningitis, cryptococcal meningitis should still be considered and the appropriate investigations and treatment for this should be implemented (see cryptococcal meningitis in adult section and paediatric protocol in Appendix 8).

9.5.3.2. Patients with pulmonary TB

Pulmonary TB is more frequent in adolescents and older children than in young children and infants.

If pulmonary tuberculosis is diagnosed, TB treatment (refer to national guidelines) should be started first and ART should be initiated as soon as possible within the first 2 weeks after TB treatment initiation.

Box 9.3: ART dose adjustment in patients with rifampicin containing treatment (HIV-TB coinfection)

ART doses adjustment: the dose of DTG needs to be increased in people who are treated for TB with Rifampicin as it lowers the concentration of DTG in the body.
An additional dose of plain DTG (equivalent in strength to the amount in the combination) should be given 12 hours after the daily dose.
For instance: for a child weighing 16 kg and receiving ABC-3TC (2,5tab once daily) + DTG10mg (2,5tab once daily), the adaptation would be:
ABC-3TC (2,5tab once daily) + DTG10mg (2,5tab twice daily)

Normal dose will be given after ending the TB treatment containing rifampicin.

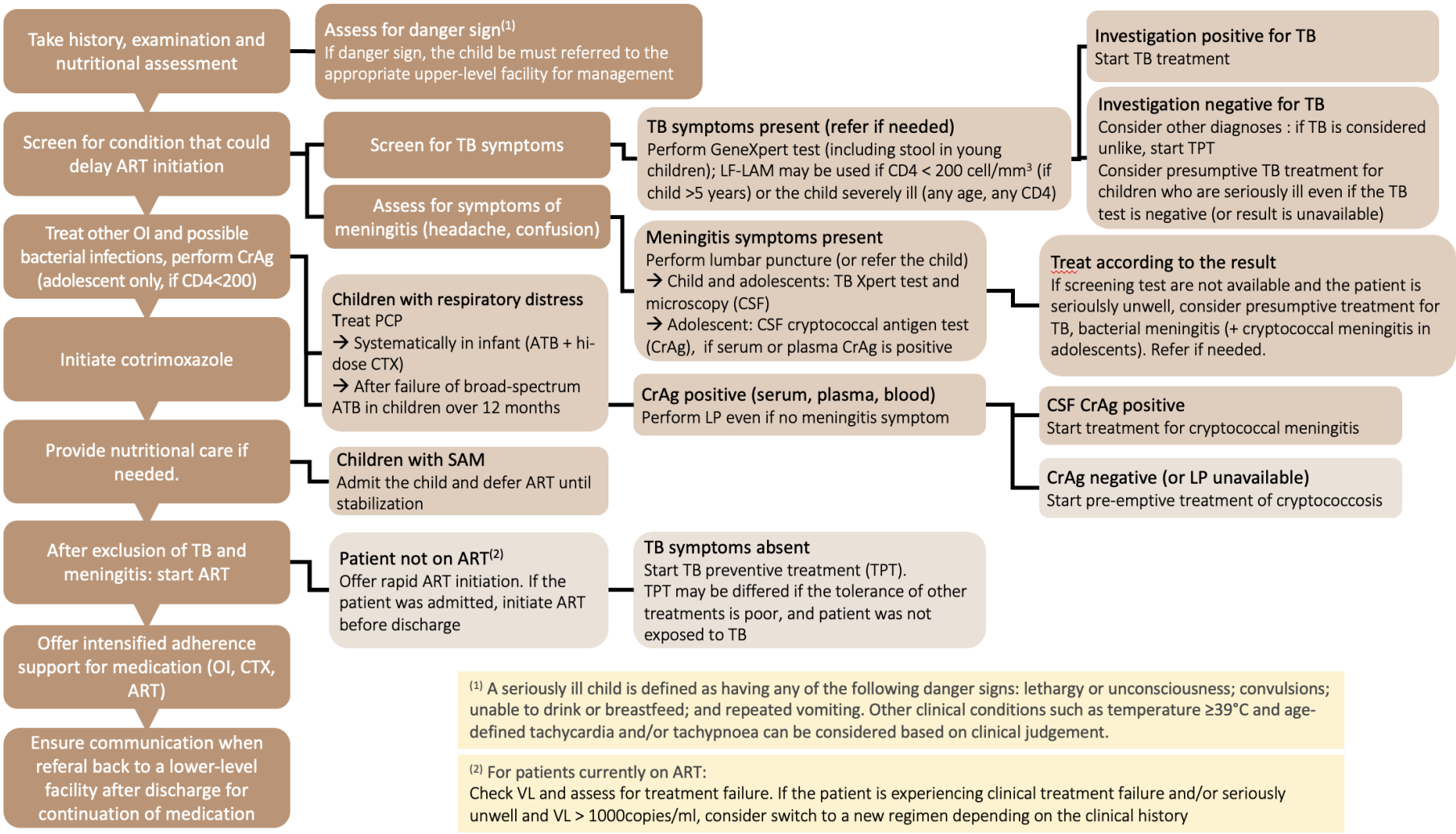
9.5.3.3 Patients with severe acute malnutrition

No clear recommendation exists about the timing of ART initiation in children with severe acute malnutrition. Urgent ART initiation (within 48 hours) does not seem to improve survival (WHO 2021, p. 115; and p. 220 [5]).

ART should be initiated as soon as possible within the first 2 weeks of nutritional care, after medical stabilization of coexisting illness (i.e hydroelectrolytic equilibration, treatment of acute bacterial infection, ...) is completed, that is, usually, around the transition phase (between the stabilization and the renutrition phase). (refer to national protocol).

9.5.4 Summary of initial assessment and treatment initiation in children

Figure 9.1: initial assessment and management of HIV infected children and adolescents



ART: antiretroviral therapy; CSF: cerebrospinal fluid; CTX: cotrimoxazole; TB: tuberculosis; LP: lumbar puncture; LF-LAM: lateral flow urine lipoarabinomannan assay; CrAg: cryptococcal antigen (rapid test); OI: opportunistic infection; SAM: severe acute malnutrition

Adapted from Algorithm for providing a package of care for people with advanced HIV disease, WHO 2021, p 225 [5]. See also "Appendix 30: normal heart and respiratory rates for children"

9.6 Monitoring on treatment

9.6.1. Principle of monitoring in children

In children, growth and development are important clinical monitoring indicators and are assessed using growth charts, together with clinical conditions.

HIV VL level is the best tool to assess response to therapy: the first test is done after 6 months of ART and is expected to be undetectable. **Because of the high incidence of treatment failure in children and adolescents, routine VL tests should be done twice a year (every 6 months).**

Laboratory indices of CD4 lymphocyte counts is no more used as monitoring tool, but CD4 count is still useful to assess the immunologic status in special circumstances in children aged 5 years or more:

- At initiation
- After treatment stop (more than 3 months)
- When virological failure is evidenced

Caution: the absolute CD4 count and the percentage values in healthy infants who are not infected with HIV are considerably higher than those observed in uninfected adults and slowly decline to adult values by the age of 5 years.

Refer to appendix 5 to interpret CD4 absolute count and % value in children less than 5 years old.

9.6.2. Important signs of infants' and children's response to ART

Improvement in growth in children who have been failing to grow

- Catch up growth is expected if ART is effective, if other opportunistic and bacterial infections (including TB) are treated and controlled and if nutrition intakes are appropriated.
- Catch up in weight is observed after some days or a few weeks of treatment.
- Catch up in height usually starts after several weeks (around 3 months) and is more complete in infants and young children (less than 3 years old at ART initiation). Children older than 6 years are usually unable to completely recover from growth retardation.

Improvement in neurological symptoms and development in children with encephalopathy or who have been demonstrating delay in the achievement of developmental milestones.

- Infant and young children who suffered from HIV-related encephalopathy may improve if ART initiation was early enough, but severe outcomes (mental retardation, death) are possible.
- Neurological deterioration has been described in infants and young children early initiated on treatment: part of them had undetectable VL and improved after some months on the same regimen, while others were failing on treatment and improved after switching regimen. [31]

→ If an infant or a child shows neurological deterioration on ART, he/she should be referred to a reference paediatric site.

Decreased frequency of infections (bacterial infections, oral thrush, and/or other OIs)

- This is usually observed when the treatment is initiated in non-advanced patients and when adherence to treatment is good.
- In advanced patients, complications are frequent during the first 3 months on ART even when adherence is good.

Clinical assessment involves the following:

- Always check the child and caregiver's understanding of ART as well as anticipated support and adherence to ART.
- Always check for symptoms of potential medicine toxicities.
- Always assess for treatment failure (i.e. reassessment of clinical stage) and analyse routine VL.

9.6.3. During the first 6 months

Rhythm of appointments during the first 6 months.

- The first consultation after initiation will be conducted 2 weeks after the ART initiation.
- Then monthly if stable and every two weeks if unstable for another 3 months.
- If the child is established on treatment – regression of the symptoms, no new clinical conditions, no side effects, improvement of nutritional status, good understanding of adherence and no issue to administer the medicines to the child - give a 3-months appointment (at M6 from initiation).

Note: if the child was symptomatic at initiation, the first 3 months are a high-risk period of complications: severe bacterial infections, opportunistic infections, tuberculosis, drug side effects.

If the child's clinical conditions are worsening on ART, the caregiver should consult immediately. Refer him/her for medical advice.

9.6.4 After 6 months on ART

After 6 months on ART, a VL test must be done.

If VL is undetectable and if the child is clinically established and nutrition status is satisfactory (normal or catch-up growth and anthropometric indexes > - 2SD), go on with appointments every 3 months.

If VL is unsuppressed (> 1000 copies/ml) or if the child is still not clinically stable or with poor nutritional status (poor growth, anthropometric indexes < - 2SD), give monthly appointments, strengthen adherence and conduct a targeted VL after 3 months.

Note: if CD4 count was < 200 cells/mm^3 at initiation, a second CD4 test could be considered 6 months after ART initiation.

9.7. Paediatric specificities during the first months of treatment

9.7.1 Allergy to ABC

The main risk factor of allergy to ABC is a genetic profile rarely met in African people. So, allergy is infrequent in The Gambia context. However, it is possible and can be severe.

Signs of allergy to Abacavir variously combine:
- a rash,
- fever,
- digestive signs (nausea and vomiting),
- malaise and fatigue.

They usually occur within the first 6 weeks of treatments (but can occur later).

In case of suspicion of allergy to ABC, immediately stop the drug and never start it again. If in doubt (especially if there is no alternative option), refer to a paediatrician at reference hospital for confirmation.

For allergy to CTX, see the adult section. In children, WHO does not propose desensitization protocols. If prophylaxis has to be reinitiated (severely immunocompromised child), ask for paediatric advice.

9.7.2 BCG-IRIS in infants

Before the age of one year, there is a fairly specific complication called BCG-IRIS. It is an abscess or adenitis ipsilateral to the vaccination site. It usually occurs between 2 and 4 to 8 weeks after initiation of ART. Disseminated forms exist but are rare. The management of this complication is poorly codified.

- In the case of a localized form, therapeutic abstention, under regular monitoring, is possible. Analgesic treatment will be prescribed in case of pain and evacuation punctures (or surgical drainage) may be proposed to limit discomfort. Spontaneous resolution is the rule, but the evolution is often prolonged (several months).
- In the event of a generalized form, treatment must be considered. The sensitivity of BCG to anti-TB drugs varies between vaccine strains, but most major anti-TB drugs are active.

9.7.3 Other complications in the first months of ART

As in adults, the first three months of ART are a high-risk period for children initiated at an advanced stage. The most frequent complications are tuberculosis (classical presentation and TB-IRIS), severe lung infections and sepsis.

Any clinical complication in the first months of ART should be assessed at hospital level and managed by paediatrician or experienced medical doctor until the child is stabilized.

9.8 Specificities of adherence in children and adolescents born with HIV

9.8.1 In infants and young children

The importance of the caregiver is of major importance. The caregiver must be stable, involved, present at the time of medicine administration.

The ritualization of ARV (and co-trimoxazole) intake is a factor in successful compliance: if possible, the same person should give ARVs every day at the same time and in the same way (for instance, at the beginning of the meal, when the child is hungry, possibly after leaving the preparation in the refrigerator for 15 minutes because freshness reduces the taste of the medicine).
In this way, at this age, the child will integrate the taking of the treatments as a norm and will accept the doses more easily (especially with an adapted treatment such as ABC-3TC + DTG). On the other hand, if the administration is not daily and the child feels that if he throws a tantrum, he will escape taking ARVs, there is a significant risk that he will start to negotiate. With a risk of escalating in whims and finally parental abandonment.

9.8.2 In old children and preadolescent

The importance of the caregiver is still of major importance, but it is not enough. Information on care, medicines and illness have to be given to the child. It is called the “disclosure process”.

The disclosure process must be initiated when the child is around 7 years old (or earlier if the child starts asking questions about the medicine intake).

What are the principles of the disclosure process?
it is a permanent transmission of information directly to the child (and adolescent), given in routine consultations or adherence sessions, in the presence of the caregiver (and with her/his approval).

Why must the disclosure process start around 7 years old?

According to the theory and stages of cognitive development of Jean Piaget, children go through four stages during childhood:

1. Sensorimotor Intelligence, from birth to age 2.
2. Preoperational Thinking, from ages 2 to 7.
3. Concrete Operational Thinking, from ages 7 to 11.
4. Formal Operational Thinking, from age 11 onward.

The stage 3 corresponds to the acquisition of logical thinking and specific capacities (reversibility, transitivity, continuity, among others) which permits to give explanations in a logical way.

In fact, from the age of 7, without explanations, the child cannot understand why he/she should take daily medicine while healthy, or why he/she should take medicines when the siblings (or friends at school) do not and start asking questions:

- Why do I have to take medicine?
- When will it stop?
- What are these medicines for?

Explanations must be given to the child for him/her to understand and to accept to go on taking the medicine.

Who must give information to the child?

Experience showed that the caregivers do not know how to explain to the child why he/she should take medicine or how he/she got the germ. They feel guilty of having transmitted the germ (especially the mothers), they are scared of the child's reaction when he/she will be informed that the germ is called HIV, they fear that the child will not be able to keep the secret and they postpone the disclosure until the middle adolescence or later.

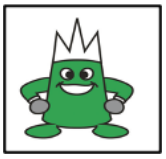
→ Trained healthcare providers (supported by the caregiver) must give these explanations. Some can be given by the clinician (doctor or nurse) during the consultations and some by lay counsellors in educative sessions.

How to give explanations?

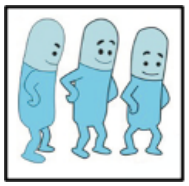
Using visual support is recommended for the child to better understand the messages. Several tools can be used. Here are the Médecins Sans Frontières' tool. Explanations are given using representations of HIV virus, CD4, medicines and children.

Figure 9.2: Cards to explain HIV and ART to children

The red germ (HIV)



The green soldier (CD4)



The drugs (ARV)

The children (girl and boy)

Example of messages are shown in appendix 18

As the capacities of understanding progress while the child is getting older, the messages have to be repeated until the child is able to explain why he must take medicine every day and why it is important not to stop.

When to mention HIV?

According to WHO recommendations and knowledge experience-based, HIV and AIDS should be mentioned around 11 or 12 years old. At this age the preadolescent is old enough to understand that HIV is a serious disease (so that it is important to go on taking the medicine) but still young enough to trust adults reassuring messages.

What to do after mentioning HIV?

The process must go on!

When getting older, adolescents will progressively discover that HIV is not an “illness as others”. They will have new questions about their future: “how to have a girlfriend or a boyfriend while living with HIV? How to get married? Should the husband (or the wife) be also HIV infected? Will it be possible to have children? Will they also be infected?”. These are questions they frequently ask, among others.

During adolescence, the healthcare providers must support adolescents and answer their questions in individual consultation or group sessions (see paragraph 9.10.2).

9.8.3 specific adherence issues in older adolescents

Even if the disclosure process was done as previously described, other reasons of poor adherence are frequently met in adolescents born with HIV.

9.8.3.1 Depression

Depression is common in adolescents in general, affecting 5 to 10% of this age group. Among adolescents living with HIV, the prevalence is more frequent, around 20% in some African countries, but the data are not known in The Gambia. [32]

In this case, the teenager, due to his or her depression, no longer has a plan for the future, has a sad mood, or even suicidal thoughts. Taking ARVs in this context does not make sense.

9.8.3.2 Denial of illness

It is favoured by certain circumstances:

- The disclosure was made early, before the age of 11 and never evaluated afterwards (no additional information transmitted to the teenager, no adherence support session);
- Non-participation in group activities;
- Reduced intra-family dialogue, due to the non-sharing of status in the family.

For some, the diagnosis of HIV is forgotten or repressed. They question this diagnosis, stop the ARV treatments to see what will happen. Since nothing happens for the first weeks or months (they remain clinically asymptomatic), they end up considering that they are not infected with HIV.

9.8.3.3 Family conflict

Adolescence is a frequent period of conflict between the adolescents and their parents. Sometimes, they negotiate the taking of the medications to pressure their parents, in order to obtain what the parents otherwise refused.

Sometimes, this conflict arises in the context of a late disclosure. The teen is angry with the adults (parents, care team) and refuses to continue treatment.

9.8.3.4 Risky behaviour

Teenagers have a strong tendency to act out. They are unable to measure the consequences of their actions until the end of adolescence (19-20 years old), due to cerebral immaturity.

In the middle of adolescence, their choices are mostly guided by immediate pleasure and benefits.

For example, when a treatment is voluntarily stopped, the adolescent notices the immediate benefits – a feeling of freedom, a reduction in constraints, sometimes the disappearance of certain side effects – but he or she is not able to anticipate the consequences that will occur in the future.

All these specificities have to be explored when assessing poor adherence in an adolescent.

9.9 Treatment failure

9.9.1. Definitions in Children

Treatment failure can be virological, immunological or clinical. As in adults, they are defined after at least 6 months of ART, but some criteria are different.

Clinical Failure:
New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 clinical conditions with exception of TB).

Immunological Failure:
• Younger than 5 years - Persistent CD4 levels below 200 cells/mm^3 or CD4 percentage <10%
• Older than 5 years - Persistent CD4 levels below 100 cells/mm^3

Virological Failure:
Plasma viral load above 1000 copies/ ml based on two consecutive viral load measurements after 3 months, with adherence support.

Virological failure is the first to happen, followed by immunological failure and clinical failure, which appear (much) later.

9.9.2. Definition used in The Gambian context

Virological failure is now possible to detect and clinicians should now diagnose treatment issues on virologic criteria of unsuppressed viral load.

For children under 5, the Visitect® test could be used, case by case (see CD4 threshold in children in Appendix 5).

9.9.3. Main reasons for a virological failure in children

9.9.3.1. Poor adherence

With the current ARV regimens, the most common cause of virological failure is poor adherence. In most cases, improving adherence (with no regimen change) will lead to undetectable viral load.

9.9.3.2. Resistance mutation

Resistance mutations are selected by patients who have prolonged replication while taking their treatment but have poor adherence. In this case, good adherence may lead to reduced level of viral load, but the regimen would not be powerful enough to suppress it.

9.9.3.3. Other reasons

Underdosing: If the child is not weighed, or the dose is not adapted to the weight gain, unsuppressed VL is possible despite good adherence. Doses should always be adapted to the current weight of the child.

Drug-drug interactions: Administration of other treatment (rifampicin, anti-epileptic drugs, and other hepatic enzymatic inductors) or traditional plants (hypericum or St john's wort) can reduce the plasmatic ARV concentration. Clinicians should check for possible drug-drug interactions before prescribing any additional treatment (especially if it is a long-term treatment) and adjust doses of ARV if needed.

Immune activation: any acute infection (malaria, bacterial or viral infection) stimulates the immune system and can increase the HIV replication for some days. Viral load test should not be performed if the child is suffering from acute infection.

9.9.4. Specificities of treatment failure management in children

The 2nd line regimen (AZT-3TC + LPV/r), in children, has two major limitations:

1. It is more complicated to take: two doses a day, no child friendly formulation, many pills, more side effects.

2. Some medicines have sometimes been used as a first-line treatment, before the transition to DTG (and could be affected by archived mutations).

As the first reason for virological failure is poor adherence, switching from a powerful and easy-to-take regimen to a more difficult to administer regimen should only be decided when strong arguments for mutation resistance exist.

