National AIDS Secretariat **Republic of The Gambia**

Guidelines for Antiretroviral Therapy and Prevention for HIV in The Gambia

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Foreword

The HIV and AIDS epidemic continues to pose a threat to public health, economy, and indeed to national security of The Gambia. The fast-changing dynamics in the comprehensive prevention, treatment, care and support of Persons Living with HIV (PLHIV) using Antiretroviral Therapy (ART) has become an inevitable stimulus for regular revision of treatment guidelines.

Recently published guidelines for the care of PLHIV by the World Health Organization (2013) coupled with emerging new evidence in therapeutic guidelines and important program and research data makes it imperative for countries including The Gambia to update their guidelines for ART. It is against this backdrop that these guidelines are being developed to improve therapeutic decisions and overall quality of management of PLHIVs.

The WHO issues its first consolidated guidelines for the use of antiretroviral drugs (ARVs) to treat and prevent HIV infection. The guidelines are ambitious in their expected impact, yet simplified in their approach, and firmly rooted in evidence. They take advantage of several recent trends, including a preferred treatment regimen that has been simplified to a single fixed-dose combination pill taken once per day, which is safer and affordable.

The guidelines also take advantage of evidence demonstrating the multiple benefits of ART. With the right therapy, started at the right time, PLHIVs can now expect to live long and healthy lives. They are also able to protect their sexual partners and infants as the risk of transmitting the virus is greatly reduced.

The national ART program continues to register successes despite several challenges. Through continued decentralization of ART services, more people are now able to access such services closest to their homes. The Government of The Gambia remains committed to offering ARVs free of charge to PLHIV at public health facilities as a policy in order to overcome potential economic access challenges. The rational use of such medicines is imperative if we are to achieve Universal Access targets. Using guidelines simplifies clinical decision making which allows the use of other cadres other than doctors in the delivery of ART.

It is my expectation that these updated guidelines will further facilitate the work of our hardworking service providers to ensure standardized treatment, care and support for PLHIV in the Gambia.

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Ag. Director of Health Services

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The Development of the guidelines was led by Lead Facilitators, Dr. Saihou T. Sabally and Mr. Momodou K. Cham who were supported by a team from partner organizations and other stakeholders. We wish to thank them all for their hard work and dedication.

We are also grateful to the following individuals who tirelessly worked to provide the evidence for the updating of the national guidelines:

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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.

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Table 2: Definition of Key Terms

Adolescent	Aged 10 to 19 years inclusive
Early Adolescent	Age 10 to 15 years
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	10 years of age and younger
Client Initiated Counseling & 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
Eligible for ART	Refers to people living with HIV for whom ART is indicated
Healthcare provider	Anyone who renders healthcare; includes doctors, nurses, counselors
HIV symptomatic Infant	Any HIV-exposed infant displaying failure to thrive, hematological 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
Infant Child	younger than one year of age
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 2-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 (<50 copies/ml)

Table 3: List of Acronyms/Abbreviations

3TC: Lamivudine	NADCs: Non-AIDS defining cancers
ABC: Abacavir	NGO: Nongovernmental organization
AIDS: Acquired immunodeficiency Syndrome	NHL: Non-Hodgkin's Lymphoma
ART: Antiretroviral therapy ARVs Medicines for treating HIV	NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor
AZT: Zidovudine	NRTI: Nucleoside Reverse Transcriptase Inhibitor
ATV/r: Atazanavir/ritonavir	NtRTI: Nucleotide reverse transcriptase inhibitor
BCG: Bacille Calmette-Guérin	NVP: Nevirapine
CHBC: Community- and home-based care	OGTT: Oral Glucose Tolerance Test
CD4: Cluster of differentiation 4	OI: Opportunistic infection
CICT: Client Initiated Counselling &Testing	PJP: Pneumocystis Jirovecii Pneumonia
CMV: Cytomegalovirus	PCR: Polymerase chain reaction
CSF: Cerebrospinal fluid	PEP: Post Exposure Prophylaxis
D4T: Stavudine	PrEP: Pre-Exposure Prophylaxis
ddI: Didanosine	PI: Protease inhibitor
DNA: Deoxyribonucleic acid	PICT: Provider-Initiated Counseling and Testing
DTG: Dolutegravir	PLHIV: People Living with HIV
EID: Early infant diagnosis	PMTCT: Prevention of Mother-To-Child Transmission of HIV
FDC: Fixed-dose combination	RNA: Ribonucleic Acid
FP: Family planning	RTV: Ritonavir
GI: Gastrointestinal	SEQAAAR: Safe, Efficacious, Quality, Affordable, Accessible, Available & Rationally used
HBIG: Hepatitis B immune globulin	SQV: Saquinavir
HBV: Hepatitis B virus	STI: Sexually Transmitted Infection
HCT: HIV Counselling and Testing	TasP: Treatment as Prevention
HCW: Health Care Worker	TB: Tuberculosis
HIV: Human immunodeficiency virus	TDF: Tenofovir
HL: Hodgkin's Lymphoma	TLD: Tenofovir Lamivudine Dolutegravir
HPV: Human papilloma virus	UNAIDS: The Joint United Nations Program on HIV and AIDS
ICP: Intracranial pressure	VCT: Voluntary Counselling and Testing
IDV: Indinavir	VEN: Vital, Essential, Necessary
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	

Chapter One

1.0 Introduction

Antiretroviral therapy (ART) remains an integral part of the provision of comprehensive services for HIV and AIDS prevention, treatment, care, and support. The goal of ART is to reduce morbidity and mortality due to HIV and AIDS as well as to improve the quality of life of people living with HIV (PLHIVs). The coverage of ART in the Gambia as at December 2019 at 29% (2019). It is envisaged that this coverage will increase to over 80% by 2019 (NSP 2014-19). This will be achieved through intensifying reduction of HIV stigma, massive scale up of HIV counselling and testing including the communities, strengthening the health system to meet increasing demand for HIV treatment, care and support services, resulting from the implementation of 2013 WHO HIV treatment guidelines.

As at December 2013, 4,006 PLHIV are on ART based on CD4 <350, clinical stages (3 and 4) and co-infection (TB and Hepatitis B and C). About 60% of these patients are enrolled in the public health facilities and 40% in private facilities. Forty four percent (44%) of the patients are enrolled in two urban sites showing the concentration of the services in major urban areas. Secondly, about 90% of the PLHIV on ART are adults over 15 years while children make up about 10%.

It is hoped that with the adoption of the 2013 WHO consolidated treatment guidelines of CD4 (equal to or below) <500, more people will be put on ART and coverage is expected to increase from about
21% (2013) to 95%.

According to the World Health Organization (WHO), "Universal access refers to establishing an environment in which HIV treatment, care and support services are available, accessible and affordable to all who need them. It covers a wide range of interventions that are aimed at individuals, households, communities and countries (WHO post- 2015 development agenda).

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

It is now widely accepted that even resource-poor countries using a public-health approach to HIV and AIDS care and treatment, can achieve similar effectiveness with these antiretrovirals (ARVs) as observed in more affluent settings.

HIV treatment, care and support service started in the Gambia on a small scale at Medical Research Council (The Gambia) before the year 2000. The Accelerated Results Implementation (ARI) funded by the World Bank kick started the HIV treatment, care and support programme in 2004. Piloted sites were then Royal Victoria Teaching Hospital (now EFSTH), Medical Research Council and Hands-On Care

In 2003, the Government of the Gambia secured a grant from the Global Fund (GFR3) to implement HIV treatment, care and support services for a period of 5 years. This was successfully implemented and subsequently moved to the GFR8 HIV grant, which ended in November 2014. The provision of ART services was later decentralized and scaled up to cover to all the regions in the country, currently 14 sites.

HIV comprehensive treatment, care and support services, is delivered at accredited treatment centres prescribed by accredited clinicians and all facilities providing ART are regularly monitored. In The Gambia, ART is part of a comprehensive HIV Care package that includes clinical care, counselling, nutritional and socio-economic support.

The increase in patient volume over time has resulted in the need for the available human resources towards multi-tasking/task-sharing to enable the ART program to achieve universal access. Decentralization of services will need to continue, to allow clients to have ART facilities nearer to their homes. Capacity building through health-care worker training and the use of treatment guidelines including HIV clinical mentoring has allowed the dramatic scaling up and standardization of HIV treatment, care and support services in the Gambia. Thus, with effective management of HIV and AIDS, PLHIVs should continue to live quality and productive lives.

The achievements and sustainability of the national ART program will depend on the rational use of available medicines and appropriate monitoring of patients to ensure medication adherence to treatment and minimize both ARV medicine resistance and adverse events.

At all levels of care, appropriate initiation of ART, using the recommended first-line regimen should be emphasized. The first-line regimen has good efficacy and careful adherence support, monitoring for side-effects, and OI management, should result in a large number of patients remaining on this regimen for many years. The 2013 WHO guidelines emphasize the need to consider the quality of life of those on ART, by using safer medicines as well as starting ARVs earlier. Thus, the CD4 count threshold for starting ART will be raised to 500.

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 and clinical wards as well as the following services: Client-Initiated counseling and Testing (CICT) or Voluntary Counseling and Testing (VCT), Provider-Initiated counseling and Testing (PICT), index testing, self-testing, family testing, mobile testing Prevention of Mother-To-Child Transmission and Early Infant Diagnosis (PMTCT/EID), Expanded Program on Immunization (EPI), TB, Sexually Transmitted Infections (STIs), Family Planning (FP), and Community- Home-Based/Palliative Care (CHBPC).