9.9.5 How to evaluate the risk of mutation resistance selection?

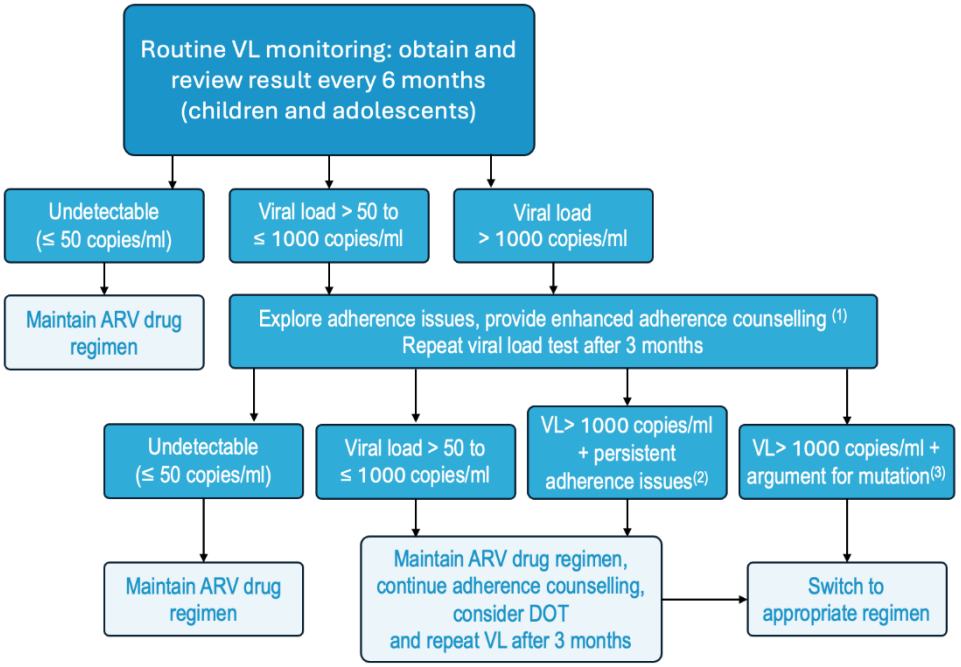
The only way to definitively identify resistance mutations is to do a resistance test. When this test is not available, the clinician should consider:

1/ The level of the viral load: when VL is more than 100.000 copies/ml (especially if the previous VL was undetectable), total discontinuation of treatment is more likely than resistance mutation selection. Usually, muted viruses have lower fitness and cannot replicate so high if adherence is good (even with high resistance level of mutation).

2/ The duration of treatment and therapeutic history: in patients recently initiated on DTG based regimens (less than 2 years), the probability of resistance mutations is low (less than 10%). If the patient has a long and complex treatment history (with multiple regimen changes prior to transition to DTG), the likelihood of mutation is higher but remains much lower than with previous regimens based on NVP or EFV.

So, before considering switching a child to second line regimens, the clinician should ensure that adherence is good and that other causes of replication (underdosing, drug interactions, etc.) are absent. If a doubt persists about adherence, ART administration on Direct Observed Treatment (DOT) can be proposed (if the child is clinically stable) for 1 to 3 months.

Figure



(1) Assess caregiver knowledge and involvement, disclosure process, verify ART dosage, exclude drug-drug interaction, …

(2) Treatment refusal, very irregular follow up, poor adherence admitted by the patient, VL > 100.000 copies/ml while previous VL was undetectable, etc.

(3) Persistent VL > 1.000 copies/ml while on DOT for 3 months or more

9.9.6. Choice of the second line regimen

Table 9.6: Preferred and alternative second line regimens in children

Population type	Failed 1st line regimen	2nd line regimens	Alternative 2nd line regimens
Children >30kg	TDF + 3TC + DTG	AZT(1) + 3TC + ATV/r(2)	AZT + 3TC + LPV/r(2) AZT + 3TC + DRV/r (3)
Children 25-30 kg	ABC + 3TC + DTG	AZT + 3TC + ATV/r	AZT + 3TC + LPV/r AZT + 3TC + DRV/r(7)
Children 20 - < 25 kg	ABC + 3TC + DTG	AZT(5) + 3TC + LPV/r](4)	AZT(5) + 3TC + DRV/r(7) [AZT(5) + 3TC + DTG] + plain DTG(4)
Children 10 - < 20 kg	ABC + 3TC + DTG	AZT(5) + 3TC + LPV/r](4)	[AZT(5) + 3TC + DTG] + plain DTG(4)
Children 3 - < 10 kg	ABC + 3TC + DTG	AZT(5) + 3TC + LPV/r](6)	[ABC + 3TC + DTG] + plain DTG
Neonates and infants < 3kg	AZT + 3TC + NVP	not applicable	not applicable

(1) the most frequent mutation selected by TDF (K65R) reduces ABC sensitivity (cross resistance) but does not affect AZT. So, switching TDF to ABC is not logical.

(2) ATV/r is much easier to take (one pill/day) and better tolerated (fewer side effects) than LPV/r

(3) In patients who previously failed on an LPV/r-based regimen, DRV/r (600mg BD) is an acceptable alternative for children weighting more than 15 kg

(4) In patients who previously failed on an LPV/r-based regimen, DTG twice daily may be considered if DRV/r is not available, after expert opinion

(5) If AZT + $3TC_{60\text{-}30mg}$ is on stockout, consider maintaining ABC + 3TC

(6) If LPV/r formulation for infants and children < 10kg is not available, consider maintaining DTG (adding plain DTG)

(7) DRV/r should be considered as the first alternative 2nd line in children who failed on LPV/r and on DTG

9.9.7 Main points to consider before switching a child to second line

Consider the following before switching ART regimen in a child who received at least 6 months treatment:

- Adherence to therapy should be assessed and considered to be optimal. If in doubt, consider DOT and repeat VL before switching.
- Always check at the central level the paediatric formulation before deciding the new regimen.
- If the virological failure is complicated by immunological failure (CD < 200 cells/mm^3) or clinical failure, the decision is urgent. Regimen switch must be done while treating any associated OI, after screening for TB (and cryptococcal meningitis in adolescents).

Caution: if cryptococcal meningitis or tuberculosis is diagnosed, the switch of ARV regimen must be delayed for 2 to 6 weeks, as in naïve patients initiating ART.

If the child failing on treatment is followed in a peripheral health facility, refer him to a specialist in HIV and AIDS care/treatment or ask support from your mentor.

9.10 Adaptation of care for adolescent born with HIV

9.10.1 Specificities of adolescents born with HIV

Adolescents born with HIV are not the same as adolescents sexually infected or adults living with HIV. The main differences are:

1/ HIV diagnoses and ART initiation was sometimes late: consequences are a damage immune system and poorer outcomes, especially when adherence is not good. Physical sequels (growth and puberty retardation, scar of skin infection such as herpes zoster) are possible and contribute to poor self-esteem.

2/ Long treatment history: some of them received LPV/r as first line treatment and failed on treatment before switching to DTG. Archived mutation on protease inhibitor or NRTI are more likely and could decrease the sensitivity of second line antiprotease-based regimen.

3/ A history sometimes punctuated by bereavement (death of parents) with more frequent placement in foster families. Some of them are stigmatized, victims of abuse, socially isolated with poor family support.

4/ A disclosure process not always adequately carried out: lack of disclosure, late or partial disclosure are frequent issues, linked to parental reluctance and the poor skills in healthcare providers. Adolescents who discover their HIV infection in the mid-adolescence may be particularly affected psychologically.

5/ The process of adolescence is often negatively impacted by HIV: the construction of personality, the acquisition of autonomy and the entry into emotional and sexual life are more difficult for these adolescents and require specific support that the family is not always able to provide. The health care team has an important role to play in supporting these adolescents, enabling them to get through this difficult period, which is often marked by poor adherence to treatment (depression, denial of the disease, risky behaviours, conflicts).

9.10.2 Adaptation to care for adolescents born with HIV

To support these adolescents and prevent poor adherence, providing adolescent-friendly package of care should be considered in health facilities that manage big cohorts of teenagers.

The principles are the following:

- Grouping teens' appointments on the same day,
- Providing a complete package of care: medical consultation, VL test, ARV refill, enhance adherence consultation (including disclosure session) if needed; SRH consultation (and contraceptive or condoms refill if needed), mental health screening (and psychological reference if indicated),
- Organizing group sessions, to transmit information on HIV, ART, SRH but also to exchange on stigmatization, abuse and any subject questioning adolescents. These sessions promote the socialization of adolescents and provide them with community support,
- Including adolescent peer education when possible,
- If feasible, providing adolescent friendly spaces.

In The Gambian context, only a few health facilities will be able to provide such package of care, as many health facilities only follow a reduced number of adolescents. The possible stigmatization should be taken in account, and the meetings could be organized outside the health facilities. In all cases, the consent of the parents (and of course the teenagers) will be sought. A pilot test could be conducted in one or two important sites.

Chapter 10: Monitoring, Evaluation and Pharmaco-Vigilance

10.1 Rational

As The Gambia adapt and implement these guidelines, monitoring and evaluation frameworks and systems need to be adapted to collect and analyse information to track the implementation and impact of new recommendations. Monitoring and evaluation will help programme managers to assess the effectiveness of interventions and linkages between services along the cascade of treatment, care and support for HIV and associated conditions. Such information is essential to detect and respond to bottlenecks or gaps in programme performance (i.e. supply chain, laboratory services, required health care providers) and to adequately characterize and respond to patient attrition.

As programme matures, monitoring individual- and population-level outcomes, including toxicity and adverse events, drug resistance, viral suppression, mortality, survival and incidence, is also essential to assess the impact of programmes.

After initiating treatment at the ART centre, the patient should be given two weeks appointment, then monthly for another three months at the referred health centre, and six-monthly review at the ART Centre that initiated the treatment.

Figure 10.1: The HIV treatment and care cascade

In the events of side effect and Adverse Drug Reactions (ADRs), patients and or relations would be required to contact the following for proper advice and intervention.

- Head of the Team
- Care Nurse
- Social worker

Data should be collected routinely from all facilities or sentinel sites. In addition, population-based surveys; surveillance data; observations on cohorts of people living with HIV and periodic evaluation should also be conducted. Programme input and processes should also be monitored through facility surveys or updated lists of services available; documenting the availability and training of human resources; and monitoring the availability of HIV medicines and diagnostics at various geographical and facility levels. Special studies should be considered where routine monitoring is inappropriate.

In considering how best to collect critical data, efforts should also be made to review monitoring systems, such as better linking the monitoring of services for PMTCT, TB and ART; and integrating AHD and HIV drug resistance monitoring into routine health information systems.

Involving civil society in monitoring and evaluation activities is also critical to better understand successes and failures, especially in assessing the perceptions, values and experiences of people living with HIV, key populations, adolescents and the broader community in accessing and using services. The community can also play a key role in designing and implementing data collection tools and analyzing and interpreting findings.

10.2 Monitoring HIV Drug Resistance

10.2.1 Definition of drug resistance

The drug resistance is a capacity of an HIV virus to resist – partially or totally - to an ARV drug. Some HIV constitutionally resist to some drug (i.e. HIV2 viruses resist to NNRTI drugs such as NVP or EFV). In other cases, the HIV virus needs to select a specific mutation.

Mutations are produced during the transcription of viral RNA to DNA (by a viral enzyme called reverse-transcriptase): these are aleatory errors of transcription. Sometimes, the error confers to the HIV the capacity of resisting to a specific drug or several same class drugs (cross resistance).

The mutations are very frequent but the only ones that will be selected are the ones which give to the muted virus an advantage on non-muted viruses to become predominant. In fact, it occurs when a patient is on ART with poor adherence: the non-muted viruses are still partially blocked by the treatment while the muted virus can replicate faster and take the place of non-muted viruses.

10.2.2. Individual consequences of drug resistance

Once the muted virus has been archived in memory cells, the mutation is selected and will decrease the power of the treatment. Even if the patient gets back to good adherence, the viral replication can persist, giving to the muted virus the possibility of acquiring and archiving additional mutations.

Persistent replication will allow viruses to attack the immune system, decrease CD4 count and lead to immunodepression.

The prevention of mutation is a good and constant adherence to treatment: when the virus does not replicate, mutations cannot appear. When resistance mutations have been selected, the ART regimen should be modified to avoid selection of multidrug-resistant viruses.

10.2.3 Public health threat of drug resistance

HIV drug resistance poses a significant threat to the success of national HIV response. Drug resistance results in more rapid virological failure among people receiving first-line regimens and increases the need for second-line regimens, which may be associated with greater toxicity, adverse events, poorer adherence on treatment and higher costs.

Drug resistance may also affect the ability to prevent HIV transmission using ARV-based pre or post-exposure prophylaxis or topical virucides. Surveillance of drug resistance should be an integral component of national HIV response. Surveillance data should inform the selection of first- and second-line regimens for ART, as well as ARV drugs for PMTCT, to optimize treatment outcomes within a public health approach.

10.2.4 Components of WHO recommended strategy

WHO and its partners have developed a standardized and complementary assessment strategy to be implemented by countries, for both adult and paediatric populations, with the following components.

10.2.4.1 Monitoring Early Warning Indicators (EWIs) for HIV Drug Resistance

EWIs use existing clinic and pharmacy records to assess the factors associated with the emergence of HIV drug resistance at the level of ART programme and clinics.

These factors include ART prescribing practices; drug supply continuity; adherence to ARV drug regimens measured by on-time pick-up of ARV drugs; retention in care; and viral load suppression, when available.

The monitoring of EWIs should be integrated into a country's monitoring and evaluation system and provides the information needed to address practices that may lead to poor outcomes and HIV drug resistance.

10.2.4.2 Surveys to monitor HIV Drug Resistance and Associated Factors

Surveys to monitor HIV drug resistance and associated factors in populations on ART.

The WHO generic protocol for monitoring acquired HIV drug resistance uses a standardized survey methodology to assess population-level virological suppression at the national level and the emergence of HIV drug resistance among populations receiving treatment.

Performed regularly at representative sites, these surveys provide evidence for action at the programme and clinic level to minimize HIV drug resistance. They also provide evidence to optimize the selection of first- and second-line ART regimens.

Surveys to Monitor Pre-treatment HIV Drug Resistance.

The WHO generic protocol for surveillance of pre-treatment HIV drug resistance provides a nationally representative estimate of HIV drug resistance in populations initiating therapy.

Performed regularly at representative ART clinics, these surveys support national, regional and global decision-making regarding the choice of first-line regimens.

Surveillance of transmitted HIV drug resistance among individuals recently infected with HIV.

The WHO generic protocol for surveillance of transmitted HIV drug resistance provides estimates of transmitted HIV drug resistance in recently infected populations, and the results should contribute to ART policy decisions, including guidelines on ART regimens and HIV prophylaxis.

Surveillance of HIV Drug Resistance among Infants under 18 months of age:

The WHO generic protocol for surveillance of HIV drug resistance among children less than 18 months of age can provide estimates of national prevalence of HIV drug resistance among infants diagnosed with HIV infection through EID testing.

The results assess differences in HIV drug resistance prevalence between populations exposed to ARV drugs for PMTCT and those with unknown exposure to support the selection of optimal first- line ART for this population.

National strategies for assessing HIV drug resistance should be developed and routinely implemented as part of comprehensive HIV treatment programs.

Appendix

Appendix 1: ARV Paediatric Dosing Table

Existing medicine	Strength of tablet or sprinkle sachet or capsule	No. of tablets or sprinkle capsule/sachets by weight band											
		3-5.9kg		6 -9.9kg		10-13.9kg		14-19.9kg		20-24.9kg		25-34.9kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
ABC/3TC	120/60mg	1		1.5		2		2.5		3			
AZT/3TC	60/30mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3		
DTG	10mg	0,5		1.5		2		2.5		3			
DTG	50mg									1			
LPV/r	100/25mg					2	1	2	2	2	2	3	3
ATV/r	300/100mg											1	
AZT/3TC	300/150mg											1	1
ABC/3TC	600/300mg											1	

Additional medicine	Strength of tablet or sprinkle sachet or capsule	No. of tablets or sprinkle capsule/sachets by weight band											
		3-5.9kg		6 -9.9kg		10-13.9kg		14-19.9kg		20-24.9kg		25-34.9kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
LPV/r sprinkles	40mg/10mg	2	2	3	3	4	4	5	5	6	6		
ABC/3TC/LPV/r	30mg/15mg/40mg/10mg	2	2	3	3	4	4	5	5	6	6		
DRV [1]	75mg							5	5	5	5		
DRV [2]	400mg											1	1
DRV [3]	600mg							1		1		1	
RTV [4]	50mg							2		2		2	

[1] DRV75mg can be used in children 14 to 25kg, after failure on LPV/r and failure on DTG. Must be associated with RTV50mg BD

[2] DRV400mg can be used in children above 25kg, after failure on LPV/r and failure on DTG. Must be associated with RTV50mg BD

[3] DRV600mg can be used in children naïve of antiprotease (never received LPV nor ATV before). Must be associated with RTV 100mg OD

[4] RTV50mg is given either OD or BD according to the prescription of DRV (OD or BD). The total daily dose remains the same (100mg/day).

Note: DRV120/20mg is under development. It could be used from 10kg.

Back to "initiating ART in children and adolescents"

Appendix 1bis: ARV paediatric dosing table for newborns

Medicine	Volume (ml) according to weight					
	2 - < 3 kg		3 - < 4 kg		4 - < 5 kg	
	AM	PM	AM	PM	AM	PM
AZT+3TC $_{(60+30mg)}$ [1]	1ml	1ml	1,5ml	1,5ml	2ml	2ml
NVP solution(10mg/ml)	1,5ml	1,5ml	2ml	2ml	3ml	3ml

[1] AZT+3TC $_{(60mg+30mg)}$ will be used after dilution (see figure below)

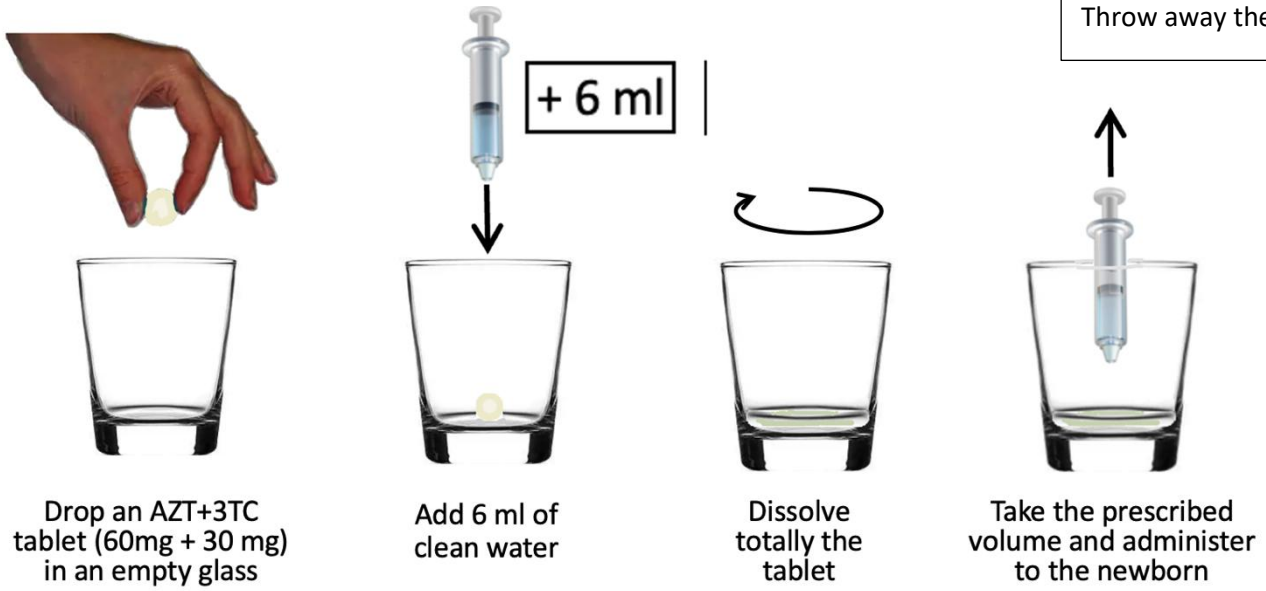
Preparation of a solution using a dispersible tablet of AZT-3TC

Explain the mother to:

--> Dissolve a tablet of AZT+3TC$_{60mg/30mg}$ in 6 ml of safe clean water (in order to get a 10mg/ml solution).

--> Take with the syringe the adapted volume of the diluted solution, based on the weight of the baby (see table), then administer.

Throw away the remaining solution.



Appendix 1ter: medicine preparation for children

Giving Your Child Paediatric Dolutegravir 10 mg Dispersible, Scored Tablets (pDTG)

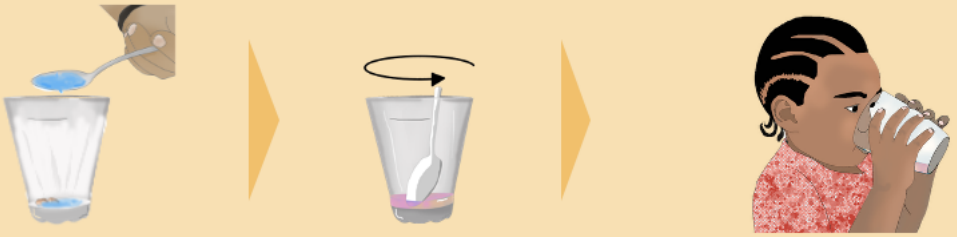
These are instructions on how to give your child pDTG alongside abacavir and lamivudine (ABC/3TC) 120/60 mg dispersible tablets. If your child is not taking ABC/3TC, there may be changes to these recommendations. Always follow the guidance of your healthcare provider.

1

Add the correct number of pDTG and ABC/3TC tablets to a clean, empty glass based on your child's weight. (See Dosing Table)

Weight	No. of pDTG Daily Tablets	No. of ABC/3TC 120/60 mg Daily Tablets
3 to < 6 kg	0.5	1
6 to < 10 kg	1.5	1.5
10 to < 14 kg	2	2
14 to < 20 kg	2.5	2.5

2

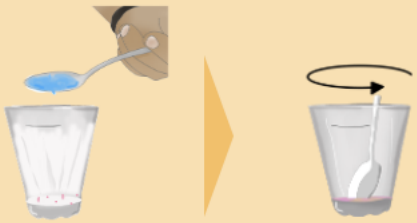


Add 2-4 teaspoons (10-20 mL) of clean water into the glass.

Stir until the tablets fully dissolve.

Give the medicine to your child to drink. Make sure they drink all the medicine right away or within 30 minutes.

3



If any medicine remains in the glass, add a little more water to the glass and give to your child. Repeat until no medicine remains in the glass.

Reminders

- *Remember to give your child their pDTG (and other ARVs) at the same time everyday*
- *Use other liquids or foods for mixing if your child is unable to take the tablets in water. Use the same amount of liquid or food as above to avoid spills and to ensure your child takes the full dose*
- *Only give your child another full dose of pDTG if they vomit within 30 minutes of taking their initial dose*

Ask your health provider if you have any questions about administering pDTG!

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Appendix 2: Revised WHO clinical staging of HIV and AIDS for Adults and Adolescents (Adapted from WHO Case Definitions of HIV for Surveillance and Revised Clinical Staging and Immunological Classification of HIV-Related Disease in Adults and Children, 2007; Available at: http://www.who.int/hiv/ pub/guidelines/hivstaging/en/index.html.) (1)

Primary HIV Infection
· Asymptomatic · Acute retroviral syndrome
Clinical Stage 1
· Asymptomatic · Persistent generalized lymphadenopathy
Clinical Stage 2
· Unexplained persistent hepatosplenomegaly · Papular pruritic eruptions (PPE) · Extensive wart virus infection · Extensive molluscum contagiosum · Recurrent oral ulcerations · Unexplained persistent parotid enlargement · Lineal gingival erythema · Herpes zoster · Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
Clinical Stage 3
· Moderate unexplained malnutrition not adequately responding to standard therapy · Unexplained persistent diarrhoea (14 days or more) · Unexplained persistent fever (above 37.5°Cintermittent or constant, for longer than 1 month) · Persistent oral candida (outside first 6 to 8 weeks of life) · Oral hairy leukoplakia · Acute necrotizing ulcerative gingivitis/periodontitis · Lymph node TB · Pulmonary TB · Severe recurrent presumed bacterial pneumonia · Symptomatic lymphoid interstitial pneumonitis · Chronic HIV-associated lung disease, including bronchiectasis · Unexplained anaemia (<8g/dL), neutropenia (<500/mm3), or chronic thrombocytopenia (<50,000/mm3) · HIV-associated cardiomyopathy or HIV-associated nephropathy
Clinical Stage 4
· Unexplained severe wasting, stunting, or severe malnutrition not responding to standard therapy · Pneumocystis pneumonia · Recurrent severe presumed bacterial infections (e.g., empyema, pyomyositis, bone or joint infection, or meningitis, but excluding pneumonia) · Chronic herpes simplex infection (orolabial or cutaneous of > 1 month's duration or visceral at any site) · Extrapulmonary TB · Kaposi's sarcoma · Oesophageal candidiasis (or candida of trachea, bronchi, or lungs) · Central nervous system toxoplasmosis (outside the neonatal period) · HIV encephalopathy · Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age > 1 month · Extrapulmonary cryptococcosis, including meningitis · Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis, penicilliosis) · Chronic cryptosporidiosis Chronic Isosporiasis · Disseminated nontuberculous mycobacteria infection

Appendix 3: WHO clinical staging of HIV and AIDS for infants and children with established HIV infection (Adapted: WHO, Case Definitions of HIV for Surveillance and Revised Clinical Staging and Immunological Classification of HIV-Related Disease in Adults and Children, 2007. Available at: http://www.who.int/hiv/ pub/guidelines/hivstaging/en/index.html.)

Primary HIV Infection
· Asymptomatic · Acute retroviral syndrome
Clinical Stage 1
· Asymptomatic · Persistent generalized lymphadenopathy
Clinical Stage 2
· Unexplained persistent hepatosplenomegaly · Papular pruritic eruptions · Extensive wart virus infection · Extensive molluscum contagiosum · Recurrent oral ulcerations · Unexplained persistent parotid enlargement · Lineal gingival erythema · Herpes zoster · Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
Clinical Stage 3
· Moderate unexplained 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 1 month) · Persistent oral candida (outside first 6 to 8 weeks of life) · Oral hairy leukoplakia · Acute necrotizing ulcerative gingivitis/periodontitis · Lymph node TB · Pulmonary TB · Severe recurrent presumed bacterial pneumonia · Symptomatic lymphoid interstitial pneumonitis · Chronic HIV-associated lung disease, including bronchiectasis · Unexplained anaemia (< 8 g/dL), neutropenia (< 500/mm3), or chronic thrombocytopenia
Clinical Stage 4
· Unexplained severe wasting, stunting, or severe malnutrition not responding to standard therapy. · Pneumocystis pneumonia. · Recurrent severe presumed bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, ...)[(1)]. · Chronic herpes simplex infection (orolabial or cutaneous of more than 1 month's duration or visceral at any site) · Extrapulmonary TB · Kaposi's sarcoma · Oesophageal candidiasis (or candida of trachea, bronchi, or lungs) · Central nervous system toxoplasmosis (outside the neonatal period) · HIV encephalopathy · Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age over 1 month · Extrapulmonary cryptococcosis, including meningitis · Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis, penicilliosis) · Chronic cryptosporidiosis or chronic Isosporiasis · Disseminated nontuberculous mycobacteria infection · Acquired HIV-associated rectal fistula · Cerebral or B-cell non-Hodgkin's lymphoma · Progressive multifocal leukoencephalopathy

[(1)] excluding pneumonia

Back to "WHO advanced HIV disease criteria"

Appendix 4: Grades of Adverse Events

Grade	Description
Grade 1 (Mild)	Transient or mild discomfort; no limitation in activity; no medical intervention/therapy required
Grade 2 (Moderate)	Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required
Grade 3 (Severe)	Marked limitation in activity; some assistance usually required; medical intervention/therapy required; hospitalization possible
Grade 4 (Life-threatening)	Extreme limitation in activity; significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probable

Appendix 5: CD4 Level in Relation to the Severity of Immunosuppression (children)

Classification of HIV associated immune deficiency	Age-related CD4 values			
	< 12 months (%)	12-35 months (%)	36-59 months (%)	≥ 5 years (cell/mm^3)
Not significant	> 35	> 30	> 25	> 500
Mild	30-35	25-30	20-25	350-499
Advanced	25-30	20-25	15-20	200-349
Severe	< 25	< 20	< 15	< 200 (or < 15%)

The absolute CD4 count and the percentage values in healthy infants who are not infected with HIV are considerably higher than those observed in uninfected adults and slowly decline to adult values by the age of 5 years.

In considering absolute counts or percentages, age must be taken into account as a variable. The absolute CD4 count associated with a specific level of immune suppression tend to change with age, whereas the CD4 percentage related to immunological damage does not vary as much.

Because CD4 tests are scarce, clinicians could estimate the likelihood of immune suppression by measuring the total lymphocytes count. This is obviously not as accurate as CD4 count but it can help in some situations.

Severe immune suppression	< 11 months	12-35 months	36-59 months	≥ 5 years
Lymphocytes	< 4000	< 3000	< 2500	< 2000
CD4	< 1500	< 750	< 350	< 200
CD4%	< 25%	< 20%	< 15%	< 15%

Source: Laboratory Guidelines for enumerating CD4 T Lymphocytes in the context of HIV/AIDS, WHO 2006 and revised version 2009

Currently, CD4 testing is not essential for the initiation of ART. However, a semi quantitative rapid test could help identifying advanced HIV children and adolescent, considering that CD4 count < 200cells/mm^3 is even more serious in children less than 5 years.

Back to "principle of monitoring children"

Back to "treatment failure"

Appendix 6: Rapid Co-trimoxazole Desensitization Protocol

- Suitable for prophylactic-dose Co-trimoxazole or high-dose Co-trimoxazole for treatment of Pneumocystis Jirovecii pneumonia (PJP)
- Desensitization can be offered rapidly or over a longer period of time.
- Do not desensitize anyone who has had an anaphylactic reaction to C-trimoxazole or a severe skin rash such as Stevens-Johnson syndrome.
- Desensitization is usually about 60% effective.
- Rapid desensitization ideally should be performed during the day in a setting where emergency resuscitation can be provided, and adrenaline can be given.
- Observations during rapid desensitization should take place every 30 minutes, before each dose is given, and should include temperature, pulse, and blood pressure.
- If only mild rash or pruritus occurs, administer antihistamine (e.g., chlorpheniramine or promethazine) and continue.
- If more serious side effects occur, such as severe wheeze, severe or symptomatic hypotension, severe rash, and so on:
  a. Discontinue desensitization, manage appropriately, and do not try to restart desensitization.
  b. Once Co-trimoxazole has been started, it can be continued indefinitely as long as no reactions are noted, but if the medicine is stopped at any time, there may be a risk of reaction when it is restarted.
  c. Using a 1 ml syringe put 0.5 ml of paediatric Co-trimoxazole 240 mg / 5 ml syrup in 1,000 ml of 5% dextrose and ensures that it is well mixed. Give the mixture as indicated below:

Table A.6.1: Co-trimoxazole desensitization steps

Minutes	Quantity of Above Mixture Given Orally
0	1 ml (use 10 ml syringe)
30	10 ml (use 10 ml syringe)
60	100 ml (use 10 ml syringe)

From this step, use Co-trimoxazole 240 mg / 5 ml syrup without dilution, and administer the following doses:

90	0.5 ml
120	5 ml
150	480 mg tablet
180	Start full prophylactic or therapeutic dose.

Back to co-trimoxazole paragraph

Appendix 7: Opportunistic Infections, their prophylaxis and recommended Treatment (adults)

OPPORTUNISTIC INFECTIONS	Symptoms/signs	TREATMENT
Acute diarrhoea (<14 days)	**Non-inflammatory diarrhoea** (small bowel): Large volume of watery stool, without blood or mucous. Unless there is severe diarrhoea of rapid onset, bacteria are rarely the cause. Antibiotics are therefore rarely needed.	**General management:** **Rehydration** with Oral rehydration solution if mild or moderate dehydration and patient is able to drink or intravenously using safe IV fluids, such as sodium chloride or Ringer's lactate or other electrolyte solution if available Viruses are the most common cause (Rotavirus, Enterovirus, Norovirus). Antibiotics are only necessary if danger signs present: ciprofloxacin 500 mg bd for 5 days. If Giardia lamblia (cramps and/or nausea) is suspected: Metronidazole 2g daily for 3 days, or tinidazole 2g single dose.
	Inflammatory diarrhoea (large bowel): Abdominal cramps, fever, blood and mucous in the stool are common.	If bloody diarrhoea with or without cramps (Amoebiasis): Metronidazole 400 mg 3 x day for 5 days. If bloody diarrhoea and/or mucous and/or cramps (shigella, Salmonella, Campylobacter, E. coli): Ciprofloxacin 500 mg 2x per day for 5 days
Chronic diarrhoea (>14 days) A history of chronic diarrhoea should be an immediate alert to WHO stage 4 (advanced HIV) and possible treatment failure in patients on ART	**Non-inflammatory diarrhoea:** large volume, watery stools; significant weight loss, renal impairment and severe electrolyte deficiencies are common.	No blood, mucous or cramps (Isospora, Cryptosporidium, Microspora • Cyclosporidium): The infections generally occur in advanced HIV: Start ART in patients who are ART-naïve and follow algorithm for patients on ART with suspicion of failing first line (pp 58, Fig 5.2) If CD4 almost always <200: Start empiric treatment with Cotrimoxazole 4 x 480 mg tablets bd for 2 weeks; then 2 tablets bd for 3 weeks; then normal prophylaxis dose 2 tablets daily. If hypersensitivity to cotrimoxazole, desensitization is usually possible (see Appendix 6). Loperamide can safely be given to adults. (Note: For children do not give loperamide.)
	Inflammatory diarrhoea: **small-volume, frequent stools**, **blood and/or mucus in stools, abdominal pain or cramping, tenesmus** (feeling of incomplete evacuation) **Fever and fatigue**	Tools laboratory: **If Amoebiasis** (e.g., *Entamoeba histolytica*): *Metronidazole 500–750 mg PO* three times a day *for 10 days* **If Shigella/Salmonella/Campylobacter**: Empiric treatment: *Ciprofloxacin 500 mg PO twice a day for 5 days* In case of laboratory confirmation not possible (no stool microscopy, culture, or PCR), follow this empirical **management recommendation:** **Step 1: Metronidazole** 500–750 mg PO three times × 7–10 days Step 2: **Ciprofloxacin** 500 mg PO *twice a day* × 5–7 days Step 3: **Cotrimoxazole** (TMP-SMX) 960 mg *twice a day* × 3–6 weeks Start ART if not on treatment or assess for treatment failure Combine from the start step 1 and 2 in case of AHD

Herpes Simplex (HSV)	Grouped vesicles with red base Rash with pain/ discomfort +/- pain +/- fever May present as shallow ulcers and/ or blisters that are painful, extensive and/or recurrent Often on lips as well.	Pain relief: paracetamol with codeine or tramadol Treated lesion with zinc sulphate in aqueous solution topically and sulphadiazine cream to prevent secondary infection. Acyclovir 400 mg three times daily for 5–10 days. (Topical acyclovir is of limited value) Prevention: Avoid skin-to-skin contact during flare, advise use of condoms in genital herpes
Herpes zoster	Prodrome of intense pain, tingling, tenderness, hyperesthesia in more than 90% of patients body Grouped vesicles on an erythematous base Zoster can involve any nerve roots and is fairly commonly seen involving the trigeminal nerve (V)	**Management of eye zoster:** Acyclovir 800 mg PO 5 x day for 10 days Chloromycetin ointment 4 x daily Analgesia: paracetamol and codeine phosphate and Amitriptyline 12.5–25 mg nocte x 3 months. **Management of** herpes zoster/ Pain control: Paracetamol ± codeine, add amitriptyline if needed For Acute vesicles: calamine lotion. Eroded areas: sulphadiazine cream or povidone-iodine cream. Treat secondary bacterial infection if present. Oral acyclovir 800 mg 5 x a day for 10–14 days, ideally started within the first 72 hours of the onset of the rash. Can be extended to a week. The main reason for doing this is to decrease the chance of the patient developing post-herpetic neuralgia, an ongoing burning pain in the distribution of the rash, even well after the lesions have cleared up
Oral candidiasis (oral thrush)	Patients often complain of having no taste. Swallowing is frequently painful, but just in the back of the throat, not lower down behind the sternum. White patches of the oral mucosa, the pharynx and inside the lips (which can be removed with a tongue depressor) surrounded by a reddish border.	Nystatin oral suspension 1 ml swished the mouth for few minutes and then swallowed 4 times a day for 5 days If the thrush persists, give Fluconazole 200 mg once a day for 1 week

Oesophageal candidiasis (thrush)	Pain behind the sternum on swallowing. Extreme discomfort often associated with patients not eating and consequent weight loss. If the patient is not able to eat or take oral fluids, refer to hospital for IV fluids and further investigation It qualifies as WHO stage 4 disease. •	Fluconazole 200 mg daily for 10–14 days check the response to treatment after 7 days. If there is a good response, continue the fluconazole for 10 days to 2 weeks. If fluconazole is not effective after one week, consider the other causes Herpes Simplex Virus and treat with aciclovir 400 mg, 3 x daily for 10 days. Assess CMV retinopathy as majority of those oesophagitis will develop it as well. Refer to hospital: Assess the fundi if possible. The treatment is ganciclovir or valganciclovir, ensure effective ART is being taken after screening for TB
Necrotizing gingivitis	Inflammation of the gingiva (gums). It may lead to tooth loss, severe pain and foul-smelling breath	Oral hygiene Antiseptic mouthwashes. Antibiotics: metronidazole 400 mg PO three times or 7 days Pain management – paracetamol or paracetamol/codeine
Anemia	HIV and TB, via their effect on the bone marrow, are the most common causes of anemia in HIV-positive patients + that include AZT or Malaria as well. The symptoms of anemia are often due to the underlying cause, rather than anemia itself.	Look for TB and treat immediately if diagnosed and if clinical suspicion is high in a patient with advanced HIV Start the patient on effective ART as soon as possible or assess for treatment failure If the cause of the anemia is AZT, see protocol for alternative Blood transfusion (usually needed when the Hb is <5.5): the cause of anemia must be identified and treated to avoid repetitive transfusion.

Scabies	Itch is a key feature, especially at night. The rash ranges from burrows, papules and nodules to pustules, involving hands, feet, web-spaces, axillae, abdomen, genitalia, trunk or limbs.	Treatment should include the patient and all close physical contacts, regardless of whether they are itching or not. Topical benzoyl benzoate lotion from shoulder down – wash off after 24 hours and repeat treatment in 7–10 days. In children (6 months–5 years) a 50% dilution of this may be used (diluted 1:1 with equal amounts of water). For infants less than 6 months, 5% sulphur ointment used nightly for 3 days. Persistent and severe cases will require oral ivermectin. Treat itch with oral antihistamines Counsel to wash clothing, bed sheets in hot water

Eczema	Itchy range from very dry thickened skin to red and weepy. Common rash seen at the flexural creases (the fronts of the elbows and the backs of the knees) but can be seen almost anywhere on the body.	Topical cortisone preparations (Hydrocortisone cream): ointment
REGIMENS FOR STI (SYNDROMIC APPROACH)		
Urethral discharge in men	Urethral discharge; dysuria; frequent urination. Most common causes: gonorrhoea; chlamydia. Gonococcus and chlamydia can also present as an anal discharge and oral/anal lesions	Treat for gonorrhoea and chlamydia: ceftriaxone 250 mg IM single dose or Cefixime 400 mg orally as a single dose is the second option if ceftriaxone is not available. and Azithromycin 1 g orally single dose If Azithromycin not available, used Doxycycline 100 mg PO twice daily for 7 days (contraindicated in pregnant women) Sexual partners should receive the same treatment, regardless of symptoms. If symptoms persist or re-appear, this may be due to reinfection or resistance: seek advice.
Vaginal discharge	Abnormal vaginal discharge of different colour, consistently and odour and/or pain (the discharge may be sometime clear or white non-odorous); dysuria (pain on urination); dyspareunia (pain during sexual intercourse) Vaginal (Vaginitis) burning or itching of the vulva (pruritus). Causative organisms: Gardnerella, trichomonas, candida, Gonorrhoea and chlamydia	Tinidazole 2 g PO single dose Or Metronidazole 2 g PO single dose. In case of "failure" to treat with tinidazole or metronidazole 1 g/day in 2 divided doses for 5 or 7 days. For Candida: Clotrimazole 500 mg vaginal pessary single dose (deep into vagina at bedtime). Clotrimazole cream can be added as an application to the genitals for 7 days but must not replace the pessaries.