1.3 Highlights from the Revised HIV Treatment Manual

ART must be started in all those with WHO clinical stages III and IV of HIV disease and in the WHO Consolidated Guidelines, 2013. However, do not insist on seeing a CD4 lymphocyte count result in such patients. Where CD4 count testing is available, ART should be started in view of our national policy of Test and Treat (2018)

Prioritization for ARVs will occur as follows:

1. Regardless of the CD4 count or percentage:
   - ART for all HIV +ve pregnant and lactating women
   - All HIV+ve partners in sero-discordant couples
   - All HIV+ve children below 5 years old
2. The preferred first-line regimen for adults, adolescents, and older children will be Tenofovir, Lamivudine and Dolutegravir.
3. Lifelong ART for HIV positive pregnant and lactating women will be given for PMTCT regardless of a CD4 count.
4. Early infant diagnosis (EID) using Dried Blood Spots (DBS) continues.
5. Early initiation of ART in HIV-infected children, under 5 years of age regardless of immunological or clinical status.
6. Promote exclusive breastfeeding for the first 6 months and thereafter complementary feeding until the child is tested at 18 months.
7. If the serology test at 18 months is negative, mother should be encouraged to stop breast feeding. If positive continue breast feeding.
8. First-line regimens for infants under 3 years will include the use of a protease inhibitor (PI).
9. Targeted gradual phasing in of viral load and CD4 monitoring will remain.

Given the maturation of our ART program, an increasing number of clients may require both second- line and third-line regimens, but those numbers can be kept low if ART services are scaled up with intensive monitoring and early warning indicator signs (EWIS) of HIV treatment failures and subsequent resistance.

1.4 Adherence to ART

After HIV diagnosis, timely entry into HIV medical care and retention in that care are essential to the provision of effective antiretroviral therapy (ART). Adherence to ART is among the key determinants of successful HIV treatment outcomes and is essential to minimize the emergence of drug resistance.

ART services are no longer primarily focused on the potency of the treatment regimens, adherence to ART treatment regimens is extremely important. We must provide support for enhanced adherence, so that adherence rates are achieved. By minimizing the pill burden through the use of fixed-dose combination (FDC), the treatment regimens have been simplified (1) check and verify.

1.5 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 4).

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 4: 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 dangers of infection, complications, modes of transmission, methods of prevention, and treatment
Promote safer sexual Behavior (behavioral change)	Encourage the following: ▪ Abstaining from sexual activity altogether ▪ Delaying first sexual experience ▪ Avoiding situations that may promote casual sexual liaisons ▪ Avoiding multiple concurrent partnering ▪ Using condoms correctly and consistently
Promote early STI-care seeking	▪ Promote good STI-care-seeking behavior ▪ Make STI services accessible and acceptable
Promote testing and counseling for HIV and AIDS	▪ Increase access to testing and counseling for HIV and AIDS ▪ Scale up PITC and VCT/CITC
Prevent mother-to-child transmission of HIV	▪ Strengthen PMTCT activities ▪ Prioritize provision of lifelong ART to pregnant and lactating
Promote ARVs	▪ Promote early access to ARVs ▪ Promote ARVs in sero-discordant couples

1.6 Guiding Principles

1.6.1 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.

In general, HIV programmes need to ensure that ARV drugs and related interventions are accessible to the people who need them most, including pregnant women, children and key populations, and that they are provided in an environment that minimizes stigma and discrimination.

Informed consent – notably for HIV testing but also for initiating ART – should always be obtained. Adequate safeguards must be in place to ensure confidentiality

A key challenge may involve the need to give priority to ensuring ART for the people who are most ill and those already receiving treatment, while also striving to implement expanded eligibility criteria. Each Program will need to plan its own approach to ensuring that current ARV programmes are not disrupted and that expanded access is fair and equitable.

1.6.2 Increasing Effectiveness and Efficiency of Programmes:

Due to the limited resources and competing priorities within a strained health system, it is essential to give priority to providing ARV drugs to people living with HIV who are eligible and most in need to achieve the desired impact.

Chapter Two

2.0 Principles of Antiretroviral Therapy (ART)

The guiding principles for effective ART include:

- Potency of regimens chosen,
- Minimum adverse events,
- Reduced pill burden, and
- Accessibility and affordability of the medicine combinations.

The reduced pill burden will be achieved by using FDCs of antiretroviral medicines. Although, the potency (efficacy) of the regimen is important, adherence to treatment with a simple regimen will ensure that the ongoing viral replication is maximally suppressed, thus allowing the immune status to recover. While Plasma viral load (VL) measures viral replication, the effect of ART on the immune system is monitored using the CD4 lymphocyte count in most patients or CD4 percentage in children under five years.

Health-care workers will need to receive continuing medical education to remain up to date on ART recommendations. Guidelines change as new evidence emerges from clinical trials and lessons are learnt from program experiences. The need for those involved in managing patients on ART to undergo frequent retraining and evaluation cannot be overemphasized.

ART requires in-depth knowledge about antiretroviral agents, their side effects, and issues such as immune reconstitution inflammatory syndrome (IRIS). Being able to detect and manage OIs, knowing when to initiate ART, and knowing when to change medicines, as toxicities occur or when to switch to second-line or even third-line therapy, as well as counseling abilities, are all necessary skills for healthcare workers. Such skills can be acquired with the relevant training and experiential learning. Clinical attachments, clinical mentoring, task shifting and supportive supervision are tools to improve health-care workers' skills in all disciplines, including ART delivery.

Adherence to treatment regimens and schedules is crucial to the success of this therapy. Without high adherence rates, viral resistance to the medicines emerges readily. Hence, there is need to be vigilant and monitor patients during ART for adherence to treatment rates, side effects, and treatment failure. Treatment failure should alert the health-care worker on the need to switch to second- line or third- line therapy where available.

Switching to second-line therapy will be based on a combination of clinical monitoring, viral load plus a minimum laboratory testing (CD4 count). Access to VL testing is improving and should be considered on targeted basis as gold standard when switching to second or third-line therapy.

Given the maturing ART program, third-line therapy may shortly become necessary. The use of such third-line regimens will require close consultations with those specialists who have experience treating clients who are "ART experienced."

2.1 Goals of ART

The aims of ART are as follows:

- Maximal and durable suppression of replication of HIV
- Restoration and/or preservation of immune function
- Reduction of HIV-related morbidity and mortality
- Improvement of quality of life
- Prevention of mother-to-child transmission of HIV (vertical transmission)
- Reduction of transmission of HIV from infected to uninfected individuals through use of ARVs by the infected individual now commonly known as 'Treatment as Prevention' (TasP)

Prior to starting ART patients should be assessed for; readiness to take ARVs, the ARV regimen, dosage and scheduling, the likely potential adverse effects and the required monitoring.

Both medical and psychosocial issues need to be addressed before initiating ART. Patients should be adequately counseled about adopting appropriate lifestyle measures such as safer sex practices (including correct and consistent use of condoms), and any other psychosocial problems that may interfere with adherence on treatment (e.g., alcohol, psychiatric disorders) should be addressed.

At each clinic visit always screen for tuberculosis using a TB symptom checklist, advice people with tuberculosis about adequate nutrition and the importance of medicine adherence and regular follow-up care. People taking ARVs should also be regularly asked on whether they are taking other medications including herbal remedies that may interfere with the efficacy of ARVs.

Early treatment initiation is associated with clinical and HIV prevention benefits, improving survival and reducing the incidence of HIV infection at the community level. Increasing evidence also indicate, that untreated HIV may be associated with the development of severe non-AIDS defining conditions, including cardio-vascular disease, kidney disease, liver disease and neurocognitive disorders.

2.2 Characteristics of Available ARVS

Medicines in use in most of our program belong to the following classes:

1. Nucleoside Reverse Transcriptase Inhibitors (NRTIs). These medicines block the HIV reverse transcriptase enzyme and prevent the copying of the viral RNA into the DNA of infected host cells by imitating the building blocks of the DNA chain. The resulting DNA chain is incomplete and cannot create new viruses.
2. Nucleotide Reverse Transcriptase Inhibitors (NtRTIs). These medicines act at the same stage of the viral life cycle as do NRTIs but have a better resistance profile.
3. Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). These medicines also block the HIV reverse transcriptase enzyme, but have a different mechanism of action than the NRTIs and the NtRTIs.

4. Protease Inhibitors (PIs). These medicines block the enzyme protease and prevent the assembly and release of HIV particles from infected cells.
5. Integrase Inhibitors (IIs). These medicines target HIV's integrase protein, blocking its ability to integrate its genetic code into human cells.

These following additional classes of ARVs are not yet in use in the Gambia:

1. Fusion Inhibitors (FIs). These work by preventing HIV from entering healthy CD4 cells by blocking proteins on the surface of CD4 cells.
2. CCR5 Inhibitors. These block the CCR5 co-receptor that HIV uses to enter and infect the cell. CCR5 works specifically against CCR5-tropic HIV. Before treating a patient with a CCR5 inhibitor, a test to determine the strain of virus is necessary.

By prescribing and dispensing FDCs, we can reduce the patient's pill burden and improve medication adherence. Use a boosted PI (a PI plus ritonavir) where a PI is indicated. Table 3 on the following page shows the different categories of ARVs.

Table 5: Classes of ARVs

Nucleoside reverse Transcriptase Inhibitors	Non-Nucleoside reverse Transcriptase Inhibitors	Integrase Inhibitors	Protease Inhibitors
Tenofovir (TDF) (NtRTI)	Nevirapine (NVP)	Dolutegravir (DTG)	Lopinavir/ritonavir (LPV/r)
Zidovudine (AZT, ZDV)	Efavirenz (EFV)	Raltegravir (RAL)	Atazanavir/ritonavir (ATV/r)
Lamivudine (3TC)			Darunavir (DRV/r)
Abacavir (ABC)			
Fusion Inhibitor			CCR5 Inhibitor
Enfuvirtide			Maraviroc

2.3 Efficacy and Safety of ARVs

Regimens based on two NRTIs plus one Integrase Inhibitor (II) are efficacious, less expensive, have generic formulations, and available as FDCs. PIs should generally be preserved for second-line or third-line therapy and for infants where available.

The preferred first line regimen is Tenofovir (TDF), Lamivudine (3TC) and Dolutegravir (DTG). Dolutegravir has relatively few adverse effects and is taken once daily. Zidovudine (as an alternative to Tenofovir) can cause anaemia but is less likely to cause peripheral neuropathy.

Dolutegravir: All ARVs have class-specific side effects, and individual medicines may cause specific side effects (*see Table 17 in Section 7.5).* In addition, significant medicine interactions and toxicities may occur when using some ARVs in combination with each other and with other medicines such as TB medicines.

Nevirapine can cause a rash and hepatotoxicity, and thus should be used with caution.

Chapter Three

3.0 Initiation of ART in Adults and Adolescents

ART initiation is now based on a Test and Treat Strategy. However, the initiation should be seen as a non-emergency intervention. Various approaches should be used to help prepare people to begin treatment to avoid them starting ARVs before they are ready. This will reduce unacceptably high rates of loss to follow-up and inadequate adherence after HIV diagnosis and treatment.

The following principles should be used to guide initiation of ART

1. Treatment should be started based on a person's informed decision to initiate ART.
2. Implement interventions to remove barriers to ART initiation
3. Promote treatment literacy among all people living with HIV,
4. Support shared decision-making.
5. Although ART initiation is rarely urgent, it may need to be expedited in certain circumstances, such as serious ill health and for pregnant women in labour whose HIV test result is positive.
6. Completion of Pre-ART counseling session(s)
7. Availability of a treatment supporter/partner

3.1 Issues to Consider when Initiating ART in Children

- **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.

- **Disclosure:**

The process of disclosure to the child should be initiated as early as possible, usually from as early as 5 – 7 years of age. Adherence is good in children who know their status and are supported to adhere to medicines.

- **Adherence to ART:**

Continued support for good adherence

Recommendations for ART in children need to take into consideration the following:

a) Age and weight of the child
b) Availability of paediatric formulations of the medicines
c) Palatability of the medicines
d) Effect of food on the absorption of the medicines.

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.

NOTE: ***STARTING ART IS GENERALLY NOT AN EMERGENCY. PATIENTS SHOULD BE ADEQUATELY PREPARED FOR IT***

3.2 Adherence to ART

WHO defines treatment adherence as 'the extent to which a person's behaviour- taking medications, following a diet and/or executes lifestyle changes' corresponds with agreed recommendations from a health care provider.

Efforts to support adherence should start before ART initiation and should include basic information about HIV, the ARV medicines, expected adverse events, preparations for long-term ART. Many factors affect adherence to treatment. Patients may just forget to take their ARVs, be away from home, be depressed or may abuse alcohol. Medication factors may include adverse events, pill burden, and dietary restrictions etc. Health care factors include medicine stock outs, long distances to health facilities and costs related to care.

Effective adherence support interventions include client-centred behavioural counseling and support, support from peer educators trained as "expert patients," community treatment supporters and mobile text messaging. High quality evidence from randomized trials has shown that text messages contributed to reduced non-adherence on treatment and unsuppressed viral load. Other interventions involve, encouraging people to disclose their HIV status and providing them with adherence tools such as pill boxes, diaries, and patient reminder aids. During follow-up, patients should be assessed for adherence on treatment to whatever treatment plan has been agreed upon in preparation and initiation of ART.

3.3 ART in Adolescent

3.3.1 Who is an adolescent?

The WHO defines "**an adolescent" as a child between the ages of 10 and 19 years**. This period of life encompasses many physiological and psychological changes that should be taken into account when treating an adolescent. Adolescences are vulnerable to and are at relatively high risk of HIV infection especially the adolescent girls and those from key affected populations. In addition, they are often underserved and given insufficient priority in many HIV programs, with poor access to and uptake of HCT and linkages to prevention and care.

3.3.2 Principles of ART in Adolescents

The principles of therapy are similar to those in adults and children. However, one should bear in mind specific issues, when monitoring and treating HIV- positive adolescents, which are discussed in the following sections.

3.3.3 Dosage of ART

Decisions regarding the choice and dosage for adolescents should take the following factors into account:

- The weight: children and adolescents weighing at least 20Kg can take the 50mg film coated adult tablet of DTG

All adolescents— regardless of age—should therefore be weighed before commencing ART.

Effective contraception should be offered to adolescent girls of childbearing age prior to prescribing DTG.

DTG can be prescribed for adolescent girls of childbearing age who wish to become pregnant or who are not otherwise using or accessing consistent and effective contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester).

3.4 Starting ART in Children using FDCs

Refer to dosing table (and also see Appendix 1). Keep the following factors in mind with regard to dosing:

- Medicine doses must be adjusted as the child grows.
- Dosing is by weight.
- Scored tablets may be divided into two equal halves

Tablets may be crushed and mixed with a small amount food or water and administered immediately.

- Give clear explanation to the caregiver.
- Use pillboxes if available.
- Standardization is important to safely dispense correct doses

3.5 Staging HIV-Positive Adolescents and Criteria for Starting ART

Refer to Appendix 2 on clinical staging for adults and adolescents.

HIV-positive adolescents are at risk not only of the HIV-associated infections typically used to stage HIV-positive adults, but also of chronic non-infective complications typically used to stage paediatric HIV. These specifically include chronic lung disease, lymphoid interstitial pneumonitis (stage 3) and HIV-associated cardiomyopathy/nephropathy and stunting (stage 4).

3.6 Disclosure of HIV Status in Adolescents

Lack of knowledge of HIV status can result in poor adherence on treatment to ART. Adolescents should be involved in the discussion about HIV testing, and their HIV status, should be disclosed to them. Do not assume that adolescents are aware of their HIV status.

Unless exceptional circumstances, make it difficult for an adolescent to understand his or her HIV status (severe mental disability), it is strongly recommended that HIV status be disclosed before the patient starts ART.

Disclosure is a gradual process and should be carried out with the involvement of the guardian, a counsellor, and the healthcare worker

3.7 Adherence to ART

Adherence to ART is particularly problematic in adolescents. Particular attention should be paid to assessing adherence at every visit and to providing adherence support. Counseling on treatment adherence should include exploring specific reasons that may contribute to poor adherence. Adolescents face many psychosocial issues that can affect their adherence, and those should be assessed:

- In particular, ways of supporting attendance at clinic appointments and taking medicines while at school (especially for those at boarding schools) should be addressed.
- Patients should be encouraged to identify a family member who will help support their treatment.
- Counseling should be adolescent-friendly, and counseling patients on their own without the presence of guardians/parents is recommended whenever possible. This ensures that patients can talk about personal issues that affect their ability to take medicines.

3.8 Education and Information on Sexual and Reproductive Health

Education about sexual and reproductive health should be part of the counseling and treatment of HIV positive adolescents. Education and information should be tailored, according to the patient's own knowledge and maturity. This clearly varies across the age groups and should be assessed during counseling.

Specific information that should be given to adolescents includes information on:

- Avoiding onward HIV transmission, including delaying sexual relationships and using condoms;
- Specific modes of HIV transmission (it is a common misconception that kissing and non-sexual physical contact can transmit HIV); and
- Where to access family planning services and STI treatment and how to seek help in cases of sexual assault.

Chapter Four

4.0: Recommended Treatment Regimens for Adults and Adolescents

4.1 Introduction

The choice of medicine regimen is based on current WHO recommendations. This guideline provides the latest recommendations based on rapidly evolving evidence of safety and efficacy and programmatic experience of using newer ARVs (DTG, RAL). Dolutegravir (DTG) in combination with a nucleoside reverse-transcriptase inhibitor (NRTI) backbone recommended as the preferred first-line regimen for people living with HIV initiating ART.

A Raltegravir (RAL)-based regimen may be recommended as the alternative first-line regimen for infants and since the National Pharmaceutical Services (NPS) has stocks of Efavirenz based regimen, the new regimen will commence after stocks have been exhausted.

As a nation we will be providing for infants exposed to HIV, NVP syrup for type 1 and AZT syrup for type 2 and dual for prophylaxis.