Genital ulcer	Single or multiple genital sore/ulcer or vesicles, with or without pain and inguinal	If painless (suspect lymphogranuloma venereum or donovanosis -Granuloma inguinale): Treat with Azithromycin 1 g orally weekly for 3 weeks

	lymph nodes which may be fluctuant; scrotal pain and swelling. Mains common causes: Herpes simplex; Syphilis; Chancroid; lymphogranuloma venereum; donovanosis (Granuloma inguinale); TB can cause inguinal nodes, cold abscesses and fistulae	Alternative: Doxycycline 100 mg orally twice daily for 21 days If painful multiple small ulcers and recurrent (suspect HSV) If painful ulcer plus lymphadenopathy (suspect chancroid): Treat with Benzathine penicillin IM 2.4 MU single dose plus Azithromycin 1 g PO/ceftriaxone 250 mg IM both single dose Penicillin allergy: • Increase Azithromycin dose to 2 g PO single dose Sexual partners should receive the same treatment regardless of symptoms. Give pain relief as required and keep area clean and dry
Lower abdominal pain (women)	Take history, assess STI risk, pregnancy and check temperature. Perform abdominal and bimanual pelvic examinations to check for: rebound tenderness; cervical motion tenderness; tender pelvic mass or urethral and vaginal discharge.	Danger signs (dehydrated or in shock; difficulty to walk upright; temperature >38.5 °C; severe abdominal tenderness or pelvic mass; abnormal vaginal bleeding; recent miscarriage, delivery or abortion; or abdominal mass) requiring referral to hospital. Immediate management, while waiting for transfer to hospital: Give ceftriaxone 1 g IM or IV; stat metronidazole 400 mg orally and azithromycin 1 g single dose. If dehydrated or in shock, give IV fluids. If no danger sign: treat as for moderate pelvic inflammatory disease (PID): Ceftriaxone 250 mg IM injection stat or cefixime 400 mg PO stat + Doxycycline 100 mg PO 12 hourly x 7 days (if pregnant give erythromycin 500 mg 6 hourly for 7 days) + Azithromycin 1 g single dose+ Metronidazole 400 mg 8 hourly for 7 days. Reassess in 3 days and refer to hospital if not improving.

Appendix 8: Opportunistic Infections, prophylaxis and recommended Treatment (children)

1/ Pulmonary specificities on children

A- Pneumocystis pneumonia (PCP)

Condition	Causes	Clinical features	Management
Pneumocystis pneumonia (PCP)	Pneumocystis Jirovecii	Common in children < 1 year Respiratory distress and hypoxemia Acute or sub-acute onset Often afebrile (but high fever possible) Dry cough Feeding difficulties in infants Chest usually clear on auscultation CRX: diffuse interstitial infiltration, hyperinflation, pneumothorax possible, can be normal (20%). Effusion very uncommon.	Administer oxygen (facemask), aiming SpO2 between 94-98% Supportive care with fluid and feeds **High-dose co-trimoxazole PO (or IV) for 21 days**: 50mg/kg SMX + 10mg/kg TMP, 2 times daily or 25mg/kg SMX + 5mg/kg TMP, 4 times daily + **For severe cases**: **Prednisone PO**: 1mg/kg 2 times daily for 5 days, then 1mg/kg once daily for 5 days, then 0,5mg/kg once daily for 5 days

Peak of prevalence of PCP is in infants under 12 months and usually under 6 months of age.

Management of severe pneumonia
According to WHO, for HIV-infected and HIV-exposed infants, Pneumocystis Jirovecii (previously Pneumocystis carinii) pneumonia should be considered in all HIV-exposed and -infected infants aged under 1 year presenting with pneumonia or severe pneumonia (especially if they are not receiving co-trimoxazole prophylaxis).
Treatment should include broad-spectrum antibiotics (Ampicillin + gentamicin or Ceftriaxone) + High-dose Co-trimoxazole.

For HIV-infected children > 12 months, empirical co-trimoxazole treatment for PCP is not recommended
→ start with broad-spectrum antibiotics: Ampicillin + gentamicin (first line) or Ceftriaxone (alternative first line).
→ If no response:
add high-dose co-trimoxazole
change Ampicillin + gentamicin to ceftriaxone
If ceftriaxone was used as first line treatment, and strong clinical suspicion (or microbiological evidence) of Aureus pneumonia, change to Cloxacillin or Vancomycin.
Sources: MSF, 2024 [33] and WHO, 2010 [34]

If no (or uncomplete) response, always consider tuberculosis as a possible associated cause.

B- Other possible cause of cough and dyspnoea: Lymphoid interstitial pneumonitis (LIP)

Condition	Causes	Clinical features	Management
Lymphoid interstitial pneumonitis (children > 3 yrs)	Lympho-proliferative infiltrate	Slow onset: cough, dyspnoea, hypoxaemia (SpO2 < 92%) Often enlarged lymph nodes, splenomegaly and chronic parotitis. Usually no fever, no weight loss. Clubbing, wheezing are possible. CRX: bilateral reticulonodular infiltrate. Similar appearance to miliary TB but more irregular distribution (and clinically distinct).	Symptomatic management if needed: Inhaled bronchodilators for wheeze Steroid may be useful. If no response after 1 month, discontinue gradually over 2 months. Provide effective ART and support adherence.

2/ Neurological infections

A- Cryptococcal meningitis

Mainly see in adolescents (and adults) severely immunosuppressed (CD4<100cell/mm^3), but rare in children.

Condition	Causes	Clinical features	Management
Cryptococcal meningitis	Cryptococcus neoformans	Adolescents and older children Fever, headache, lethargy, vomiting, neck stiffness, convulsions Serum CrAg positive CSF findings: Opening pressure very elevated CSF aspect: clear Test: Crypto Ag +; Indian ink + WBC: often < 20, mainly lymphocytes Protein: moderate high Glucose: normal or moderate low	**Single high dose of Ambisome IV**: 10mg/kg + 14 days of treatment with: **Flucytosine PO**: 25mg/kg four times daily + **Fluconazole PO**: 12mg/kg once daily (max 1200mg/d) Then 8 weeks consolidation regimen: **Fluconazole PO alone** 6-12 mg/kg once daily (max. 800mg/day) Then maintenance regimen: **Fluconazole PO** 6mg/kg once daily (max 200mg/day) until CD4 > 200 and VL suppressed on ART Repeated therapeutic lumbar puncture should be done if raised intracranial pressure (headache, vomiting, visual disturbance), to maintain the pressure < 20cm H_20. Remove 1ml/kg (max 25ml) per puncture.

B-Toxoplasmosis

Condition	Causes	Clinical features	Management
Toxoplasmosis (reactivation)	Toxoplasma gondii	Headache, fever, focal neurological symptoms, such as weakness, ataxia, or paralysis, and encephalitis-like symptoms, including altered mental status and decreased levels of consciousness.	See appendix 27

C- Tuberculosis

Condition	Causes	Clinical features	Management
CNS tuberculosis	Koch bacillus	Meningitis Tuberculoma: space occupying lesions causing encephalitis symptoms and focal symptoms → LP: lymphocyte predominance, high protein, low glucose → CSF GeneXpert → look for TB evidence elsewhere → lymph nodes, TB LAM, stools, gastric aspirate, CXR,…	TB treatment + Steroids (refer to national protocol) Note: CNS-TB and toxoplasmosis cannot be distinguished on clinical symptoms → if CD4 are < 200 and patient not receiving CTX prophylaxis, treat both. In young children, disseminated TB is more frequent than reactivation of toxoplasmosis

Other common infectious causes:

Malaria, bacterial meningitis must be excluded (or treated) first.

3/ Gastro-intestinal infections

A- candidiasis

Frequent in children and adolescents severely immunocompromised (CD4< 200 cells/mm^3 or < 15%)

Condition	Causes	Clinical features	Management
Oesophageal candidiasis	Candida albicans	Infant and young child: breastfeeding refusal, cry after starting eating, possible vomiting. Older children: pain behind the sternum on swallowing. Oral thrush often associated (inconstant) Anorexia, weight loss, malnutrition.	Fluconazole: Loading dose: 6mg/kg, then 3 – 6mg/kg once daily for 21 days (max: 400mg/day) If oral thrush associated, provide local treatment. Soft alimentation Nutritional support if malnutrition.

If no response after 1 week, consider:

→ Other germs: HSV and CMV are other possible causes, in very severely immunosuppressed patients (CD4<50).
→ Gastro-esophageal reflux disease (especially in infants).
→ Resistance to fluconazole. Try to treat with another class of antifungal medicine.

Oesophageal candidiasis classifies as Stage 4 and may be associated with other opportunistic infections or tuberculosis. Do not attribute only to candidiasis all the symptoms.

B- Diarrhoea

Very frequent symptom in HIV infected children.

All usual germs can cause acute – bloody or watery – diarrhoea. In HIV-infected children, evolution is often prolonged.

In immunocompromised children (CD4<200 cells/mm^3 or < 15%), opportunistic protozoa and viruses (CMV) may be responsible for chronic and sometimes severe diarrhoea or colitis.

Condition	Causes	Clinical features	Management
Persistent diarrhoea (> 14 days) or chronic diarrhoea (> 28 days)	Bacterial, parasitic, protozoal and viral infections. Food allergy or intolerance Medicine side effects[(1)]	More than 3 stool per day – bloody or watery Dehydration (more or less severe) Weight loss, malnutrition, wasting	All cases[(2)]: Rehydration as required with low-osmolarity ORS Zinc supplementation (as other children) ART to restore immunity +++ [(3)] Nutritional care +++ Etiologic treatment Ciprofloxacine PO: 15mg/kg/day for 3 days, only for bloody diarrhoea. Metronidazole PO: 10-15mg/kg, three times daily, for 10 days, if arguments for amoebiasis (or giardiase) Co-trimoxazole high dose (as PCP): can be tried if argument for Cystoisospora (ex-Isospora Belli). Deworming if not done in the past 6 months.

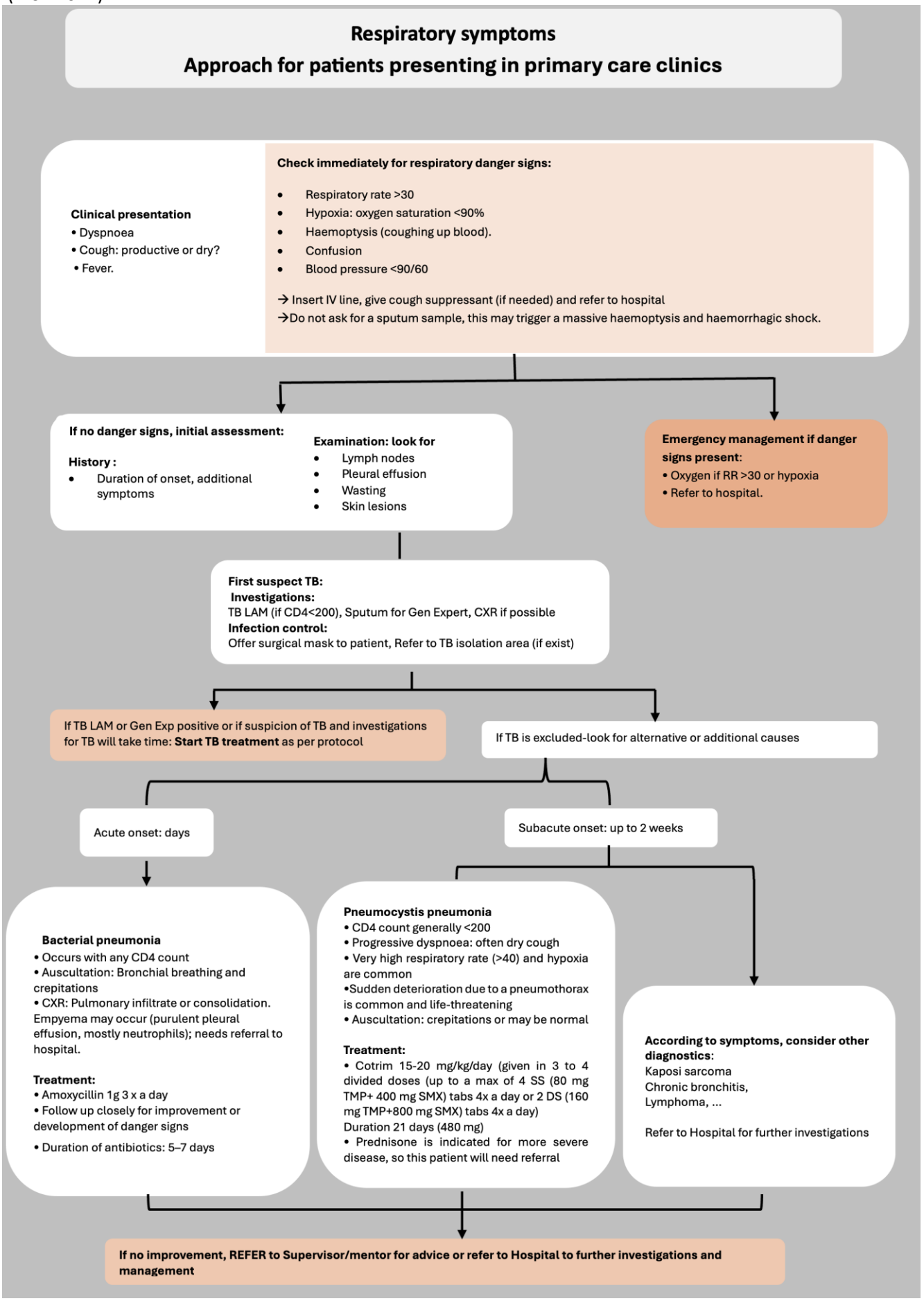
[(1)] LPV/r: watery diarrhoea and abdominal pain are common side effects

[(2)] Immunocompromised children with chronic diarrhoea and malnutrition should be managed at hospital level.

[(3)] Immune restauration is often the only possibility to improve the symptoms, as no etiologic treatment exists.

Appendix 9: Algorithm for management of positive HIV client with respiratory problems

(MSF-2021)



Appendix 10: Algorithm for management of HIV positive client with Neurological disorder (MSF-2021)

Appendix Common Neurological Disease and management

The Big 3 Adolescents and Adults CND Opportunistic Infections

Cryptococcal meningitis

Symptoms and Signs:

- ✓ Headache, meningitis symptoms (neck stiffness, and a positive Kernig's or Brudzinski's sign),
- ✓ Altered level of consciousness;
- ✓ Focal neurological deficit: ophthalmoplegia and visual disturbance are common.

Investigations:

- ✓ CD4 <200 cells/mm^3.
- ✓ serum, plasma or whole blood (finger-prick) blood and/or CSF CrAg LFA

Treatment:

Induction phase

- ✓ Liposomal Amphotericin B single dose (10 mg/kg)
- ✓ Flucytosine (100 mg/kg/day in 4 times): 2 weeks
- ✓ Fluconazole 1200 mg/day: 2 weeks

Consolidation phase

- ✓ Fluconazole 800 mg for 8 weeks

Maintenance Phase

- ✓ Fluconazole 200mg/day for a minimum of 12 to 18 months of maintenance phase.

Measurement of opening pressure and therapeutic LPs are essential
Delay ART Initiation to 4 to 6 weeks
Full protocol: see 'Cryptococcal meningitis', pp 70.

Toxoplasmosis (Encephalitis)

Symptoms and Signs:

- ✓ Headache, confusion, fever, seizures, focal neurological symptoms deficits
- ✓ Neurological abnormalities: focal symptoms, any type of altered mental state, visual impairment in case of ocular toxoplasmosis.

Investigations:

- ✓ CD4 <200 cells/mm^3.
- ✓ Serum, plasma or whole blood (finger-prick) for Toxoplasma IgG LFA (not validated for CSF)

Treatment:

Treat if CD4 <200 cells/mm^3 and any neurological symptoms

Acute Treatment:

- ✓ *Dosage:* Trimethoprim 5 mg/kg and sulfamethoxazole 25 mg/kg administered orally or intravenously twice daily.
- ✓ Duration: At least 6 weeks, with extension if clinical or radiologic response is incomplete.

Chronic Maintenance Therapy (Secondary Prophylaxis):

- ✓ *Dosage*: One double-strength tablet (800 mg SMX/160 mg TMP) **twice daily.**

Tuberculosis

Symptoms and Signs:

- ✓ TB symptoms (chronic cough of > 2 weeks, loss of appetite and weight (>10% of previous weight), night sweats
- ✓ Meningitis symptoms
- ✓ Tuberculomas: space-occupying lesions – causing encephalitis symptoms and focal neurology.

Investigations:
LP: Lymphocyte predominance, high protein, low glucose (however, LP may be normal);
GeneXpert may be positive on centrifuged CSF;
Look for evidence of TB elsewhere: TB LAM, sputum microscopy, CXR, abdominal ultrasound.

Treatment:
Treat for CNS TB if any abnormal neurology and evidence of TB elsewhere,

Refer to National TB guidelines for specific recommendations on the treatment.

Others common infectious causes to be considered

Malaria

Rapid malaria test positive
Malaria may not be the only cause of an altered mental state in a patient with a low CD4 count

Bacterial meningitis

Raised white cell count on CSF with >80% neutrophils
Microscopy can identify organisms
If LP is done after antibiotics, organisms rarely seen and cell count may be reduced

Neurosyphilis

Positive CSF VDRL
Rapid test positive on blood, with suggestive clinical presentation.
Note rapid test is not validated for CSF.

Other HIV-related causes

HIV-associated dementia (HAD): due to chronic HIV infection of the brain with the triad of impaired short-term memory and concentration; behavioural changes (apathy, withdrawal, irritability and depression); motor changes of tremor (leg weakness, ataxia and Parkinson's-type symptoms).
Non-infectious causes: Cerebro-vascular accident (stroke) and metabolic abnormalities (hypoglycaemia, hypotension, hypoxia, abnormal sodium, renal and lever impairment)

Adapted from MSF Guidelines (2021)

Back to "Diagnosis of cryptococcal meningitis"

Appendix 11: Intensified TB case finding guide

Step 1: Health worker should ask following questions:

1	Has the patient been coughing for 2 weeks or more? (for known HIV patients assess cough regardless of duration)	Yes	Non
2	Has the patient had persistent fevers for 2 weeks or more?	Yes	Non
3	Has the patient had noticeable weight loss (more than 3 kg)	Yes	Non
4	Has the patient had excessive night sweats for 3 weeks or more? (for adults)	Yes	Non
5	Has the patient had TB or had contact with a TB patient at least 3 months back	Yes	Non

Step 2: Action to be taken

If yes to one of question of step 1 request for urine LAM test and sputum collection for GeneXpert Test and direct the patient to a designated area for people with chronic cough.