4.2 First-line ARV Regimens

Table 6: First-line regimen for Adults and Adolescents including pregnant and breastfeeding women

Population Type	Preferred Regimens	Alternative Regimens
Adults and adolescents (≥ 30kg, TB/HIV, HBV/HIV)	TDF + 3TC + DTG	TDF + 3TC + LPV/r TDF + 3TC + ATV/r TDF + 3TC + RAL
Children (20-30kg)	ABC + 3TC + DTG	ABC+ 3TC + NVP ABC + 3TC + LPV/r
Children (<20kg)	ABC + 3TC + NVP	ABC + 3TC + LPV/r ABC + 3TC + RAL
Neonates	AZT + 3TC + RAL	AZT + 3TC + LPV/r AZT + 3TC + NVP

NOTE: The regimens above are effective for both HIV 1 and 2.

CAUTION: Tenofovir (TDF) may be associated with acute kidney Injury or chronic kidney disease as well as reduced bone mineral density in pregnant women.

Clinical considerations when using TDF:

1. Laboratory monitoring is mandatory in initiating treatment with TDF.
2. Routine blood pressure monitoring may be used to assess for 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.

Table 7: Calculation of GFR or Creatinine clearance in ml/min using Cockcroft Gault Equation

Male:	1.23 X (140-age) x wt in Kg/ Creatinine (in micromols/L)
Female:	1.04 X (140-age) x wt in kg/ Creatinine (in micromols/L)

Do not initiate TDF when the estimated GFR is <50 ml/min, or in long term diabetes, uncontrolled hypertension and renal failure.

4.3 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 only after assessing for treatment adherence and failure and 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.

4.4 Definition of Treatment Failure in Children

Clinical Failure:

New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 clinical condition with exception of TB) after 6 months of effective treatment

1. **Immunological Failure:**

Younger than 5 years - Persistent CD4 levels below 200 cells/mm3 or CD4 percentage <10% Older than 5 years - Persistent CD4 levels below 100 cells/mm3

2. **Virological Failure:**

Plasma viral load above 1000 copies/ ml based on two consecutive viral loads measurements after 3 months, with adherence support. **OR**

If using DBS technology, a viral load above 3000 copies/ml based on two consecutive viral load measurements after 3 months, with enhanced adherence support

Table 8: Preferred second line regimens

Population group	**Failed first-line regimen**	**Second-line regimens e regimen**	**Alternative second line**
Adults and Adolescents	TDF + 3TC + DTG TDF + 3TC + LPV/r	AZT + 3TC + LPV/r AZT+ 3TC + DTG	AZT + 3TC + ATV/r AZT + 3TC + DRV/r (or LPV/r or DRV/r)
Children and Neonates	ABC + 3TC + DTG ABC + 3TC + RAL ABC + 3TC + LPV/r	AZT+ 3TC + LPV/r (or ATV/r) AZT + 3TC + DTG AZT + 3TC + DTG	AZT + 3TC + DRV/r AZT + 3TC + LPV/r (or ATV/r) AZT + 3TC + RAL

Table 9: Recommendations for transition to TDF + 3TC + DTG among adults and adolescents

Treatment transition scenario	Recommendation	Comments
DTG for recently diagnosed people initiating ART		
Adults and adolescents	Initiate TDF + 3TC + DTG	Potential risk of neural tube defects among infants exposed to DTG during the conception period Women not using or accessing contraception or who want to be pregnant can use DTG or LPV/r based on informed choice of the risks and benefits of each regimen
Pregnant and breastfeeding women	Initiate TDF + 3TC + DTG	Possibility of conception during breastfeeding Remains
TB co-infection	Initiate TDF + 3TC + DTG (DTG dose adjustment needed)	Additional DTG 50 mg twice daily if rifampicin is being used.
DTG for people living with HIV already using a first-line ART regimen		
Clinical or immune failure or viral load not suppressed.	Switch to AZT + 3TC + DTG	No evidence to support the efficacy of DTG when used in combination with an inactive NRTI backbone. Provide enhanced adherence support.
Viral load suppressed.	Substitute to TDF + 3TC + DTG.	Substitution may cause new side-effects and interfere with adherence. DTG regimens may be more durable in the long term.
Clinically and immunologically stable and viral load unknown.	Check viral load and if not available use clinical indications for substitution to DTG based ART.	There is no evidence to support the efficacy of DTG when used in combination with an inactive NRTI backbone. Provide enhanced adherence support.
Stable on suboptimal first-line ART regimens.	Substitute to TDF + 3TC + DTG	Substitution may cause new side-effects. Provide enhanced adherence support.

4.5 Third-line Treatment Recommendation for Adults and Adolescents (As a nation third line regimen is not in use for now)

Table 10. Recommendations for transition to new ARV regimens among children

Recommendations for recently diagnosed children initiating ART			
Weight	**Recommendation**		**Comments**
<20 kg	ABC + 3TC + NVP ABC + 3TC + LPV/r		
20–30kg	ABC + 3TC + NVP ABC + 3TC + DTG		Children can be transitioned to TDF + 3TC + DTG when they reach 30 kg
> 30 kg	TDF + 3TC + DTG		
Recommendations for children living with HIV already using a first-line ART regimen			
Current regimen	**Weight**	**Recommended regimen for transition**	**Comments**
ABC + 3TC + NVP	<20 kg	ABC + 3TC + LPV/r	
	20–30kg	ABC + 3TC + DTG	If stable, children can be transitioned to TDF + 3TC + DTG when they reach 30 kg.
	> 30 kg	TDF + 3TC + DTG	
ABC + 3TC + LPV/r	<20 kg	No change until they reach 20 kg unless treatment failure occurs.	
	20–30kg	ABC + 3TC + DTG	If stable, children can be transitioned to TDF + 3TC + DTG when they reach 30 kg.
	> 30 kg	TDF + 3TC + DTG	

Those failing second-line therapy will need to be referred for Specialist assessment which may include viral load and genotype testing prior to recommending the third-line medicines. Adherence on treatment needs to be reinforced all the time.

In adults, requiring 3rd line regimen consider using Raltegravir (400mg) twice a day and Darunavir (800mg)/ Ritonavir (100mg) once daily will be used as well as any other medicines as determined by the laboratory tests where available. You will need to be advised by the Pediatricians regarding doses for children.

4.6 Use of ARVs in Patients with Tuberculosis (TB)

TB is the most common OI encountered among people with HIV infection in The Gambia. There is therefore, a need to integrate the HIV and TB services, as TB and HIV co-infection is common.

The regimen for HIV/TB co-infections is the same (TDF/3TC/DTG) as that for those without co-infections.

However, 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. The dose of DTG should be increased with an additional 50 mg of DTG taken 12 hourly after the dose of TDF/3TC/DTG (TLD).

Similarly, in children an additional dose of DTG (equivalent in strength to the amount in the combination) should be given 12 hourly after the first as for adults.

Early initiation of ART for patients with HIV-associated TB is critical in reducing morbidity and mortality. Therefore, ART should be started as soon as possible in patients with TB.

4.7 Patients who develop TB when already on ART

Treat TB as per the latest National TB guidelines.

4.8 ART initiation in patients with Cryptococcal Meningitis

Immediate ART initiation is not recommended in HIV-infected patients with cryptococcal meningitis due to the high risk of IRIS that may be life threatening.

ART initiation should be deferred until there is evidence of a sustained clinical response to antifungal therapy, and after 4 weeks of induction and consolidation treatment with Amphotericin B–containing regimens combined with Fluconazole or Flucytosine, or after 4–6 weeks of treatment with a high-dose oral Fluconazole induction and consolidation regimen.

4.8.1 Prevention of Cryptococcal Disease

Patients initiating ART with undiagnosed cryptococcal disease are at higher risk of early mortality than patients who are pre-emptively diagnosed and treated for cryptococcal disease.

- All patients initiating ART should be clinically screened for evidence of symptomatic cryptococcal disease (headache, neck stiffness, fever, focal neurologic signs, confusion, altered mental status)
- All those who screen positive should be referred for further diagnostic work up for meningitis with consultation.
- Screening of asymptomatic ART naïve individuals with CD4 count <100cells/mm3 is recommended and should be done with a Cryptococcal neoformans antigen test (CrAg), using latex agglutination tests (LA) or lateral flow assays (LFA) on serum, plasma or CSF.
- A lumbar puncture should be offered to individuals who screen positive for cryptococcal antigen, as a positive cryptococcal antigen may precede the onset of clinical cryptococcal meningitis by many weeks.
- Individuals who are screened for cryptococcal disease should be managed as indicated in Table below.

Table 11: Treatment Decisions for Asymptomatic Cryptococcal Disease

Serum CrAg negative	No LP is necessary. No fluconazole is required.
Serum CrAg positive	If available recommend LP:
	If CSF CrAg positive, manage for cryptococcal meningitis
	If CSF CrAg negative treat with Fluconazole 800mg orally once daily for 2 weeks, then Fluconazole 400mg orally daily for 8 weeks, followed by maintenance therapy with Fluconazole 200mg orally daily until CD4>200 cells/mm3 for 6 months

Timing of ART for individuals with asymptomatic cryptococcal antigenemia is unknown. **We recommend initiation of ART 2-4 weeks after initiation of antifungal therapy in individuals who screen positive for serum CrAg without any evidence of disseminated cryptococcal meningitis.**

4.8.2 Treatment of Cryptococcal Meningitis

Cryptococcal meningitis remains a major cause of death in HIV infected patients. Early diagnosis and prompt treatment of cryptococcal meningitis is critical to improving clinical outcomes.

The mainstay of treatment is rapid diagnosis, prompt initiation of appropriate antifungal therapy and management of raised intracranial pressure.

Patients at greatest risk of cryptococcal meningitis are those with low CD4 counts and clinical suspicion must be at a higher index for all patients presenting with headaches, confusion, and altered mental status.

Diagnosis of cryptococcal meningitis must be made by lumbar puncture. Opening pressure must be measured. If a manometer is not available, intravenous tubing may be used and a tape measure used to measure the column of CSF fluid.

CSF samples must be tested for Cryptococcus by India ink staining and/or CSF cryptococcal antigen test. Sensitivity and specificity for Indian ink staining are not as high as cryptococcal antigen testing, and a negative test does not exclude cryptococcal meningitis in the right clinical setting.

Combination therapy with amphotericin B and fluconazole is strongly recommended. In the absence of Amphotericin B, high dose fluconazole can be used as alternative therapy (See Table 10). Therapy is characterized by a 2-week induction phase, followed by an 8-week consolidation phase, and maintenance therapy which is continued until adequate immune reconstitution is achieved.

Table 12: Recommended therapy for Cryptococcal Meningitis

	Treatment phase	Regimen	Duration of therapy
Preferred	Induction phase	IV Fluconazole 400mg stat	
	Consolidation phase	IV Fluconazole 200mg-400mg once daily	8 weeks
	Maintenance/ Secondary prophylaxis	Fluconazole 200mg orally once daily	Until CD4 count >200 cells/mm3 for 6
Alternate	Induction Phase	Fluconazole 1200mg orally daily	2 weeks
	Consolidation Phase	Fluconazole 800mg orally daily	8 weeks
	Maintenance/ Secondary prophylaxis	Fluconazole 200mg orally once daily	Until CD4 count >200 cells/mm3 for 6 months

4.8.3 Management of Raised Intracranial Pressure (ICP)

Mortality and morbidity from cryptococcal meningitis is high with a significant proportion attributable to raised intracranial pressure. Management of raised ICP is critical to ensure good clinical outcomes. If the intracranial pressures is >25cm of water, remove 10-30ml of CSF and continue with daily lumbar punctures until CSF pressures have normalized (<25cm of water).

Failure to adequately manage ICP can result in persistent headache, cranial nerve abnormalities which include hearing loss, vision loss, and death.

A repeat lumbar puncture at 2 weeks after initiation of appropriate induction antifungal therapy is not necessary except in the setting of persistently elevated intracranial pressure and evidence of poor clinical response. Cryptococcal latex agglutination titres, are not indicated for monitoring response to therapy.

4.8.4 Timing of ART in Cryptococcal Meningitis

The timing of the initiation of ART, in patients with cryptococcal meningitis, is still uncertain. Early initiation of ART is recommended for all OIs except for intracranial OIs such as TB meningitis and cryptococcal meningitis.

In patients who are predominately treated with fluconazole monotherapy, ART should be initiated at least 4 weeks after initiation of antifungal therapy

ART should not be commenced at the same time that fluconazole therapy is commenced for Cryptococcal meningitis

Chapter Five

5.0 Prevention of Mother-to-Child Transmission of HIV (PMTCT)

5.1 Introduction

Mother-to-child transmission is responsible for more than 90% of HIV infection in children, and at least two-thirds of such infections occur during pregnancy, and delivery, whilst the remainder occur 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-positive mother and her children, and it is essential to reinforce the importance of HIV follow up care for mother and her children, as well as her partner.

5.2 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

NB: Pregnant and breastfeeding women who tested HIV-positive should be initiated on life-long ART as per WHO recommendations

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

Emphasize modes of HIV transmission and prevention, PMTCT, and access to care and treatment.

- Encourage health facility delivery and the importance of skilled birth attendants, clean and safe delivery, and newborn care including ARV prophylaxis for infants.
- Counsel on infant and young child feeding and maternal nutrition. Emphasize exclusive breastfeeding (no mixed feeding) for the first six months of an infant's life and safe introduction of complementary foods from six months of age.
- Counsel on sexual and reproductive health including family planning and the need for dual contraception (reliable hormonal contraceptive plus barrier method like male or female condoms)
- Make an appointment for EID and family planning at six weeks postpartum.
- Stress the need for condom use for prevention of STIs and HIV during pregnancy and in the postpartum period. New HIV infections during pregnancy and lactation pose additional risk of HIV transmission to the infant.
- Stress the importance of follow-up for the HIV exposed infant.
- Commence Co-trimoxazole prophylaxis from 6- 8weeks of age
- Collect Dried Blood Spot (DBS)/whole blood for HIV DNA PCR test at 6-8 weeks of age i.e. Early Infant Diagnosis (EID).
- Infants should be re-tested one week after the end of the breast-feeding period.

Retest previously negative women in 3rd trimester of pregnancy and/ or at delivery or 6 weeks post-natal.

Table 13: Initiation of ART for Mother (PMTCT)

Population Type	Preferred Regimens	Alternative Regimens
Pregnant and Lactating Women	TDF + 3TC + DTG	TDF + 3TC + LPV/r TDF + 3TC + ATV/r

5.3 Special Considerations when using ARVs in Pregnant Women

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

5.3.1 Dolutegravir (DTG)

Previously there was a recommendation not to use Dolutegravir during the first trimester and in women at risk of becoming pregnant. However, WHO issued evidence-based update on Dolutegravir safety in pregnancy in July 2019, which recommends it to be safe for use even in the first trimester.

5.3.2 Health Education Needs for Pregnant Mothers

When dealing with pregnant women, health-care providers should take the following steps:

- Provide routine counselling and blood testing, including HIV testing in pregnancy, haemoglobin level, blood group, hepatitis screen, urinalysis and syphilis.
- Pregnant women of unknown HIV status who present in labour and delivery should be tested for HIV and if test positive, commence ART.
- The baby should be commenced on ARV prophylaxis for 6 weeks and do DNA PCR test.
- If a woman tests positive postnatally, commence ART, the exposed infant should be given ARV prophylaxis for 6 weeks and have DNA PCR done.
- The infant should have Co-trimoxazole prophylaxis from 6-8 weeks until HIV is excluded.
- Where PCR is positive for the child, both mother and child should be linked to ART site for continuum of care.

5.3.3 Infant and young child feeding recommendations

In order to give HIV exposed infants, the greatest chance of HIV-free survival, the recommendation is to promote and support breastfeeding, while providing maternal lifelong ART and infant Nevirapine (NVP) prophylaxis.

All mothers whether known to be infected with HIV or not should exclusively breastfeed their infants (no mixed feeding) for the first 6 months of life, introducing safe, adequate and nutritious complementary foods thereafter, with continued breastfeeding up to 18 months.

5.3.4 For an effective postpartum MTCT prevention strategy

- The HIV infected mother who is breastfeeding and on lifelong ART should receive continued counseling and support for enhanced adherence on treatment to minimize the risk of HIV transmission through breast milk.
- 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 inadequate ARV medicine coverage during breastfeeding.
- Thus, 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 commenced on lifelong ART.

5.3.5 ARV Prophylaxis in an HIV Exposed Infant

HIV-exposed infants whose mothers are on lifelong ART, should be commenced on ARV prophylaxis for six weeks.

Table 14: Infant ARV Prophylaxis

Age	HIV1	HIV2 and Dual
	NVP dosage	**AZT dosage**
Birth to six weeks	BW <2500*: 10mg once daily	BW <2500*: 10mg BD
	BW ≥ 2500: 15mg once daily	BW ≥ 2500: 15mg BD

* For very low birth weight babies below 2000g dose of NVP is 2 mg/kg once daily for 6 weeks

* For non-breastfeeding infants NVP as above or AZT 4mg/kg 12 hourly for 6 weeks

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

5.3.6 Other Essential Package of Prevention & Care of PLHIVs

5.3.6.1 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 (PMCT) 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 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 (Only if she meets the criteria for chronic care especially adherence to lifelong ART).
- The choice of contraceptive methods in HIV positive women is the same as in HIV uninfected women. Hormonal contraception may be used in HIV-infected women; however, choice of hormonal contraception should take into account ARV drug use.
- HIV positive women on Dolutegravir should be informed of the risk of fetal abnormalities associated with this drug if pregnancy occurs. Effective contraception should be availed to women at risk of pregnancy if Dolutegravir needs to be used.

Chapter Six

6.0 Anti-Retroviral Therapy in Children

6.1 Introduction

More than 90% of HIV-infected children acquire their infection through mother -to -child transmission of HIV (vertical transmission). Thus, elimination of new HIV infections among children through effective PMTCT interventions should be prioritized. HIV disease progression occurs very rapidly in the first few months of life in infants acquiring HIV in utero, often leading to death. The importance of early infant diagnosis (EID) of HIV infection and early initiation of ART can therefore not be over-emphasized.

6.2 Early Infant Diagnosis (EID) (see algorithm in the Appendix 15)

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), 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.

At 9 months of age, most infants (93%) no longer possess maternally transferred antibodies. Prior to the age of 18 months, a DNA PCR test for HIV is more reliable.

A DNA PCR test should be offered 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.

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.