If no to question of step 1 repeat TB Assessment at subsequent visits

And consider TPT

Appendix 12: Some Important Medicine Interaction

ARV drugs	Key interactions	Suggested management
DTG	Carbamazepine, phenobarbital and phenytoin	Use an alternative anticonvulsant agent valproic acid or gabapentin)
	Rifampicin	Increase DTG to 50 mg twice daily; avoid in the presence of integrase class resistance. Continue with twice daily dosing of DTG in children for 2 weeks after use of rifampicin has ended
	Metformin	Avoid high-dose metformin with DTG; adjust the metformin dose as appropriate
	Polyvalent cation products containing Mg, Al, Fe, Ca and Zn	Use DTG at least two hours before or at least six hours after supplements containing polyvalent cations, including but not limited to the following products: Fe-, Ca-, Mg- or Zn-multivitamin supplements; mineral supplements, cation-containing laxatives and Al-, Ca- or Mg-containing antacids. Monitor for antiviral efficacy
TDF	Ledipasvir- or velpatasvir-containing regimens (hepatitis C treatment)	Monitor for TDF-associated adverse effects, including renal dysfunction, particularly when TDF is co-prescribed with boosted HIV PIs
	Lithium	monitor renal function closely
Boosted PI LPV/r ATV/r DRV/r	Rifampicin	Replace rifampicin with rifabutin Adjust the dose of LPV/r or substitute with DTG or three NRTIs (for children)
	1 HP or 3 HP	Avoid the combination Consider alternative ARV drugs such as EFV or DTG Consider a non-rifamycin-based approach, such as daily INH
	Bedaquiline or delamanid (R-TB)	Use with caution as there is a risk of QT prolongation
	Lumefantrine	Potential for increased lumefantrine exposure Risk of QT prolongation with ATV/r and LPV/r
	Amlodipine	Consider reducing the dose of amlodipine by 50%
	Antidiabetic drugs (such as glibenclamide and gliclazide)	Adjust the antidiabetic drug dose as appropriate
	Statins	Simvastatin: contraindicated because of the risk of rhabdomyolysis; use alternative dyslipidaemia agent Atorvastatin: dose adjustment required; total daily dose should be limited to 10 mg with ATV/r, 40 mg with DRV/r and 20 mg with LPV/r
	Fluticasone or budesonide	Risk of Cushing's syndrome; use alternative corticosteroid (such as beclomethasone
	Acid-reducing agents	ATV/r: use at least 2 hours before or 1 hour after antacids; contraindicated with proton pump inhibitors
EFV	Bedaquiline	Avoid the combination
	Amodiaquine, DHA/piperaquine	Use an alternative antimalarial agent or substitute EFV for DTG
	Artemisinin or lumefantrine	Use an alternative antimalarial agent or substitute EFV for DTG
	Hormonal contraceptives implants	Use alternative or additional contraceptive methods
	Amlodipine	Adjust the amlodipine dose as appropriate
	Simvastatin and atorvastatin	Adjust the statin dose as appropriate

Source: WHO 2021, p. 177, 178

Back to "Regimen efficacy and safety"

Appendix 13: Some developmental Milestones

Age	Psychosocial	Gross Motor	Fine Motor /Visual	Communication
Hearing				
1 month	Follows faces to the midline	Moves all extremities equally; lifts head when lying on stomach	Opens hands spontaneously	Startled by loud sounds; cries; quiets when fed and comforted
2 months	Follows faces past midline; smiles responsively	Lifts head up 45 degrees when on stomach	Looks at own hand	Makes baby sounds (cooing, squealing, gurgling)
3 months	Recognizes mother; smiles responsively	Supports head for a few seconds when held upright	Opens hands frequently	Responds to voices; Laughs
4 months	Follows an object with eyes for 180 degrees; regards own hand; anticipates food on sight	Bears weight on legs; good neck control when pulled to sitting; lifts chest and supports self on elbows when pulled to sit	Brings hands together in midline (clasps hands); grabs an object (such as a rattle); reaches for objects	Turns head to sound

Age	Psychosocial	Gross Motor	Fine Motor / Visual	Communication
6 months	Reaches for familiar people	Rolls from stomach to back or back to stomach; sits with anterior support	Plays with hands by touching them together; sees small objects such as crumbs	Responds to name; Babbles
9 months	Indicates wants; waves bye-bye; has stranger anxiety	Can sit without support; creeps or crawls on hands and knees	Looks for a toy when it falls from his or her hand; takes a toy in each hand; transfers a toy from one hand to the other.	Responds to soft sounds such as whispers
12 months	Has separation anxiety; social interactions intentional and goal directed	Pulls self-up to standing position; walks with support	Points at objects with index finger	Says at least one word; makes “ma-ma” or “da-da” sounds; locates sounds by turning head.
15 months	Imitates activities; finds a nearby hidden object	Can take steps by himself or herself; can get to a sitting position from a lying position	Can stack one cube on top of another	Able to say mama and dada to respective parents
18 months	Initiates interactions by calling to adult	Walks without help	Takes off own shoes; feeds self	Says at least 3 words
2 years	Does things to please others; engages in parallel (imitative) play	Runs without falling	Looks at pictures in a book; imitates drawing a vertical line	Combines 2 different words

Back to “the 6-week consultation”

Appendix 14: Developmental Red Flags

Birth to 3 months	• Failure to alert to environmental stimuli • Rolling over before 2 months (hypertonia) • Persistent fisting at 3 months
4 to 6 months	• Poor head control • Failure to smile • Failure to reach for objects by 5 months
6 to 12 months	• No baby sounds or babbling • Inability to localise sounds by 10 months
12 to 24 months	• Lack of consonant production • Hand dominance prior to 18 months (contralateral weakness)
Any age	• Loss of previously attained milestones

Appendix 15: children who should be tested for HIV

Clinical condition	Proposition of HIV test	Comment
Severe acute malnutrition	**Systematic**	
Tuberculosis	**Systematic**	
Severe bacterial infection	**Systematic**	**especially if recurrent**
Diarrhoea > 15 days	**Systematic**	
Fever > 30 days	**Systematic**	
Psychomotor developmental delay	Conditional	Especially if loss of psychomotor skills, neurologic localisation signs or associated with seizure
Moderate malnutrition, poor weight gain, weight loss	Conditional	If no response to nutritional support or recurrence after support stopped
Oral thrush	Conditional	If extensive, recurrent or suspicion of oesophageal localisation
Parotid enlargement	Conditional	If persistent, after exclusion of mumps
Enlarged lymph glands	Conditional	If 2 or more extra-inguinal sites
Hepatomegaly	Conditional	If unexplained by malaria or other cause of liver enlargement
Ear discharge	Conditional	If chronic or recurrent
Skin rash	Conditional	If chronic, recurrent or unusual (extensive molluscum, herpes zoster, disseminated scabies, …)

(Back to text)

Appendix 16: ART readiness assessment checklist

This checklist is adapted from Uganda's ART Readiness Assessment tool, aligned with WHO 2021 guidelines. It helps clinicians decide on same-day or rapid ART initiation.

Psychosocial/knowledge criteria (applies to patients and caregivers)	**Yes**	**No**
Knowledge & Understanding		
1. Understands how HIV affects the body and benefits of ART.		
2. Has received demonstration of how to take/administer ART and other prescribed medication.		
3. Has received information on predictable side effects of ART and understands what steps to take in case of these side effects.		
4. Is aware of the DSD system and support group meeting times.		
Psychosocial Readiness		
5. Has screened negative for alcohol or other drug use.		
6. Is willing to disclose/has disclosed HIV status to a sexual partner or relative.		
7. For patients dependent on a caregiver: caregiver is committed to long-term support of the patient and meets criteria above.		
8. There are no identified adherence issues (or likely barriers to adherence have been identified and a plan is in place to address them)		
9. Are there no signs of severe depression or cognitive impairment in the patient?		
10. Patient/caregiver feels ready to start ART today.		
Support Systems		
11. Patient/caregiver has provided address, contact details and agrees to be contacted.		
12. Has treatment supporter been identified and engaged in HIV education or will attend next counseling session?		
13. Agrees to be enrolled into SMS reminder system (if available).		
14. Are other support systems in place or planned (e.g., setting phone alarm, pill box)?		
Operational Planning		
15. Has identified convenient time(s) of the day for taking ART.		
16. Patient has given informed consent to initiate ART.		
Eligibility		
17.Clinician confirms no contraindications (e.g., meningitis symptoms) for patient to start ART		

Summary Table for Decision Making

Response Pattern	Recommended Action
All questions “Yes”	Start ART immediately
One or more “No”, but with plan to address	Start ART, but follow up closely
One or more critical “No” (e.g., not willing, no understanding, clinical red flag)	Delay and reassess after support/counseling

Appendix 17: questions to clarify when initiating ART in children

1/ Who will administer the medication or supervise its intake?

Regardless of the child or teen's age, the person administering the medication or supervising the intake must be identified and well informed. If this person differs from the one present at the initiation, he or she should be informed and trained as soon as possible. This person can be one of the parents, both, or a parental substitute.

It is also important, especially for young children, to identify a second person who can assist the adult in the event of the adult's absence when taking ARV.

2/ Who knows the child's diagnosis (or who will be informed in the family)?

This question helps assess how much the family has shared about the diagnosis. The more limited is the disclosure (in the worst case, even the other parent is unaware), the more difficult it will be to administer the treatment properly.

This information should be recorded in the patient's file. Regular efforts should be made to convince the parents to share the child's status (and possibly their own) with other family members.

3/ When (what time) will the drugs be administered?

The schedule choice must be determined according to the availability of the parent and the child. The parent must be present at home at the time of administration. Therefore, the schedule must be chosen by the parent (and possibly by the teenager) based on this criterion.

4/ What strategy will be used to avoid missed doses?

During the first weeks/months of treatment, the risk of forgetting to take medication is high, as the parent and the child need to establish a routine. Some choose a specific moment, such as mealtime, brushing teeth, a favourite TV show, or the call to prayer. An alarm on the phone can also be recommended.

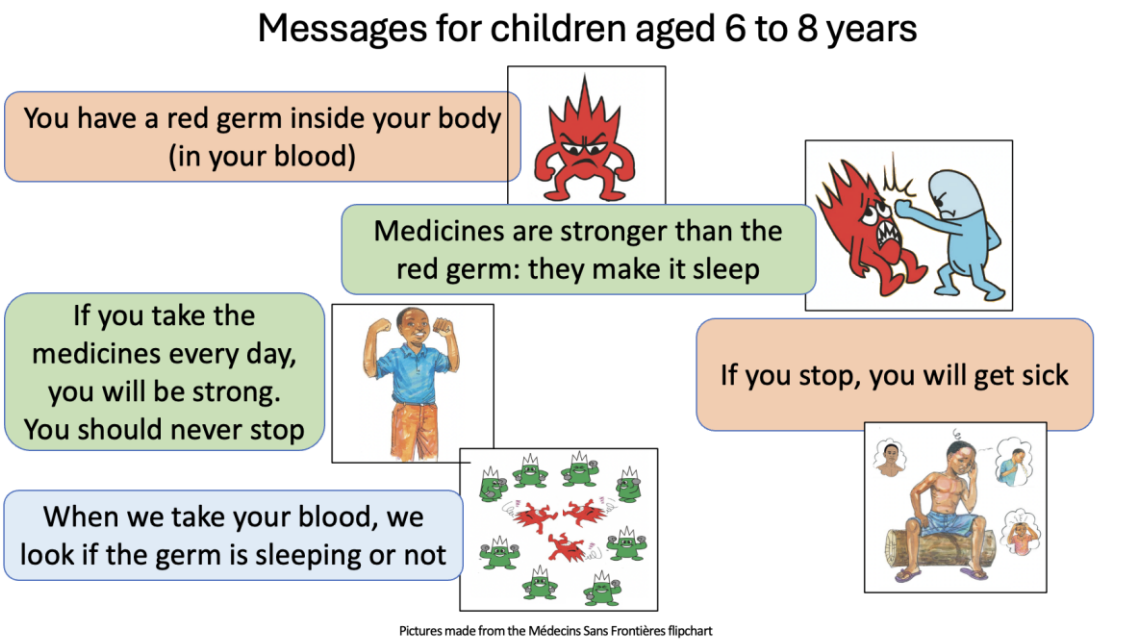
This choice belongs to the parent and child. It will be important to check remotely (but soon enough) whether it was relevant.

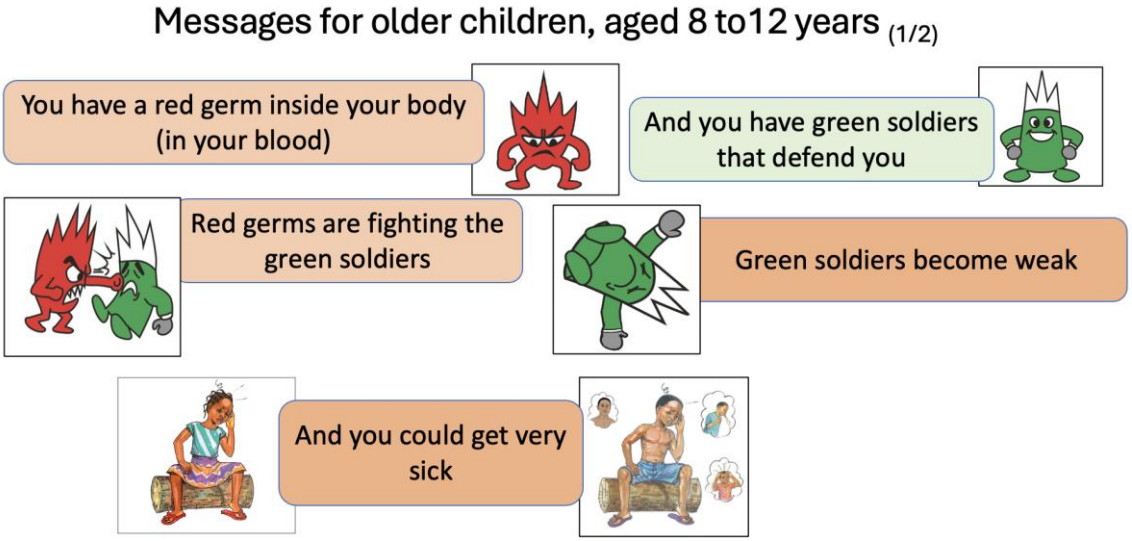
5/ How will the medication be stored, and where will it be kept?

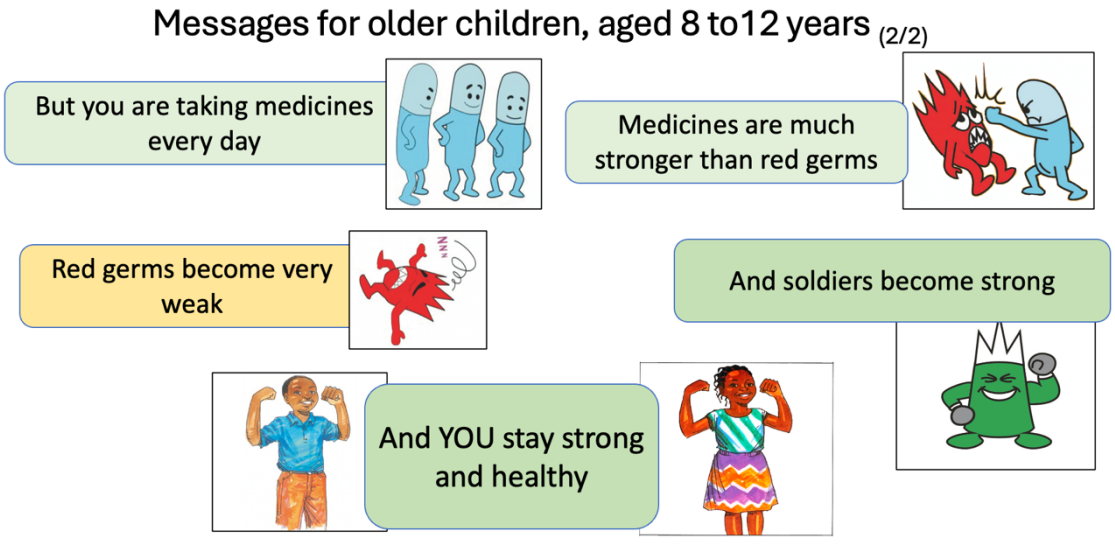
Medicines can be stored at room temperature (< 30°C). However, if the partner is not informed, it is important to discuss with the parent where the boxes will be kept (they must remain easily accessible). Suppose the child is old enough to take his or her medication independently. In that case, it is important that they can access it even if the parent is not available (avoid hiding it in a locked cupboard in the master bedroom!).

(Back to "psychosocial factors")

Appendix 18: pictures to explain HIV and ART to children

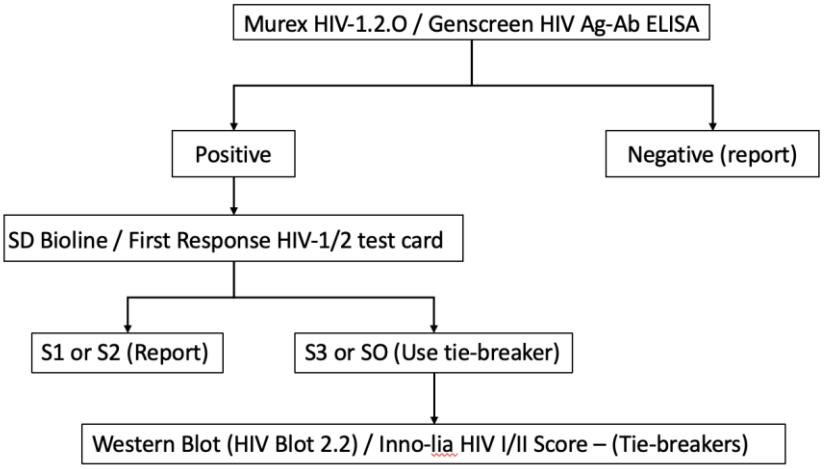




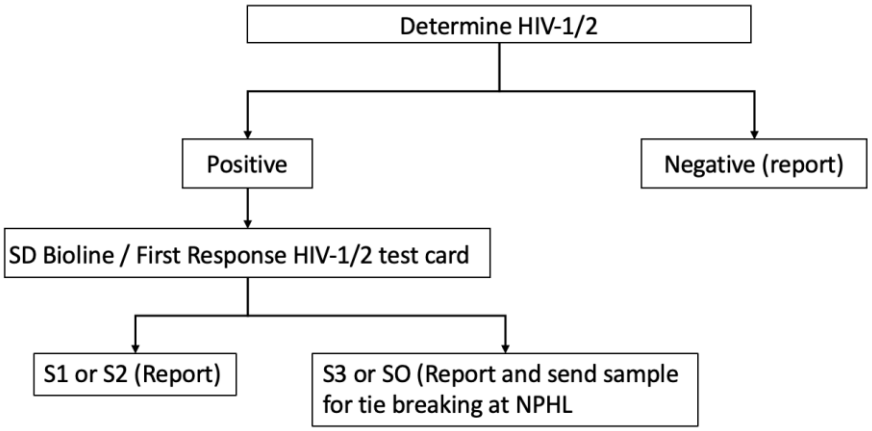


Back to "the disclosure process"

Appendix 19: Reference serology laboratory – HIV 1/2 testing algorithm

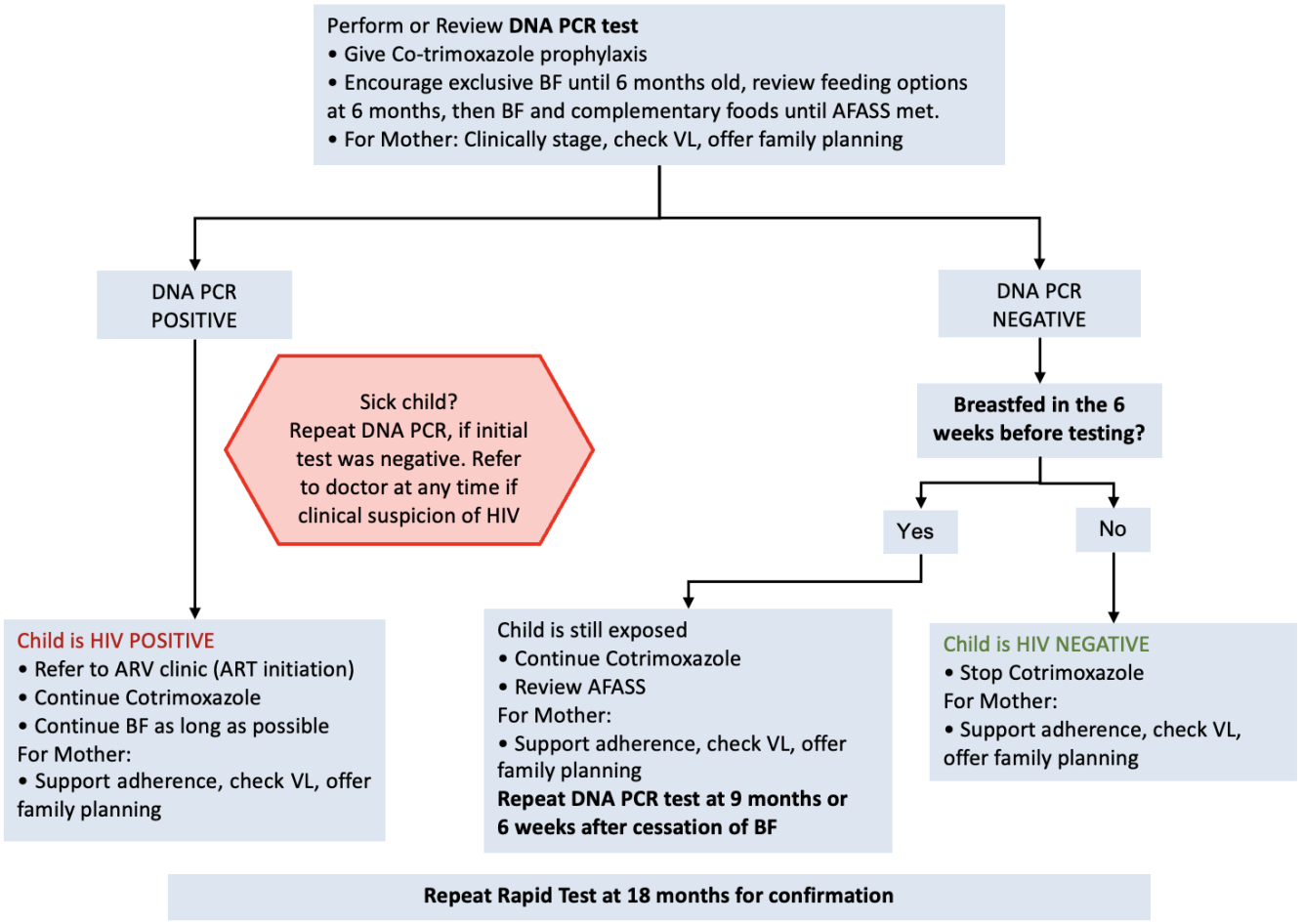


Appendix 20: Peripheral laboratory HIV-1/2 testing algorithm



NB: All HIV positives plus 10% of negatives from each health facility are sent to the Reference Laboratory for further testing and confirmation.