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:
    - Oral thrush
    - Severe pneumonia
    - Severe sepsis

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

6.3 Recommendations for Antibody Testing in Infants

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

In a child less than 18 months, who has never been breastfed 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 under 18 months who has not breastfed for more than six weeks, HIV antibody tests that are negative mean the child is uninfected.

HIV antibody tests that are positive at any age under 18 months require virological tests (i.e., the child is HIV exposed but needs definitive test with HIV DNA PCR to confirm HIV infection).

6.4 Care of an HIV-Exposed Infant

6.4.1 Initial Care

Care for HIV-exposed infants should include the following:

1. Make sure HIV-exposed infants are entered into the "PMTCT and Infant ARV register".
2. All HIV-exposed infants should have HIV DNA PCR testing performed at six weeks of age or at the earliest possible time thereafter if 6 weeks testing is missed.
3. Co-trimoxazole prophylaxis should be given at six weeks of age until the HIV status of the infant is known. If the HIV infection is confirmed, continue Co-trimoxazole and commence on ART.

During these visits, the following services should be provided:

- Growth monitoring and promotion
- Developmental assessment (see appendix 8 & 9)

6.4.2 Counseling on Infant and Young Child Feeding:

- Counseling and support for the HIV infected mother to adhere to ART is crucial.
- Weaning should not be abrupt, but rather should be gradual over a one-month period.
- HIV infected infants diagnosed by virological testing or infants with symptoms suggestive of HIV should continue breastfeeding for as long as possible.
- Immunizations should be given according to the national guidelines. The BCG vaccination should still be given at birth, but BCG should not be given to children with symptomatic HIV infection.
- Always look for and treat opportunistic infections.
- Be aware of and watch for potential medicine interactions.
- Counselling on safer sex practices, including the use of condoms during the breastfeeding period is recommended to minimize risk of maternal sero-conversion during breastfeeding.
- Counsel on family planning (see PMTCT sub-section 5.3.6.1)

The management of TB in HIV-infected children, and the treatment of advanced HIV infection with ARV drugs, is complicated by the potential for multiple medicine interactions. Refer to TB treatment guidelines or cross- reference with appropriate chapter.

6.5 Management of an HIV-Infected Child using ARVs

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.

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

Table 15: Choice of ARV for Children and Neonates

Population Type	Preferred Regimens	Alternative Regimens
Children (20-30kg)	ABC + 3TC + DTG	ABC + 3TC + LPV/r ABC + 3TC + ATV/r ABC + 3TC + RAL ABC + 3TC + NVP
Children (<20kg)	ABC + 3TC + NVP	ABC + 3TC + LPV/r ABC + 3TC + RAL
Neonates	AZT + 3TC + RAL	AZT + 3TC + LPV/r AZT + 3TC + NVP

6.5.1 Criteria to Initiate ART in Children

Initiate all HIV positive children on ART.

6.5.2 Issues to Consider when Initiating ART in Children

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.

Disclosure:

The process of disclosure to the child should be initiated as early as possible, usually from 5 – 7 years of age. Adherence is good in children who know their status and are supported to adhere to medicines.

Adherence to ART:

Continued support for good adherence.

Recommendations for ART in children need to take into consideration the following:

- Age and weight of the child
- Availability of paediatric formulations of the medicines
- Palatability of the medicines
- Effect of food on the absorption of the medicines
- PMTCT regimens used

6.5.3 Monitoring Children on ART

- Urine dipsticks for glycosuria and estimated Glomerular Filtration Rate (eGFR) and/or serum creatinine when on Tenofovir;
- CD4 count every 6 months.
- Viral load once every year or when clinical signs are suggestive of treatment failure.

6.6 Recommended Second-line Treatment for Children

6.6.1 Definition of Treatment Failure in Children

Clinical Failure:

New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 clinical condition with exception of TB) after 6 months of effective treatment

Immunological Failure:

- Younger than 5 years - Persistent CD4 levels below 200 cells/mm3 or CD4 percentage <10%
- Older than 5 years - Persistent CD4 levels below 100 cells/mm3

Virological Failure:

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

If using DBS technology, a viral load above 3000 copies/ml based on two consecutive viral load measurements after 3 months, with adherence support.

Table 16: Preferred second line regimens

Population group	Failed first-line regimens	Second-line regimens	Alternative second line
Children and Neonates	ABC + 3TC + DTG ABC + 3TC + NVP ABC + 3TC + LPV/r ABC + 3TC + RAL	AZT+ 3TC + LPV/r (or ATV/r) AZT + 3TC + DTG	AZT + 3TC + DRV/r AZT + 3TC + LPV/r (or ATV/r) AZT + 3TC + RAL

Discuss the child with your Care Team, IF NOT SURE OF SECOND LINE TREATMENT

Chapter Seven

7.0 Monitoring Patients on Anti-retroviral Therapy

7.1 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. Adolescents' growth, including puberty and schooling, may be delayed, and these issues will need to be managed carefully if they are to become well-adjusted individuals later in life

7.2 Starting ART in Children using FDCs

Refer to dosing table (and also see Appendix). Keep the following factors in mind with regard to dosing:

- Medicine doses must be adjusted as the child grows.
- Dosing is by weight.
- Scored tablets may be divided into two equal halves
- Tablets may be crushed and mixed with a small amount of food or water and administered immediately.
- Give clear explanation to the caregiver.
- Use pillboxes if available.
- Standardization is important to safely dispense correct doses.

7.3 Initial Evaluation

Before commencing ART, all patients should have a detailed history taken, a physical examination carried out, and basic laboratory tests performed.

Prior to commencing ART, the patient should have a confirmatory HIV test, plus it is essential to test for TB in all patients. Document the patient's WHO clinical staging in his or her file/folder.

It is important to perform the following baseline tests:

- Full blood count (especially if Zidovudine will be used)
- Blood grouping
- Blood sugar test (Random or Fasting)
- Liver function tests (LFTs)
- Lipid Profile
- Serum creatinine test (if Tenofovir will be used)
- Mantoux test (useful in children) where available
- Gene Xpert test or Chest X-ray (to exclude TB)
- CD4 lymphocyte count (or CD4 percentage for children under 5 years)

- Syphilis serology test
- Hepatitis B and C virus screening
- Pregnancy test

NOTE: *Ensure that all the above-mentioned tests are documented in the patient folders and registers.*

7.4 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 (pill box, pill count, self-reporting) should be provided, and patients/careers 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.

7.5 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. Any inter-current illness should be treated appropriately. If in doubt, refer the patient to your clinical mentor or higher- level ART clinic.

After initiating treatment, the patient should be seen at two weeks, then monthly for another three months, and thereafter every three months. The patient should be provided with written and verbal information on potential side effects and should be requested to report immediately for examination should side effects occur. See Appendix for the grading of side effects. There is a need to watch out for common side effects such as anaemia, renal impairment, peripheral neuropathy, and lactic acidosis, as well as lipodystrophy or fat redistribution.

Anaemia

Check haemoglobin before initiation, two weeks after initiation and the first month of Zidovudine use. Deworm and give Ferrous Sulphate if needed.

Lactic Acidosis

Lactic acidosis is characterized by non-specific symptoms and signs such as shortness of breath, hyperventilation, fatigue, weight loss, abdominal pain, vomiting, and tachycardia. Lactate levels are currently not routinely available, but one needs to have a high index of suspicion. Use a full urea and electrolytes screen with bicarbonate levels as a surrogate marker.

The treatment for this is to stop all ARVs and keep the patient well hydrated. When the patient's symptoms have settled down, restart an ARV regimen that contains Tenofovir. **Referral to a higher level of care or a specialist is encouraged where available.**

Lipodystrophy / Fat Redistribution

With longer duration of use of ART, cosmetic problems such as loss of fat in the face or limbs and buttocks or increasing breast size and abdominal fat accumulation will be encountered more frequently. If the patient is on a Zidovudine -containing regimen, consider changing to Tenofovir, but counsel the patient appropriately.

Central Nervous System Toxicities

Hallucinations, abnormal dreams, depression, mental confusion and convulsions can occur especially with **Dolutegravir**. These events tend to occur within the first month. Patients should be warned about them but if the symptoms do not settle down, consider using Nevirapine. However, if both NNRTIs cannot be tolerated, use boosted PIs.

Metabolic Abnormalities

Hyperglycaemia i.e. development of diabetes and hyperlipidaemia should be anticipated with the long-term use of ARVs. Check blood sugar and lipid profile at least with every CD4-level check or when clinically indicated.

Other Side Effects

Mild side effects such as headache, fatigue, gastrointestinal upsets, and diarrhoea occur fairly frequently, but serious side effects occur rarely. Mild side effects usually occur early in treatment and often wear off and should be treated symptomatically. Side effects of medicines are summarized below.

Table 17: Some Important Side Effects of Antiretroviral Agents

Medicine	Side Effects	Action to Be Taken
Nucleotide/ Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		
Tenofovir	Gastrointestinal (GI) symptoms, rash, and renal complications, decreases in bone mineral density	Monitor creatinine. Substitute with Zidovudine
Zidovudine	Anaemia, neutropenia, headache, myopathy, lactic acidosis, lipoatrophy or lipodystrophy	Monitor full blood count; if severe anaemia, change to Tenofovir or Abacavir.
Lamivudine	Usually rare	
Abacavir	Severe hypersensitivity reactions	Withdraw medicine immediately;
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
Nevirapine	Fever, fatigue, nausea, mild or severe skin rashes (e.g., Stevens-Johnson syndrome [rare]), liver toxicity, abnormal liver function tests (LFTs)	If LFTs are suggestive of hepatitis or if jaundice is present, discontinue; if rash is severe, discontinue and replace with Dolutegravir.
Protease Inhibitors (PIs)		
Lopinavir/ritonavir	Lipodystrophy, GI intolerance, diarrhoea, hyperglycaemia, hyperlipidaemia	Give loperamide for the diarrhoea.
Ritonavir	Lipodystrophy, pancreatitis, hepatitis, skin sensitivity, circum- oral paraesthesia, nausea, vomiting, diarrhoea	Monitor; withdraw medicine if symptoms are severe.
Atazanavir	Headache, Insomnia, dizziness, peripheral neurologic symptoms, depression, Mild to moderate rash occurs commonly usually within the first 3-weeks of therapy, hepatotoxicity, cardiac conduction abnormalities, immune-reconstitution syndrome, nausea, vomiting, diarrhoea, abdominal pain, increased bleeding (in patients with hemophilia A & B), severe rash occurs less frequently and may be accompanied by systemic symptoms.	Discontinued if severe rash develops.

Integrase Inhibitor (IIs)		
Dolutegravir	Central nervous system symptoms (confusion, headache, sleep disturbance, abnormal dreams) usually during the first three weeks and then resolve. Gastro-intestinal (diarrhea, nausea) headache (mild), insomnia (mild). Rash (generalize macular rash, macular-papular rash, pruritic rash) Liver abnormality (raised ALT in few patients Naso-pharyngitis (mild)	Monitor; withdraw medicine if symptoms persist.

7.6 Immune Reconstitution Inflammatory Syndrome (IRIS)

Immune reconstitution inflammatory syndrome (IRIS) is characterized by a clinical deterioration after starting ART. It is the immune system interacting with latent infections. This syndrome should be considered if the following occur within 2 to 12 weeks of commencing ART:

- Patients with advanced HIV disease, particularly those with a CD4 count of less than 50, may become ill with IRIS. Typical symptoms are fever, sweats, loss of weight, and occasionally skin rash and lymphadenopathy.
- Immune reconstitution illnesses occur when improving immune function unmasks a previously occult OI (an infection that was present in the patient's body but was not clinically evident).
- Common immune reconstitution illnesses in the Gambia are TB and cryptococcal meningitis related as well as recurrent herpes simplex virus.

An immune reconstitution illness is not indicative of treatment failure or medicine side effects. It is not a reason to stop ART or to change the ARV regimen, but the emerging OI must be treated.

7.7 Monitoring Effectiveness of ART

The effectiveness of ART may be monitored by assessing clinical improvement, immunologic function (CD4 count or CD4 %), and HIV viral load (VL). It is necessary to make an assessment of response to treatment through regular careful clinical examinations backed where possible by simple laboratory tests.

WHO is recommending VL testing as the gold standard for monitoring response to ARV medicines as it is more sensitive and can detect adherence problems and treatment failure much earlier than CD4 count testing? Given reduced access to VL testing in The Gambia, VL testing should be conducted for all patients newly initiated on ART and annually. CD4 testing should be conducted six monthly for all patients.

7.8 Clinical Monitoring

7.8.1 Monitoring ART in Adults and Adolescents

The following clinical indications suggest that the patient is responding to ART:

- The patient feels better and has more energy to perform daily tasks.
- The patient is gaining weight (record the patient's weight at each visit).
- There is an improvement in symptoms and signs of the original presenting illness.
- Infections such as oral thrush, hairy leukoplakia, genital herpes, skin rash, and molluscum contagiosum have improved.
- There has been an improvement in chronic diarrhoea.
- There has been an improvement in Kaposi's sarcoma.
- The patient is free of new moderate or severe infections.

7.8.2 Monitoring of ART in Children

In children, growth and development are important clinical monitoring indicators and are assessed using growth charts. Laboratory indices of CD4 lymphocyte counts and HIV VL levels may also be used in assessing response to therapy, noting that sometimes the VL will come down but may still not be undetectable.

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).

Important signs of infants' and children's response to ART include the following:

- Improvement in growth in children who have been failing to grow
- Improvement in neurological symptoms and development in children with encephalopathy or who have been demonstrating delay in the achievement of developmental milestones
- Decreased frequency of infections (bacterial infections, oral thrush, and/ or other OIs)

7.9 Virological (HIV Viral Load) Monitoring

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. The following are indications for targeted viral load testing:

When treatment failure is suspected, whether clinically or immunologically;

- CD4 fall by >30% from (on treatment) peak,
- New or recurrent WHO stage 3 or 4 disease as well as recurrent Pruritic papular eruptions (PPE) after 6 months of ART
- Failure of CD4 count to rise to >100 cells/mm3 after at least 12 months of therapy (less than expected CD4 response).

A viral load persistently ≥ 1000 copies/ml implies on-going viral replication and the possibility of non-adherence on treatment to ART and/or drug-resistant virus and therefore treatment failure.

Some patients may however have a poor CD4 response despite full virological suppression. Once viral suppression is confirmed they should not be considered to be failing treatment and should stay on the same regimen.

The VL usually decreases **to undetectable levels within six months of greater than 95% adherence to ART i.e. plasma viral load less than 1000 copies per ml OR viral load less than**

3000 copies per ml if using DBS technology.

However, this response also depends on the initial pre-treatment VL. The VL measurement is useful in assessing treatment failure. **If there has been a threefold increase in the VL from the lowest point following treatment, it is an indication of treatment failure.** In such situations, one must review the treatment regimen.

WHO is recommending VL testing as the gold standard for monitoring response to ARV medicines and this should be done routinely once a year.

NOTE: Ensure all baseline and disease monitoring investigations are well documented in the patient's file and the registers.

See an algorithm for Viral Load testing strategies to detect or confirm treatment failure and switch in adults, adolescents and children in the appendix

7.10 Immunological Monitoring (CD4 count)

With successful ART, the CD4 lymphocyte count increases. The rate of increase depends on the initial CD4 count. Persistently declining CD4 counts (as measured on two occasions, at least three to six months apart) and clinical deterioration as described above, are suggestive of treatment failure. CD4 count testing should be performed six-monthly, particularly after the first two years of initiation of ART. More frequent testing should be performed if immunological failure is suspected.

7.10.1 Immunological Categories for Paediatrics

Immunological staging for children is also possible. 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.

Currently, therefore, the measurement of the CD4 percentage is recommended in children less than 5 years of age. CD4 testing is not essential for the initiation of ART, and should only be used in conjunction with the clinical stage.

As for adults, immunological staging assists clinical decision making and provides a link with monitoring and surveillance definitions. It is usually reversed by successful ART.

7.11 Treatment Failure

7.11.1 Clinical Criteria Suggestive of Treatment Failure

Before diagnosing treatment failure, one must assess adherence to treatment. The decision to switch from first-line to second-line or even third- line therapy should not be taken lightly.

Treatment failure can be determined clinically (this tends to result in delayed switching to second- line therapy), immunologically using CD4 trends over time, or virologically (e.g., VL greater than 1000 copies/ml based on 2 consecutive VL measurements 3-6 months apart with enhanced adherence support).

Table 18: Treatment Failure (WHO. 2013)

Clinical Failure	Children: New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO stage 3 and 4 clinical conditions with exception of TB) after 6 months of effective treatment Adults & Adolescents: New or recurrent clinical event indicating severe immunodeficiency (WHO stage 4) after 6 months of effective treatment
Immunological Failure (CD4 Failure)	Children: Decrease to pre-therapy CD4 count/percentage Younger than 5years: Persistent CD4 level below 200 cells/ mm3 or CD4% < 10%
	Adults and adolescents: CD4 count falls to the baseline (or below) or persistent CD4 levels below 100 cells/mm
Virological Failure	Viral load greater than 1000 copies/ml based on two consecutive VL measurements after 3 months with enhanced adherence support

Note: A second-line regimen should be started only after consultation with an appropriate specialist in HIV and AIDS care/treatment or your mentor.

7.12 Monitoring HIV 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 microbicides. 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.

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.

7.12.1 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.

7.12.2 Surveys to monitor HIV Drug Resistance and Associated Factors

7.12.2.1 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.

7.12.2.2 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.

7.12.2.3 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.

7.12.2.4 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.

7.13 Treatment Failure in Children

Consider the following before switching ART regimen:

The child should have received the regimen for at least 24 weeks (six months).

- Adherence to therapy should be assessed and considered to be optimal.
- Any inter-current OIs should have been treated and resolved.
- Before considering changing treatment due to growth failure, ensure that the child is receiving adequate nutrition.

In children on ART, the main clinical indications to switch therapy are the development of new or recurrent stage 3 or 4 events at least 24 weeks (six months) after starting therapy with a first-line regimen.

Note:

- A lack of or decline in growth rate in children who showed an initial response to treatment (moderate or severe unexplained malnutrition not adequately responding to standard therapy despite adequate nutritional support and without other explanation); loss of neuro-developmental milestones (see Appendix 8 & 9) or development of encephalopathy; **or**
- Occurrence of new OIs or malignancies or recurrence of infections, such as oral candidiasis that is refractory to treatment or oesophageal candidiasis.