Appendix 21: Algorithm for DNA PCR of HIV-exposed infant aged 6-8 weeks (EID)

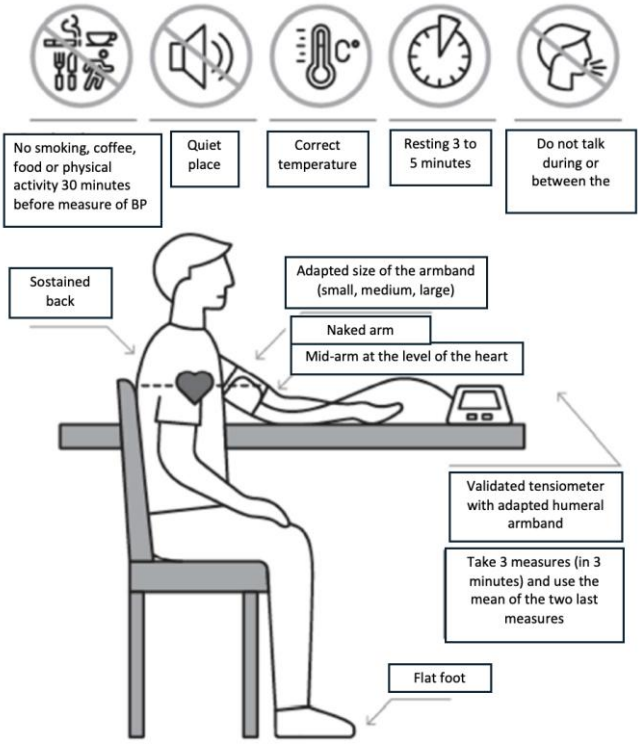


Appendix 22: Body surface area estimation for calculation of paclitaxel dose

BSA	Height in cm																									
Weight in kg	140	142	144	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190
36	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
38	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
40	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5
42	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
44	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
46	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6
48	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6
50	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
52	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7
54	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7
56	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
58	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
60	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8
62	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8
64	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8
66	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9
68	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9
70	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9
72	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9
74	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0
76	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0
78	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
80	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1
82	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1
84	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1
86	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
88	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2
90	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2
92	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2
94	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2
96	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3
98	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3
100	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3
102	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3
104	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
106	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4
108	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4
110	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4
112	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4
114	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5
116	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.5
118	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.5	2.5	2.5
120	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.5	2.5	2.5	2.5

Appendix 23: measure of blood pression

Procedure for measuring and interpreting Blood Pressure (BP)



Interpretation of blood pressure (PB)

	Normal BP	Normal-high BP	HTA grade 1	HTA grade 2-3
Measure systolic	< 130mmHg	130-139mmHg	140 to 159mmHg	≥ 160mmHg
Measure diastolic	< 85mmHg	85 to 89 mmHg	90 to 99mmHg	≥ 100mmHg
Action	Routine FU	Control after 3 months	Refer for medical advice	Refer urgently

For patients with normal-high BP, take another measure 15 minutes of resting. If the BP remains at the same level, control BP after 3 months. If BP is still “normal-high”, refer for medical advice.

If there is a dissociation between the systolic and diastolic measures, the patient should be classified according to the higher result. Example: a measure of 150/80mmHg should be classified as grade 1-HTA; and a measure of 150/105 should be classified as Grade 2-3-HTA.

If persistence of Grade 1 HTA after 15 minutes of resting, refer to medical advice.

Adapted from the 2021 recommendations of the European society of arterial hypertension for the measure of blood pressure.

https://www.sfhta.eu › wp-content › uploads › 2021 › 12 › Guidelines-mesure-PA-traduites-Fr-23-11-2021-1.pdf

Back to “hypertension”

Appendix 24 Major types of toxicity associated with first-, second-and third-line ARV drugs

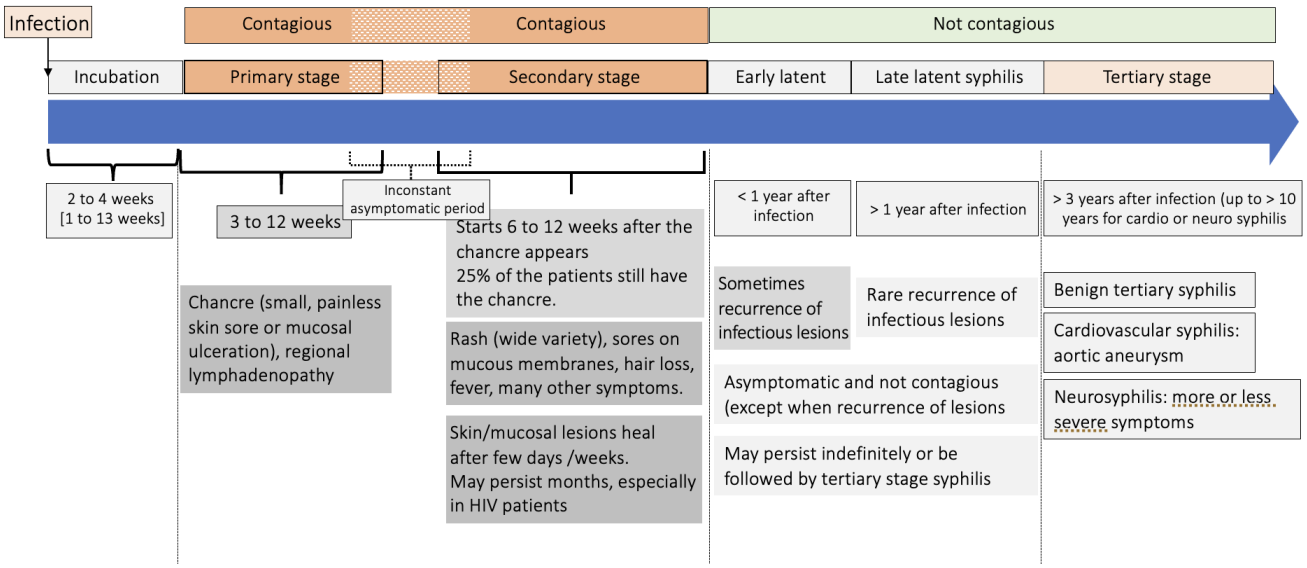
ARV drug	Major type of toxicity	Risk factor	Suggested management
ABC	Hypersensitivity reaction	Presence of HLA-B*5701 gene	Do not use ABC in presence of HLA-B*5701 gene Substitute AZT or TDF
TDF	Chronic kidney disease Acute kidney injury and Fanconi syndrome	Underlying renal disease > 50 yrs, BMI<18.5 or weight <50kg Untreated diabetes or untreated hypertension Concomitant use of nephrotoxic drugs or boosted PI	Substitute AZT or ABC (or TAF) in special circumstances (see section on TAF) Do not initiate TDF at an estimated glomerular filtration rate < 50ml/mn, uncontrolled HTA, untreated diabetes or kidney failure
	Decreases in bone mineral density	History of osteomalacia (adults) and rickets (children) and pathological fracture Risk factors for osteoporosis or bone mineral density loss Vitamin D deficiency	
	Lactic acidosis or severe hepatomegaly with steatosis	Prolonged exposure to nucleoside analogues Obesity or liver disease	
AZT	Anaemia, neutropenia	Baseline anaemia or neutropenia CD4 < 200 cells/mm^3	Substitute TDF or ABC Consider using low-dose AZT
	Lactic acidosis or severe hepatomegaly (steatosis) Lipoatrophy, dystrophy Myopathy	BMI>25 (or weight > 75kg) Prolonged exposure to NRTIs	Substitute TDF or ABC
DTG	Hepatotoxicity Hypersensitivity reaction	HBV or HCV coinfection Liver disease	Substitute other class drug: boosted PI (or NNRTI)
	Insomnia Body weight gain, obesity	> 60 yrs, female Low CD4 or high VL Concomitant use of TAF	Consider morning dose or substitute boosted PI (or EFV) Monitor body weight and promote anti-obesity measures. If increase despite measures, consider substitute bPI or EFV

LPV/r	Electrocardiographic abnormalities (PR and QRS interval prolongation, torsade de pointes)	People with pre-existing conduction system disease Concomitant use of drug that may prolong PR or QRS intervals Congenital long QT syndrome Hypokalaemia	Use with caution for people with pre-existing conduction disease or taking concomitant drugs that may prolong PR or QRS intervals
	Hepatotoxicity	Underlying hepatic disease HBV or HCV coinfection Concomitant use of hepatotoxic drugs	If LPV/r is used in second-line ART and DTG has been used in first line, ATV/r or DRV (or EFV) can be considered as alternative.
	Pancreatitis	Advanced HIV disease, alcool	Substitute another ART class (DTG)
	Dyslipidaemia	Cardiovascular risk factor such as obesity or diabetes	Substitute another ART class (DTG)
	Diarrhoea	Risk factor unknown	Substitute ATV/r or DRV or DTG
ATV/r	Electrocardiographic abnormalities (PR and QRS interval prolongation)	People with pre-existing conduction system disease Concomitant use of drug that may prolong PR or QRS intervals Congenital long QT syndrome	Use with caution for people with pre-existing conduction disease or taking concomitant drugs that may prolong PR or QRS intervals
	Indirect hyperbilirubinemia (clinical jaundice)	Presence of UGT1A1*28 gene	Clinically benign but potentially stigmatizing. Substitute only if adherence is compromised
	Nephrolithiasis	History of nephrolithiasis	Substitute LPV/r or DTG (according to ART history). DRV/r can be considered
DRV/r	Hepatotoxicity	Underlying hepatic disease HBV or HCV coinfection Concomitant use of hepatotoxic drugs	Substitute with ATV/r or LPV/r When used in third-line ART, limited options are available.
	Severe skin and hypersensitivity reactions	Sulfonamide allergy	Substitute another ART class

Adapted from: WHO 2021, HIV prevention, testing, treatment, service delivery and monitoring, p. 168 (box 4.13)

Back to "clinical monitoring at follow up visits"
Back to "monitoring adverse medicine events"

Appendix 25: evolution of syphilis without treatment



Source: MSD manual https://www.merckmanuals.com/professional/infectious-diseases/sexually-transmitted-infections-stis/syphilis?query=syphilis#Diagnosis_v1024301

Back to Prevention of congenital syphilis

Appendix 26: Example of oral penicillin suspension protocol desensitization

Dose Number	Penicillin Concentration (Units/mL)	Amount (mL)	Dose (Units)	Cumulative Dose (Units)
1	1000	0.1	100	100
2	1000	0.2	200	300
3	1000	0.4	400	700
4	1000	0.8	800	1500
5	1000	1.6	1600	3100
6	1000	3.2	3200	6300
7	1000	6.4	6400	12,700
8	10,000	1.2	12,000	24,700
9	10,000	2.4	24,000	48,700
10	10,000	4.8	48,000	96,700
11	80,000	1.0	80,000	176,700
12	80,000	2.0	160,000	336,700
13	80,000	4.0	320,000	656,700
14	80,000	8.0	640,000	1,296,700

Interval between doses was 15–30 min, with a total time of 4–8 h. Observation before full parenteral therapeutic dose was 30 min. Each dose was diluted in 30 mL of water prior to oral administration.

For more information or alternative protocols, refer to [11]

Back to Prevention of syphilis

Appendix 27: Toxoplasmosis protocol in children

Acute induction therapy

Preferred treatment:

First 3 days[1] (loading dose), by mouth:	Following days:
Pyrimethamine: 2mg/kg/day (max 50mg/d) once daily + Sulfadiazine: 25–50 mg/kg body weight (max 1g/dose to 1.5 g/dose) per dose, 4 times daily. + Leucovorin (folinic acid): 10–25 mg/day, once daily	Pyrimethamine 1mg/kg/d (max 25mg/d) once daily + Sulfadiazine 25mg/kg per dose, 4 times daily (or 50mg/kg/dose, twice daily) + Leucovorin (folinic acid)10–25 mg once daily

Rem: Some protocols recommend only 1 day for loading dose, then going on with standard dose.

Alternative treatment:

Co-trimoxazole:
5 mg/kg of TMP[1] + 25mg/kg of SMX[2] per dose, twice daily

+ Leucovorin (folinic acid): 10–25 mg/day, once daily

[1] TMP= trimethoprim
[2] SMX= sulfamethoxazole

Source: reference Appendix 27

Treatment duration

At least 6 weeks.

Consider longer duration if clinical or radiologic disease is extensive or response is incomplete at 6 weeks

Expected evolution

Improvement in the first days of treatment (< 15 days). If the patient has not improved after 15 days, consider another diagnostic.

Additional treatments:

1/ Anticonvulsants should be administered to patients with a history of seizures and continued through the acute treatment; but should not be used prophylactically.

2/ Corticosteroids (e.g., prednisone, dexamethasone) may be considered when CSF protein is very elevated (>1,000 mg/dL) or if there are focal lesions with significant mass effects. Discontinuation as soon as clinically feasible.

(Only in admitted patients)

Remark on administration of co-trimoxazole in severe patients (disorders of consciousness):

1/ If co-trimoxazole injectable is available, administer intravenously (infusions of 30 minutes duration) the doses (as indicated above).

2/ If co-trimoxazole injectable is NOT available and the patient is unable to drink syrup (nor swallow the tablets).
→ insert a gastric tube and administer co-trimoxazole directly through the gastric tube.

Solution or co-trimoxazole should be prepared using either the paediatric solution (240mg/ml) or the dispersible tablets (120mg/ml).

Use the following table to calculate the dose, administer the dose and flush the gastric tube after administration.

Table: doses of co-trimoxazole for the treatment of cerebral toxoplasmosis.

body weight (in kg)	Suspension 240mg/ml		Tablet 120mg
	N spoon	ml	N tablets to dissolve
8	1	5,0	2
10	1,25	6,3	2,5
12	1,5	7,5	3
14	1,75	8,8	3,5
16	2	10,0	4
18	2,25	11,3	4,5
20	2,5	12,5	5
22	2,75	13,8	5,5
24	3	15,0	6
26	3,25	16,3	6,5
28	3,5	17,5	7
30	3,75	18,8	7,5

Special situation: allergy to sulfamide (= sulfadiazine and co-trimoxazole are both contraindicated)

2 options:

OR

Pyrimethamine 1mg/kg/j (maximum 25mg/j) once daily

+ Clindamycin: 20mg/kg/dose, twice daily

Pyrimethamine 1mg/kg/d (maximum 25mg/d) once daily

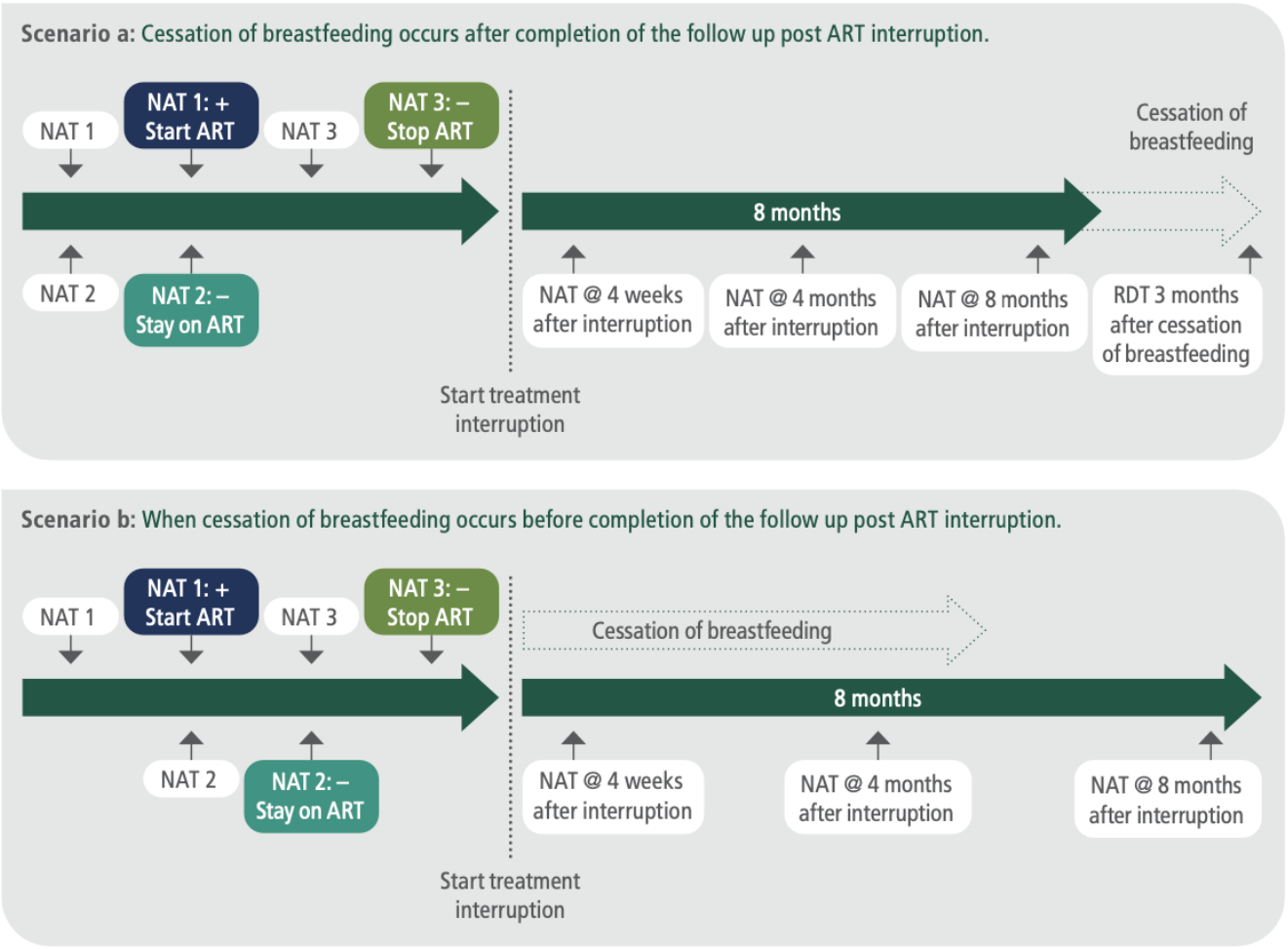
+ Azithromycin: 20mg/kg/d once daily

Chronic suppressive therapy

Co-trimoxazole (usual prophylactic doses) should be prescribed after ending the treatment of acute induction therapy.
Duration: until adulthood if possible, and at least 6 months (established on ART with undetectable VL).

Back to "Patients with neurologic conditions"

Appendix 28: management of discordant results of PCR



Source: WHO, 2021, p. 56 and 57

When 1st PCR is positive, start ART and repeat PCR (confirmation test).

If the confirmation PCR is positive, the child is HIV infected and the treatment must be continued.

If the confirmation PCR is negative, perform a third PCR:

If positive, the child is HIV infected and the treatment must be continued.

If the 3rd PCR is negative, and the infant has no clinical signs or symptoms suggesting HIV infection:

→ Stop ART

→ Perform PCR (or viral load):

- 4 weeks after ART interruption
- 4 months after ART interruption
- 8 months after ART interruption

If all PCRs (or viral loads) are negative but the child is still breastfed, perform rapid test 3 months after cessation of breastfeeding (if the child is more than 18 months of age). If breastfeeding was stopped at least 6 weeks before the 8 months PCR (or VL) and the result was negative, the child is not infected.

If one of the PCR (or VL) is positive, reinitiate ARV treatment and take another sample for confirmation.

Caution: infants who develop signs and symptoms indicating HIV infection should undergo immediate testing.

Appendix 29: interactions between ARV and contraceptive methods

TABLE 3. WHO MEDICAL ELIGIBILITY CRITERIA CATEGORY SUMMARY TABLE FOR CONTRACEPTION, ARV DRUGS AND TB MEDICATIONS

	CHC[a]	POP	DMPA/ NET-EN	LNG/ETG implants	LNG-IUD initiation	LNG-IUD continuation
Nucleoside reverse-transcriptase inhibitors (NRTIs)						
ABC, TDF, AZT, 3TC, ddI, FTC, d4T	1	1	1	1	2/3[b]	2
Non-nucleoside reverse-transcriptase inhibitors (NNRTIs)						
EFV, NVP	2	2	1	2	2/3[b]	2
EFV, rilpivirine	1	1	1	1	2/3[b]	2
Protease inhibitors (PIs)						
ATV/r, LPV/r, DRV/r, RTV	2	2	1	2	2/3[b]	2
Integrase inhibitors						
Raltegravir	1	1	1	1	2/3[b]	2
TB medications						
Rifampicin or rifabutinc	3d	3	DMPA=1 NET-EN=2	2	1	1

[a]CHC includes the combined oral contraceptive pill, the combined contraceptive vaginal ring, the combined contraceptive patch and the CIC.
[b]No drug–drug interactions but depends on clinical disease status.
[c]3HP and 1HP used for TB preventive therapy contain rifapentine.
[d]CIC is WHO medical eligibility criterion 2 for concomitant rifampicin or rifabutin therapy.

For information on DTG, see subsection 4.2.2.

Source: *Medical eligibility criteria for contraceptive use (19).*

Source: WHO, 2019, p. 22 [16].

CHC: Combined hormonal contraception
POP: progestogen-only pill
DMPA/NET-EN: depot medroxyprogesterone acetate/norethisterone enanthate
LNG/ETG implants: levonorgestrel/etonogestrel implants
LNG-IUD: levonorgestrel-releasing intrauterine device

Interpretation of WHO eligibility criteria:

MEC categories for contraceptive eligibility	
1	A condition for which there is no restriction for the use of the contraceptive method
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks
3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method
4	A condition which represents an unacceptable health risk if the contraceptive method is used.

Source: WHO, 2015, P.5 [17]
Criterion 1 or 2 means that it is always or generally always safe to use the contraceptive method with respect to the particular health condition or characteristic.

(Back to family planning)

Appendix 30: normal heart and respiratory rates for children

Normal ranges heart rate:

Age	Heart rate
Premature:	120–170
0–3 months:	100–150
3–6 months:	90–120
6–12 months:	80–120
1–3 years:	70–110
3–6 years:	65–110
6–12 years:	60–95
>12 years:	55–85

Normal ranges respiratory rates:

Age	Normal range
Premature	40–70
0–3 months	35–55
3–6 months	30–45
6–12 months	25–40
1–3 years	20–30
3–6 years	20–25
6–12 years	14–22
>12 years	12–18

Source: MSF, 2021 [23]

Appendix 31: Weight for height tables

Weight-for-height GIRLS
2 to 5 years (z-scores)

World Health Organization

cm	-3 SD	-2 SD	-1 SD	Median	1 SD	2 SD	3 SD
65.0	5.6	6.1	6.6	7.2	7.9	8.7	9.7
65.5	5.7	6.2	6.7	7.4	8.1	8.9	9.8
66.0	5.8	6.3	6.8	7.5	8.2	9.0	10.0
66.5	5.8	6.4	6.9	7.6	8.3	9.1	10.1
67.0	5.9	6.4	7.0	7.7	8.4	9.3	10.2
67.5	6.0	6.5	7.1	7.8	8.5	9.4	10.4
68.0	6.1	6.6	7.2	7.9	8.7	9.5	10.5
68.5	6.2	6.7	7.3	8.0	8.8	9.7	10.7
69.0	6.3	6.8	7.4	8.1	8.9	9.8	10.8
69.5	6.3	6.9	7.5	8.2	9.0	9.9	10.9
70.0	6.4	7.0	7.6	8.3	9.1	10.0	11.1
70.5	6.5	7.1	7.7	8.4	9.2	10.1	11.2
71.0	6.6	7.1	7.8	8.5	9.3	10.3	11.3
71.5	6.7	7.2	7.9	8.6	9.4	10.4	11.5
72.0	6.7	7.3	8.0	8.7	9.5	10.5	11.6
72.5	6.8	7.4	8.1	8.8	9.7	10.6	11.7
73.0	6.9	7.5	8.1	8.9	9.8	10.7	11.8
73.5	7.0	7.6	8.2	9.0	9.9	10.8	12.0
74.0	7.0	7.6	8.3	9.1	10.0	11.0	12.1
74.5	7.1	7.7	8.4	9.2	10.1	11.1	12.2
75.0	7.2	7.8	8.5	9.3	10.2	11.2	12.3
75.5	7.2	7.9	8.6	9.4	10.3	11.3	12.5
76.0	7.3	8.0	8.7	9.5	10.4	11.4	12.6
76.5	7.4	8.0	8.7	9.6	10.5	11.5	12.7
77.0	7.5	8.1	8.8	9.6	10.6	11.6	12.8
77.5	7.5	8.2	8.9	9.7	10.7	11.7	12.9
78.0	7.6	8.3	9.0	9.8	10.8	11.8	13.1
78.5	7.7	8.4	9.1	9.9	10.9	12.0	13.2
79.0	7.8	8.4	9.2	10.0	11.0	12.1	13.3
79.5	7.8	8.5	9.3	10.1	11.1	12.2	13.4
80.0	7.9	8.6	9.4	10.2	11.2	12.3	13.6
80.5	8.0	8.7	9.5	10.3	11.3	12.4	13.7
81.0	8.1	8.8	9.6	10.4	11.4	12.6	13.9
81.5	8.2	8.9	9.7	10.6	11.6	12.7	14.0
82.0	8.3	9.0	9.8	10.7	11.7	12.8	14.1
82.5	8.4	9.1	9.9	10.8	11.8	13.0	14.3
83.0	8.5	9.2	10.0	10.9	11.9	13.1	14.5
83.5	8.5	9.3	10.1	11.0	12.1	13.3	14.6
84.0	8.6	9.4	10.2	11.1	12.2	13.4	14.8
84.5	8.7	9.5	10.3	11.3	12.3	13.5	14.9
85.0	8.8	9.6	10.4	11.4	12.5	13.7	15.1
85.5	8.9	9.7	10.6	11.5	12.6	13.8	15.3
86.0	9.0	9.8	10.7	11.6	12.7	14.0	15.4
86.5	9.1	9.9	10.8	11.8	12.9	14.2	15.6
87.0	9.2	10.0	10.9	11.9	13.0	14.3	15.8
87.5	9.3	10.1	11.0	12.0	13.2	14.5	15.9
88.0	9.4	10.2	11.1	12.1	13.3	14.6	16.1
88.5	9.5	10.3	11.2	12.3	13.4	14.8	16.3
89.0	9.6	10.4	11.4	12.4	13.6	14.9	16.4
89.5	9.7	10.5	11.5	12.5	13.7	15.1	16.6
90.0	9.8	10.6	11.6	12.6	13.8	15.2	16.8
90.5	9.9	10.7	11.7	12.8	14.0	15.4	16.9
91.0	10.0	10.9	11.8	12.9	14.1	15.5	17.1
91.5	10.1	11.0	11.9	13.0	14.3	15.7	17.3
92.0	10.2	11.1	12.0	13.1	14.4	15.8	17.4
92.5	10.3	11.2	12.1	13.3	14.5	16.0	17.6
93.0	10.4	11.3	12.3	13.4	14.7	16.1	17.8
93.5	10.5	11.4	12.4	13.5	14.8	16.3	17.9
94.0	10.6	11.5	12.5	13.6	14.9	16.4	18.1
94.5	10.7	11.6	12.6	13.8	15.1	16.6	18.3
95.0	10.8	11.7	12.7	13.9	15.2	16.7	18.5

Weight-for-height GIRLS
2 to 5 years (z-scores)

World Health Organization

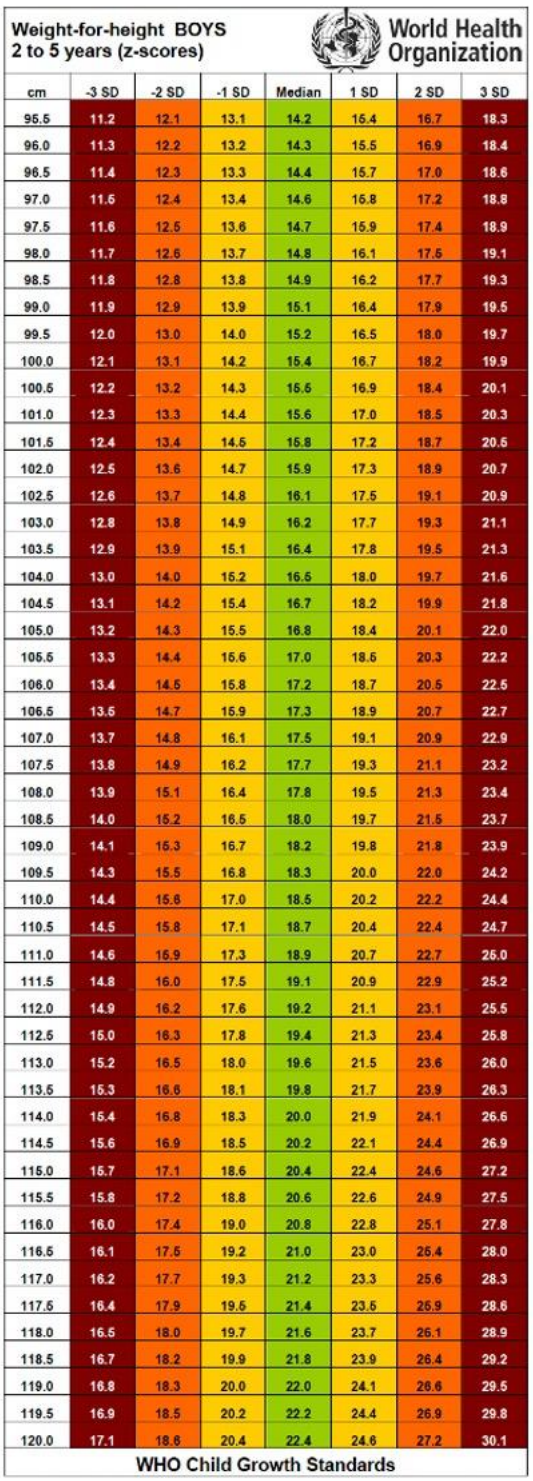
cm	-3 SD	-2 SD	-1 SD	Median	1 SD	2 SD	3 SD
95.5	10.8	11.8	12.8	14.0	15.4	16.9	18.6
96.0	10.9	11.9	12.9	14.1	15.5	17.0	18.8
96.5	11.0	12.0	13.1	14.3	15.6	17.2	19.0
97.0	11.1	12.1	13.2	14.4	15.8	17.4	19.2
97.5	11.2	12.2	13.3	14.5	15.9	17.5	19.3
98.0	11.3	12.3	13.4	14.7	16.1	17.7	19.5
98.5	11.4	12.4	13.5	14.8	16.2	17.9	19.7
99.0	11.5	12.5	13.7	14.9	16.4	18.0	19.9
99.5	11.6	12.7	13.8	15.1	16.5	18.2	20.1
100.0	11.7	12.8	13.9	15.2	16.7	18.4	20.3
100.5	11.9	12.9	14.1	15.4	16.9	18.6	20.5
101.0	12.0	13.0	14.2	15.5	17.0	18.7	20.7
101.5	12.1	13.1	14.3	15.7	17.2	18.9	20.9
102.0	12.2	13.3	14.5	15.8	17.4	19.1	21.1
102.5	12.3	13.4	14.6	16.0	17.5	19.3	21.4
103.0	12.4	13.5	14.7	16.1	17.7	19.5	21.6
103.5	12.5	13.6	14.9	16.3	17.9	19.7	21.8
104.0	12.6	13.8	15.0	16.4	18.1	19.9	22.0
104.5	12.8	13.9	15.2	16.6	18.2	20.1	22.3
105.0	12.9	14.0	15.3	16.8	18.4	20.3	22.5
105.5	13.0	14.2	15.5	16.9	18.6	20.5	22.7
106.0	13.1	14.3	15.6	17.1	18.8	20.8	23.0
106.5	13.3	14.5	15.8	17.3	19.0	21.0	23.2
107.0	13.4	14.6	15.9	17.5	19.2	21.2	23.5
107.5	13.5	14.7	16.1	17.7	19.4	21.4	23.7
108.0	13.7	14.9	16.3	17.8	19.6	21.7	24.0
108.5	13.8	15.0	16.4	18.0	19.8	21.9	24.3
109.0	13.9	15.2	16.6	18.2	20.0	22.1	24.5
109.5	14.1	15.4	16.8	18.4	20.3	22.4	24.8
110.0	14.2	15.5	17.0	18.6	20.5	22.6	25.1
110.5	14.4	15.7	17.1	18.8	20.7	22.9	25.4
111.0	14.5	15.8	17.3	19.0	20.9	23.1	25.7
111.5	14.7	16.0	17.5	19.2	21.2	23.4	26.0
112.0	14.8	16.2	17.7	19.4	21.4	23.6	26.2
112.5	15.0	16.3	17.9	19.6	21.6	23.9	26.5
113.0	15.1	16.5	18.0	19.8	21.8	24.2	26.8
113.5	15.3	16.7	18.2	20.0	22.1	24.4	27.1
114.0	15.4	16.8	18.4	20.2	22.3	24.7	27.4
114.5	15.6	17.0	18.6	20.5	22.6	25.0	27.8
115.0	15.7	17.2	18.8	20.7	22.8	25.2	28.1
115.5	15.9	17.3	19.0	20.9	23.0	25.5	28.4
116.0	16.0	17.5	19.2	21.1	23.3	25.8	28.7
116.5	16.2	17.7	19.4	21.3	23.5	26.1	29.0
117.0	16.3	17.8	19.6	21.5	23.8	26.3	29.3
117.5	16.5	18.0	19.8	21.7	24.0	26.6	29.6
118.0	16.6	18.2	19.9	22.0	24.2	26.9	29.9
118.5	16.8	18.4	20.1	22.2	24.5	27.2	30.3
119.0	16.9	18.5	20.3	22.4	24.7	27.4	30.6
119.5	17.1	18.7	20.5	22.6	25.0	27.7	30.9
120.0	17.3	18.9	20.7	22.8	25.2	28.0	31.2

WHO Child Growth Standards

Weight-for-height BOYS
2 to 5 years (z-scores)

World Health Organization

cm	-3 SD	-2 SD	-1 SD	Median	1 SD	2 SD	3 SD
65.0	5.9	6.3	6.9	7.4	8.1	8.8	9.6
65.5	6.0	6.4	7.0	7.6	8.2	8.9	9.8
66.0	6.1	6.5	7.1	7.7	8.3	9.1	9.9
66.5	6.1	6.6	7.2	7.8	8.5	9.2	10.1
67.0	6.2	6.7	7.3	7.9	8.6	9.4	10.2
67.5	6.3	6.8	7.4	8.0	8.7	9.5	10.4
68.0	6.4	6.9	7.5	8.1	8.8	9.6	10.5
68.5	6.5	7.0	7.6	8.2	9.0	9.8	10.7
69.0	6.6	7.1	7.7	8.4	9.1	9.9	10.8
69.5	6.7	7.2	7.8	8.5	9.2	10.0	11.0
70.0	6.8	7.3	7.9	8.6	9.3	10.2	11.1
70.5	6.9	7.4	8.0	8.7	9.5	10.3	11.3
71.0	6.9	7.5	8.1	8.8	9.6	10.4	11.4
71.5	7.0	7.6	8.2	8.9	9.7	10.6	11.6
72.0	7.1	7.7	8.3	9.0	9.8	10.7	11.7
72.5	7.2	7.8	8.4	9.1	9.9	10.8	11.8
73.0	7.3	7.9	8.5	9.2	10.0	11.0	12.0
73.5	7.4	7.9	8.6	9.3	10.2	11.1	12.1
74.0	7.4	8.0	8.7	9.4	10.3	11.2	12.2
74.5	7.5	8.1	8.8	9.5	10.4	11.3	12.4
75.0	7.6	8.2	8.9	9.6	10.5	11.4	12.5
75.5	7.7	8.3	9.0	9.7	10.6	11.6	12.6
76.0	7.7	8.4	9.1	9.8	10.7	11.7	12.8
76.5	7.8	8.5	9.2	9.9	10.8	11.8	12.9
77.0	7.9	8.6	9.2	10.0	10.9	11.9	13.0
77.5	8.0	8.6	9.3	10.1	11.0	12.0	13.1
78.0	8.0	8.7	9.4	10.2	11.1	12.1	13.3
78.5	8.1	8.8	9.5	10.3	11.2	12.2	13.4
79.0	8.2	8.8	9.6	10.4	11.3	12.3	13.5
79.5	8.3	8.9	9.7	10.5	11.4	12.4	13.6
80.0	8.3	9.0	9.7	10.6	11.5	12.6	13.7
80.5	8.4	9.1	9.8	10.7	11.6	12.7	13.8
81.0	8.5	9.2	9.9	10.8	11.7	12.8	14.0
81.5	8.6	9.3	10.0	10.9	11.8	12.9	14.1
82.0	8.7	9.3	10.1	11.0	11.9	13.0	14.2
82.5	8.7	9.4	10.2	11.1	12.1	13.1	14.4
83.0	8.8	9.5	10.3	11.2	12.2	13.3	14.5
83.5	8.9	9.6	10.4	11.3	12.3	13.4	14.6
84.0	9.0	9.7	10.5	11.4	12.4	13.5	14.8
84.5	9.1	9.9	10.7	11.5	12.5	13.7	14.9
85.0	9.2	10.0	10.8	11.7	12.7	13.8	15.1
85.5	9.3	10.1	10.9	11.8	12.8	13.9	15.2
86.0	9.4	10.2	11.0	11.9	12.9	14.1	15.4
86.5	9.5	10.3	11.1	12.0	13.1	14.2	15.5
87.0	9.6	10.4	11.2	12.2	13.2	14.4	15.7
87.5	9.7	10.5	11.3	12.3	13.3	14.5	15.8
88.0	9.8	10.6	11.5	12.4	13.5	14.7	16.0
88.5	9.9	10.7	11.6	12.5	13.6	14.8	16.1
89.0	10.0	10.8	11.7	12.6	13.7	14.9	16.3
89.5	10.1	10.9	11.8	12.8	13.9	15.1	16.4
90.0	10.2	11.0	11.9	12.9	14.0	15.2	16.6
90.5	10.3	11.1	12.0	13.0	14.1	15.3	16.7
91.0	10.4	11.2	12.1	13.1	14.2	15.5	16.9
91.5	10.5	11.3	12.2	13.2	14.4	15.6	17.0
92.0	10.6	11.4	12.3	13.4	14.5	15.8	17.2
92.5	10.7	11.5	12.4	13.5	14.6	15.9	17.3
93.0	10.8	11.6	12.6	13.6	14.7	16.0	17.5
93.5	10.9	11.7	12.7	13.7	14.9	16.2	17.6
94.0	11.0	11.8	12.8	13.8	15.0	16.3	17.8
94.5	11.1	11.9	12.9	13.9	15.1	16.5	17.9
95.0	11.1	12.0	13.0	14.1	15.3	16.6	18.1



Weight-for-height BOYS
2 to 5 years (z-scores)

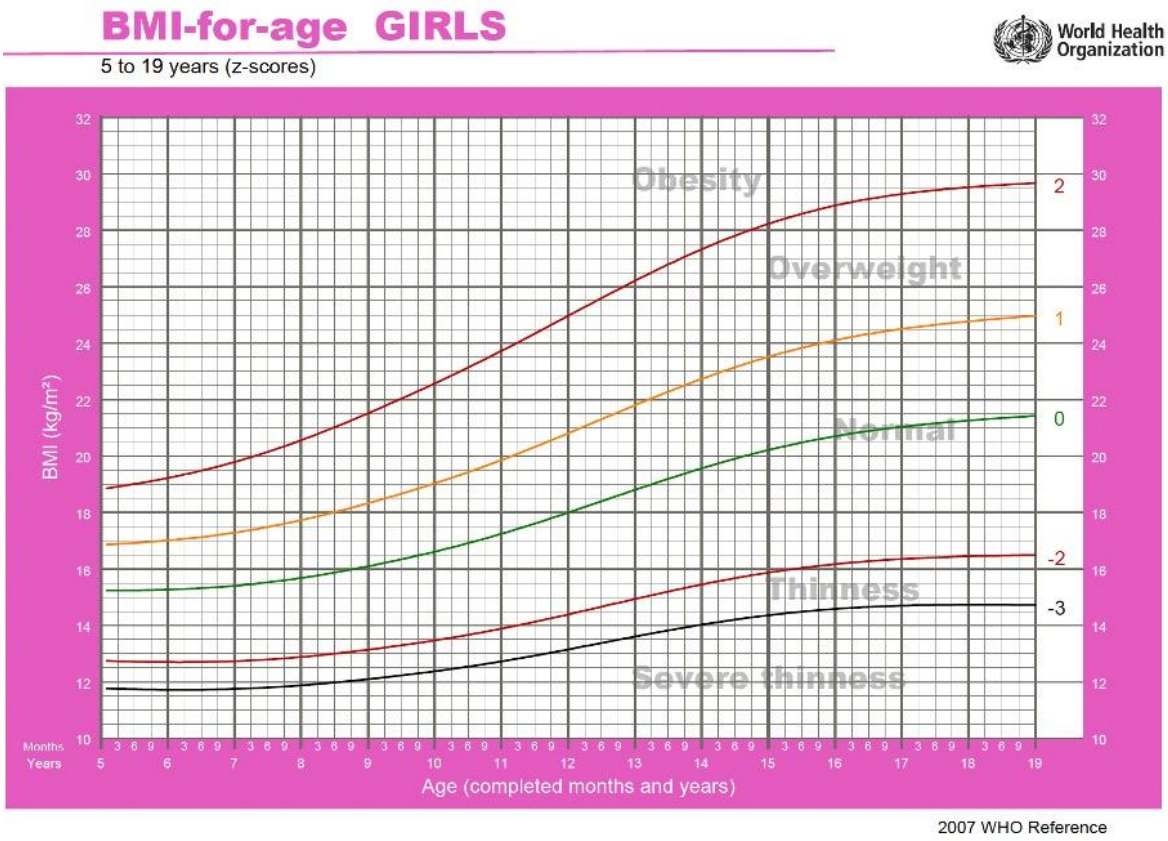
World Health Organization

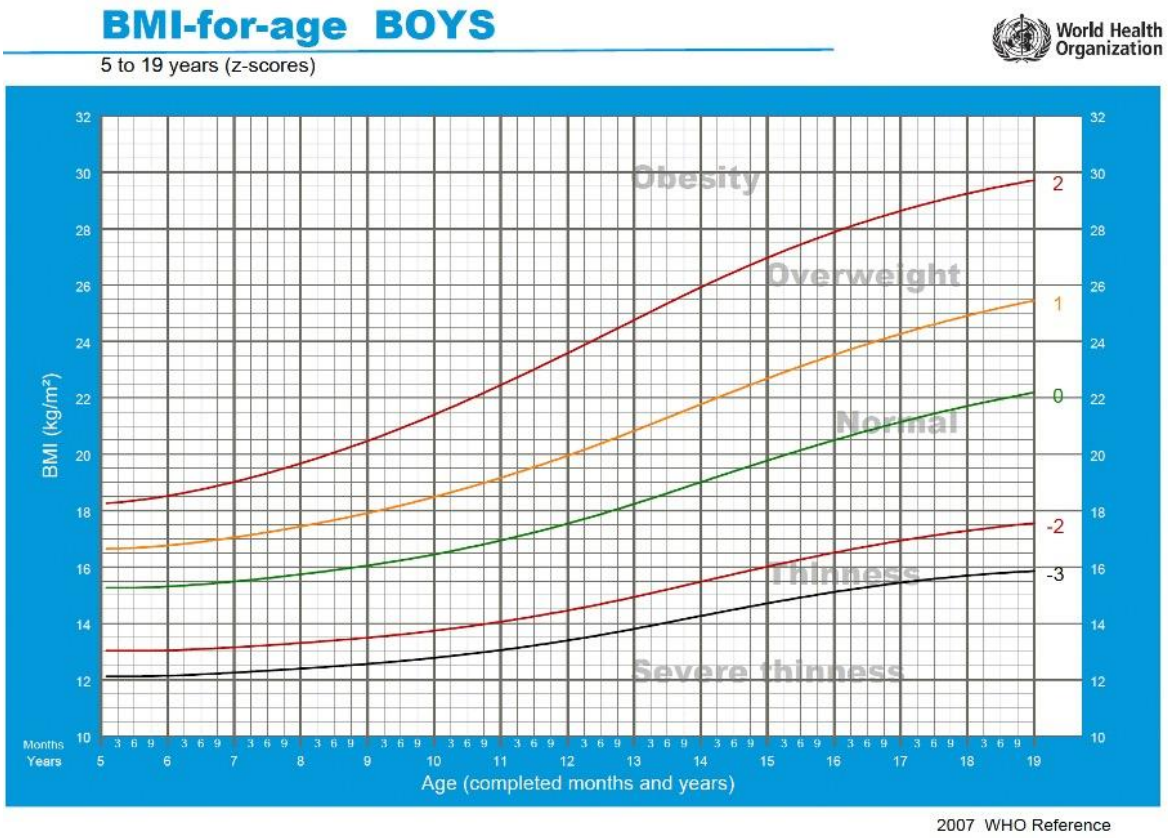
cm	-3 SD	-2 SD	-1 SD	Median	1 SD	2 SD	3 SD
95.5	11.2	12.1	13.1	14.2	16.4	16.7	18.3
96.0	11.3	12.2	13.2	14.3	15.5	16.9	18.4
96.5	11.4	12.3	13.3	14.4	15.7	17.0	18.6
97.0	11.6	12.4	13.4	14.6	16.8	17.2	18.8
97.5	11.6	12.5	13.6	14.7	15.9	17.4	18.9
98.0	11.7	12.6	13.7	14.8	16.1	17.5	19.1
98.5	11.8	12.8	13.8	14.9	16.2	17.7	19.3
99.0	11.9	12.9	13.9	15.1	16.4	17.9	19.5
99.5	12.0	13.0	14.0	15.2	16.5	18.0	19.7
100.0	12.1	13.1	14.2	15.4	16.7	18.2	19.9
100.5	12.2	13.2	14.3	15.6	16.9	18.4	20.1
101.0	12.3	13.3	14.4	15.6	17.0	18.5	20.3
101.5	12.4	13.4	14.5	15.8	17.2	18.7	20.5
102.0	12.5	13.6	14.7	15.9	17.3	18.9	20.7
102.5	12.6	13.7	14.8	16.1	17.5	19.1	20.9
103.0	12.8	13.8	14.9	16.2	17.7	19.3	21.1
103.5	12.9	13.9	15.1	16.4	17.8	19.5	21.3
104.0	13.0	14.0	15.2	16.5	18.0	19.7	21.6
104.5	13.1	14.2	15.4	16.7	18.2	19.9	21.8
105.0	13.2	14.3	15.5	16.8	18.4	20.1	22.0
105.5	13.3	14.4	15.6	17.0	18.6	20.3	22.2
106.0	13.4	14.5	15.8	17.2	18.7	20.5	22.5
106.5	13.5	14.7	15.9	17.3	18.9	20.7	22.7
107.0	13.7	14.8	16.1	17.5	19.1	20.9	22.9
107.5	13.8	14.9	16.2	17.7	19.3	21.1	23.2
108.0	13.9	15.1	16.4	17.8	19.5	21.3	23.4
108.5	14.0	15.2	16.5	18.0	19.7	21.5	23.7
109.0	14.1	15.3	16.7	18.2	19.8	21.8	23.9
109.5	14.3	15.5	16.8	18.3	20.0	22.0	24.2
110.0	14.4	15.6	17.0	18.5	20.2	22.2	24.4
110.5	14.5	15.8	17.1	18.7	20.4	22.4	24.7
111.0	14.6	15.9	17.3	18.9	20.7	22.7	25.0
111.5	14.8	16.0	17.5	19.1	20.9	22.9	25.2
112.0	14.9	16.2	17.6	19.2	21.1	23.1	25.5
112.5	15.0	16.3	17.8	19.4	21.3	23.4	25.8
113.0	15.2	16.5	18.0	19.6	21.5	23.6	26.0
113.5	15.3	16.6	18.1	19.8	21.7	23.9	26.3
114.0	15.4	16.8	18.3	20.0	21.9	24.1	26.6
114.5	15.6	16.9	18.5	20.2	22.1	24.4	26.9
115.0	15.7	17.1	18.6	20.4	22.4	24.6	27.2
115.5	15.8	17.2	18.8	20.6	22.6	24.9	27.5
116.0	16.0	17.4	19.0	20.8	22.8	25.1	27.8
116.5	16.1	17.5	19.2	21.0	23.0	25.4	28.0
117.0	16.2	17.7	19.3	21.2	23.3	25.6	28.3
117.5	16.4	17.9	19.5	21.4	23.5	25.9	28.6
118.0	16.5	18.0	19.7	21.6	23.7	26.1	28.9
118.5	16.7	18.2	19.9	21.8	23.9	26.4	29.2
119.0	16.8	18.3	20.0	22.0	24.1	26.6	29.5
119.5	16.9	18.5	20.2	22.2	24.4	26.9	29.8
120.0	17.1	18.6	20.4	22.4	24.6	27.2	30.1

WHO Child Growth Standards

Back to clinical and nutritional assessment

Appendix 32: BMI for age Charts





Back to clinical and nutritional assessment

Supervision Checklist

INTRODUCTION

The checklist has been developed to guide those officers who conduct supervision of HIV services as part of their responsibilities at the various levels of the health delivery system in The Gambia. The check list covers several aspects of the HIV services delivery system which need regular supportive supervision in hospitals and health centers. It helps to systematize the process so that you're comparing "apples to apples" and asking the same questions at every health facility you decide to visit.

Supervision of service delivery levels is particularly important because this is where services are provided to the public. The National AIDS Secretariat has a responsibility to ensure that these services are of acceptable quality.

The checklist provides the M&E team with a standard, summarized tool that can be used for effective and quick assessments of the health facility performance.

MAIN OBJECTIVE:

Its main objective is to guide and document supportive supervision with the aim of improving the quality of data as well as HIV and AIDS service delivery and management.

SPECIFIC OBJECTIVES:

To make onsite corrections in the field

To educate and train concerned health staff on the job

To collect critical information to take managerial decisions and provide feedback to concerned authorities and recommend measures for improvement

METHODOLOGY

Monitoring and Evaluation team conduct the supportive supervision exercise in selected district by visiting selected health facilities in the district providing HIV services.

Inform concerned authorities at the district level before the supervisory visit and give prior notice to the health facilities regarding the purpose and timing of the supportive supervisory visit.

Conduct the visit using the checklists provided.

Praise health center managers and health providers for any correct practices observed and provide on-site correction for any incorrect practices.

Train and orient health workers on correct practices. Also provide spot feedback to the concerned staff.

Conduct a repeat visit after an interval of 6 months in the same district and health facilities. Compare the results and assess if any progress has been made since the previous visit. Share the findings with concerned authorities

SUPERVISION CHECKLIST FACILITY LEVEL

Part A

Name of the Health Region _____

Name of Health Facility……

Date_____

Names of supervisory team members:

Name	Title	Responsibility

Person(s) contacted at the Health Region/ Health Facility

Name	Title	Responsibility

Part B.

Follow-Up

Action taken on key issues identified from the last supervisory visit:

_____

_____

_____

_____

_____

_____

Part C

Service Delivery Area

Voluntary Counseling and Testing (VCT)					
Service Delivery Area	Available		Reported data	Verified data	Any comment(s)
	Yes	No			
Number of women and men aged 15+ who received an HIV test and know their results					
Proportion of new individuals who test positive for HIV, enrolled in care (pre-ART or ART) services					

No	Counselling room arrangement	Yes	No	Any comment(s)
1	Private room for counseling			
2	Lockable cabinet for storing test results			
3	Availability of the current HCT guidelines, SOPs, protocols (including QA protocols)			
4	Availability and use of recording and reporting tools			
5	Availability/status of HCT services (VCT, PICT)			
6	Availability of minimum number of trained staff (3) for (VCT and PICT)			
7	Conduct referral and linkage with other interventions			
8	Conduct TB screening to PLHIV			
9	Space adequacy and privacy for counselling			
10	Availability and use of HIV test kits			
11	Availability of IEC messages specific for HCT			
12	Uninterrupted supply of HIV test kits (stock out days)			

Prevention of Mother-to-Child Transmission of HIV(PMTCT)

Service Delivery Area	Available		Reported data	Verified data	Remarks
	Yes	No			
Percentage of pregnant women who know their HIV status					
Number of pregnant HIV positive women enrolment into ART					
Percentage of antenatal care attendees tested for syphilis					
Percentage of infants born to HIV-positive women receiving virological test for HIV within 6-8 weeks of birth					

No	Room arrangement/Availability of commodities	Yes	No	Any comment(s)
1	Private room for counseling			
2	Lockable cabinet(s) for storing test results			
3	Availability and utilization of the current PMTCT guidelines and SOPs			
4	Availability and use of reporting forms and registers			
5	Availability of efficacious regimen for HIV positive pregnant women and exposed babies			
6	Space adequacy and privacy for counselling			
7	Availability and correct use of HIV test kits			
8	Availability and use of Syphilis rapid test kits			
9	Access to HIV Early Infant Diagnosis (EID-DNA/PCR) collection and transportation of Dried Blood Spot (DBS) samples			
10	Feedback of DBS results to health facility			
11	Follow-up of HIV exposed babies who have missed 6 weeks / 2months for initiation of NVP/ Co-trimoxazole			
12	Availability and use of TB screening tool			
13	Availability of IEC messages and materials			

Treatment, Care and Support Services					
Service Delivery Area	Available		Reported data	Verified data	Any comment(s)
	Yes	No			
Percentage of adults and children currently receiving antiretroviral therapy among all adults and children living with HIV					
Percentage of adults and children that initiated ART, with an undetectable viral load at 12 months (<1000 copies/ml)					

No	Room arrangement/Availability of commodities	Yes	No	Comments
1	Availability and utilization of current National Guidelines for the management of HIV and AIDS			
2	Availability of minimum number of trained staff for ART			
3	Availability and usage of reporting forms and registers			
4	Data management and its utilization			
5	CD4 testing to all pre-ART and ART patients for baseline and follow-up in every six Months			
6	Adherence assessment of all ART patients at every visit			
7	All patients on ART return to clinic for follow-up within one month of starting ART			
8	Co-trimoxazole prophylaxis given to all eligible HIV patients			
9	Availability and utilization of TB Screening tool			
10	Management of missed appointments and loss to follow up			
11	Number of patients on 2nd line regimen			
12	Conduct referral and linkage with other interventions / health and social services			
13	Space adequacy and privacy			

Collaborative TB and HIV

Service Delivery Area	Available		Reported data	Verified data	Comments
	Yes	No			
Percentage of HIV-positive patients who were screened for TB during HIV care or treatment					

No	Room arrangement/Availability of commodities	Yes	No	Comments
1	Availability and utilization of current national policy, treatment guidelines, and SOPs			
2	Status of HIV testing for TB patients			
3	Status of TB screening among PLHIV			
4	Conduct referral and linkage with other interventions / health and social services			

Part D

Drugs Supply Management

Anti-Retro-Viral Therapy				
Pharmaceutical services	Available		Days out of stock in past month	Remarks
	Yes	No		
Availability and adequacy of ARVs				
Availability and adequacy of medicines for co-infections				
Availability of the updated inventory control system (Tally cards)				
Availability and adequacy of medical supplies related to HIV and AIDS Services				

Monitoring and Evaluation (M&E)				
No	Room arrangement/Availability of commodities	Yes	No	Any comment(s)
1	Management of stock of the recording and reporting tools for each intervention			

2	Existence of Health Facilities data audit committee in the Regional Health Directorate			
3	Availability of Health Facilities data audit report			
4	Existence of the Joint ART Centre management and Heads of Health facilities in the catchment area and Regional Health Directorate quarterly meetings			
5	Minutes of the Joint ART Centre management and Heads of Health facilities meetings			
6	Implementation status of data quality assurance exercise to improve correctness and completeness of recording and reporting			
7	Timeliness of reporting from health facility to region			
8	Filing and storage of data/reports			
9	Evidence of data analysis, visualization, interpretation, feedback and use			
10	Data flow from health facility to national level			

LABORATORY

No	Services delivery area/ Laboratory	Yes	No	Any comment(s)
1	Conducive laboratory room for blood donation and counseling			
2	Lockable cabinet for keeping records.			
3	Availability of laboratory SOPs, including QA protocols			
4	Availability and use of recording and reporting tools			
5	Availability of minimum number of trained laboratory staff for the health facility level (refer national minimum staffing norms for health facilities)			
6	Availability and use of HIV test kits			
7	Availability and use of Hepatitis test kits			
8	Availability and use of syphilis test kits			
9	Availability and use of glucose meter			
10	Availability and use of molecular platform for viral load testing and EID			
11	Availability and use of CD4 count Machine			
12	Availability and use of Biochemistry machine			
13	Availability and use of Biochemistry reagents			
14	Availability of storage facilities (Refrigerator)			
15	Regular supply of electricity			
16	Availability of alternative sources of electricity supply			
17	Has the Health Facility's laboratory being accredited			

Challenges.

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Patient/Family Education Leaflet

Spontaneous Adverse Drug Reactions Reporting

There is no medicine which does not have side effects, even Paracetamol has side effects

Pleas avoid Over the Counter Medications and herbal medicines unless prescribed by the health care provider.

Please call any of the following immediately you feel any of the following symptoms:

Care Provider; Telephone Number:

Counselor; Telephone Number:

Adverse Reactions (Symptoms):

Headache; dizziness; drowsiness, sleep disturbances; depression; not able to sleep and other sleep disorders; depressive disorders

Rash; pruritus.

Nausea; vomiting; diarrhea; anorexia; abdominal pain/cramps; dyspepsia; stomatitis. Pale stools, dark urine, yellowing eyes/skin

Fast/difficult breathing; abnormal breath sounds/wheezing.

Fatigue; fever; musculoskeletal pain; muscle weakness

Note: Women to inform health care provider if pregnant or planning to become pregnant

<table>
<tr><td colspan="3">Medicines Control Agency
54 Kairaba Avenue
TEL: (+220) 9946188 /4380632/3515273
Reporting Form for Suspected Adverse Drug Reactions (STRICTLY CONFIDENTIAL)</td></tr>
<tr><td>1</td><td colspan="2">*PATIENT'S DETAILS</td></tr>
<tr><td></td><td colspan="2">Full Name or Initials: _____ Patient Record No: _____
AGE/DATE OF BIRTH: _____ SEX: M F WEIGHT (Kg): _____
Pregnant Yes ☐ No ☐ Not applicable ☐
HOSPITAL/ Treatment Center: _____</td></tr>
<tr><td>2</td><td colspan="2">*ADVERSE DRUG REACTION (ADR)/ADVERSE EVENT</td></tr>
<tr><td>A</td><td>DESCRIPTION</td><td rowspan="3">C. OUTCOME OF REACTION
TICK AS APPROPRIATE
Recovered fully ☐
Recovered with disability ☐
(Specify)_____
_____
Congenital Abnormality ☐
(Specify) _____
Life Threatening ☐
(Specify) _____
Death ☐
Others ☐
(Specify)_____</td></tr>
<tr><td></td><td>DATE Reaction Started</td><td>DATE Reaction Stopped</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>B</td><td colspan="2">Was Patient Admitted Due to ADR Yes ☐ ☐
If Already Hospitalized, Was It Prolonged Due to ADR Yes ☐ ☐
Duration of Admission (days) _____
Treatment of Reaction: _____</td></tr>
<tr><td>3

A</td><td colspan="2">*SUSPECTED DRUG (including Biologicals, Traditional/Herbal medicines)
DRUG DETAILS (state name and other details if available/ attach product label/ Sample (available)
Brand Name: _____ Generic Name: _____ Batch No._____
MCA No: _____ Expiry Date: _____</td></tr>
</table>

	Name & Address of Manufacturer: _____				
B	Indication for use	Dosage	Route of Administration	Date Started	Date Stopped

4	*CONCOMITANT MEDICINES (All medicines taken within the last 3 months including herbal and self-medication)					
	Brand or Generic Name	Dosage	Route	Date started	Date stopped	Reason for use
5	*SOURCE OF REPORT:					
	Name of Reporter: _____ Address: _____ Profession: _____ Signature: _____ Date: _____ Tel No/Email: _____ *MANDATORY FIELDS					

FORMS CAN BE SENT BY EMAIL TO MEDICINES CONTROL AGENCY: info@mca.gm

Annex: Standard Operating Procedures (SOPs) for Linkage to HIV Care

These SOPs provide standardized guidance to ensure that individuals diagnosed with HIV are promptly linked to care, treatment, and support services in The Gambia. They are aligned with WHO 2021 guidelines and the Gambia National DSD Guideline (2023).

1. Purpose and Scope

To ensure consistent and timely linkage of all individuals newly diagnosed with HIV to ART and related services. These SOPs apply to all HTS points, ART clinics, and community outreach programs providing HIV testing services in The Gambia.

2. Definitions

• Linkage to Care: The process of connecting individuals diagnosed with HIV to HIV treatment, prevention, and support services.

• Same-Day ART Initiation: Starting ART on the same day as HIV diagnosis, unless contraindicated.

• Linkage Focal Person: A trained staff member responsible for supporting and tracking linkage of clients from diagnosis to ART initiation.

3. Roles and Responsibilities

• HTS Provider: Conduct testing, provide pre- and post-test counselling, and refer for ART.

• Linkage Focal Person: Escort clients, initiate referral, track and follow-up linkage within 7 days.

• ART Provider: Confirm diagnosis, assess readiness, initiate ART, and document linkage.

• Community Health Worker (CHW): Conduct follow-up of clients diagnosed in the community or lost to follow-up.

4. Linkage Workflow

Step 1: HIV diagnosis and post-test counselling with referral to ART services.

Step 2: Escort by Linkage Focal Person to ART clinic.

Step 3: ART readiness assessment and same-day ART initiation when possible.

Step 4: Schedule follow-up counselling and enrolment into chronic care.

Step 5: For community diagnoses, initiate referral within 24 hours and confirm enrolment within 14 days.

5. Documentation and Monitoring

• Use linkage registers to record all diagnosed clients and track ART initiation.

• Record referral outcomes and follow-up attempts.

• Report monthly on linkage indicators: % initiated on ART within 7 days.

6. Quality Assurance

• Supervisors to review linkage data during site visits.

• Regular feedback to HTS and ART teams on performance.

• Address gaps through coaching and review meetings.

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