NOTE: A second-line regimen should be started only after consultation with a specialist in HIV and AIDS care/treatment or your mentor.

Chapter Eight

8.0 Prevention and Treatment of Common Co-infections and Co-morbidities

8.1 Introduction:

Various opportunistic infections (TB, Cryptococcosis) co-infections (hepatitis B or C), co-morbidities and other health conditions are common among PLHIVs and have implications for the treatment and care, including the timing and choice of antiretroviral medicines.

HIV is also associated with cancers such as Kaposi Sarcoma, Non-Hodgkins' Lymphoma, invasive cervical cancer as well as non-communicable diseases such as diabetes, cardio myopathies and chronic kidney disease. This chapter provides a brief overview of the most common and important conditions.

8.1.1 Fixed dose combination for OIs prophylaxis

Isoniazid 300mg, Pyridoxine 25mg (Vitamin B6), Sulfamethoxazole 800mg and trimethoprim 160mg is now available as a fixed dose combination. The program is now shifting from an individual OI medicine to the fixed dose combination to avoid pill burden and improve adherence in the management and prevention of OIs such as Tuberculosis, Bacterial Pneumonia, Malaria and Isosporiasis and to reduce mortality and hospitalizations in HIV- infected patients without active TB.

Dosage and Administration

1. **Adults and children weighing 25kg and above**

- **One tablet of** Sulfamethoxazole 800mg, trimethoprim 160mg, Isoniazid 300mg and Pyridoxine 25mg (B6) once daily.

2. **Children weighing 14kg to less than 25kg**

- **Half a tablet** of Sulfamethoxazole 800mg, trimethoprim 160mg, Isoniazid 300mg and Pyridoxine 25mg (B6) once daily.

NOTE: Children less than 14 kg are not to be given the above fixed dose combination for OIs prophylaxis.

8.2 Co-trimoxazole Preventive Therapy (CPT)

Immunosuppressed people are prone to develop OIs such as Pneumocystis Jirovecii pneumonia (PJP), toxoplasmosis, and lower respiratory tract bacterial infections and bacterial skin infections.

Co-trimoxazole prophylaxis can potentially prevent the following OIs:

- Streptococcus pneumoniae pneumonia
- Non typhoid salmonellosis
- Pneumocystis Jirovecii pneumonia (PJP)
- Cerebral toxoplasmosis
- Nocardiosis
- Isosporiasis

Co-trimoxazole prophylaxis should be given to the following:

- Co-trimoxazole prophylaxis should be initiated regardless of CD4 cell count or WHO stage (Check with your supervisor).
- Pregnant women with CD4 counts of <500 cells/mm3.
- Avoid Co-trimoxazole in 1st trimester of pregnancy and in the last four weeks of pregnancy.
- All children born to HIV-positive mothers at six weeks of age until they are tested and confirmed to be negative
- Co-trimoxazole prophylaxis should be started as soon as any of the above conditions are suspected.
- Co-trimoxazole prophylaxis in adults
- Co-trimoxazole (sulphamethoxazole 800 mg and trimethoprim 160 mg) should be given once daily orally.
- Co-trimoxazole prophylaxis in children
- Give once daily orally according to the following table:

Table 19: Dosage of Co-trimoxazole for Children

Age	Dose (ml)		
	Suspension (240 mg / 5 ml)	Adult tablets (480 mg)	Paediatric tablets (120 mg)
0 to 6 months	2.5	¼	1
7 months through 3 years	5	½	2
Over 3 years	10	1	4

Notes on the provision of Co-trimoxazole to adults and children:

- Health-care providers should keep the following recommendations in mind when offering Co-trimoxazole prophylaxis:
- Co-trimoxazole prophylaxis should be commenced at least one to two weeks before the commencement of ART. This allows time to identify those who might be allergic to Co-trimoxazole.
- Co-trimoxazole prophylaxis should be continued until when the CD4 is equals to or more than 500 copies/ml
- For patients who are allergic to Co-trimoxazole, consider desensitization or Dapsone (see Appendix 6)
- Dose of Dapsone available as 25 mg and 100 mg tabs

  Children: 4 mg /kg per week OR 2 mg/kg once daily; maximum dose is 100 mg.
- Adults: 100 mg once daily.

- Dapsone should be commenced in patients with WHO stage 4 disease and/or those with a CD4 <200.
- Dapsone should be discontinued once the CD4 has been greater than the following values for at least 6 months: 200 cells/mm3 for adults and children >5 years, the age specific threshold for severe immunodeficiency for younger children.

8.3 Tuberculosis Prevention and Treatment among PLHIVs

Among PLHIV, TB is the most frequent serious opportunistic infection and a leading cause of death. HIV Infection increases the risk of TB-disease ten-fold; together with a higher risk of death, recurrence and re-infection.

ART substantially decreases the risk of TB disease, but additional interventions are needed to reduce the risk burden of TB disease among PLHIV.

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

- Intensified TB case- finding
- Isoniazid Preventive Therapy (IPT)
- Infection control at all clinical encounters.

Activities to be undertaken in managing TB/HIV co-infected persons are summarized below:

- Offer HIV counseling and testing routinely to all persons suspected or known to have TB.
- HIV-related prevention, care and support services should be routinely offered to all persons suspected or known to have TB.
- Case definitions and anti-TB treatment regimens are the same for HIV- positive and HIV-negative TB patients, and medicine dosages in mg/kg are also the same.
- In TB/HIV co-infection the first priority is to initiate anti-TB treatment followed by Co-trimoxazole, and then ART
- All TB patients co-infected with HIV should be given Co-trimoxazole preventive therapy (CPT) for the whole duration of TB treatment.
- All people living with HIV with active TB disease, irrespective of CD4 cell count and the site of TB disease, should be initiated on ART as soon as practicable.
- All PLHIV should be screened for TB at every contact with health services. Patients should be screened for current cough, fever, night sweats and loss of weight.
- PLHIV who develop TB should be started on anti-TB treatment immediately.
- TB/HIV patients benefit from the use of steroids for the same indications as found in HIV-negative TB patients (refer to TB National Guidelines)
- TB preventive therapy should be provided to all PLHIV after thorough exclusion of TB
- TB screening is done based on clinical symptoms, according to the TB screening tool. CXR should only be done if indicated, and is not a pre-requisite for IPT in asymptomatic patients.

- TB-preventive therapy should not be given to PLHIV with symptoms suggestive of TB, especially those with advanced HIV disease in whom TB cannot be excluded with confidence.
- Previous treatment for TB is not a contraindication to TB preventive therapy; if treatment was completed more than 2 years previously IPT should be considered.
- A tuberculin skin test is not a necessary pre-condition to imitate TB preventive therapy. The recommended regimen for TB preventive therapy is isoniazid given daily for six months.

Indications for IPT:

- All children regardless of HIV sero-status <5 years exposed to "open" PTB in a close contact, with a negative TB screen should be given IPT
- All children living with HIV with more than 1 year of age in whom TB has been excluded,
- All HIV-positive patients in whom TB has been excluded (universal use of IPT for PLHIV)

Healthcare settings present suitable conditions for transmission of TB; particularly among vulnerable individuals like PLHIV. All healthcare settings should follow TB infection control guidelines to reduce the risk of transmission of TB among patients, visitors and staff.

NB: Refer to the National TB guideline for MDR-TB.

8.4 Sexually Transmissible Infections and Other Reproductive Tract Infections

Ulcerative and inflammatory diseases of the reproductive tract often co-exist with HIV infection, increase HIV infectiousness and shedding and 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 more frequently.

8.5 Cervical Cancer Screening

Cervical cancer is caused by the human papilloma virus (HPV) and is the most common cancer in women in The Gambia, more prevalent in HIV-positive than in HIV uninfected women. Cervical cancer is an AIDS defining disease and therefore an indication for ART initiation.

Screening for cervical cancer results in:

- Early detection of pre-malignant lesions,
- Early initiation of treatment and
- Curative therapy of early stage cancer.

Therefore:

- All HIV-infected women (and HIV uninfected sexually active women) should be screened for cervical cancer.
- All HIV positive women need regular check-ups for cervical cancer as they are at a higher risk of pre-cancer and invasive cervical cancers.
- Refer all women for PAP smears or Visual Inspection using Acetic Acid (VIAC). Such reviews should be offered at least every three years.
- Patients should be on fully suppressive ART. Immediate management of pre-cancerous and cancerous lesions should be offered.
- Each tumour should be treated on its own merit; Patients should be on fully suppressive ART.
- Effective vaccination against HPV is now available and where possible should be offered to all eligible girls and women irrespective of HIV status.
- All HIV comprehensive care clinics should integrate cervical cancer screening and management of cervical dysplasia into routine care and treatment.
- Women with HIV infection should be screened for cervical cancer at initial assessment and at regular intervals thereafter in line with common Reproductive Health guidelines for cervical cancer screening.
- HIV-positive women should be encouraged to practice primary prevention strategies to reduce likelihood of HPV infection. This includes abstinence where possible, avoidance of multiple sexual partners and condom use.

- It is also advisable that they avoid behavior that predisposes to progression of HPV into cancer e.g. Tobacco use and alcohol consumption.

8.6 Kaposi Sarcoma and Other Cancers

HIV infected individuals are at greater risk of developing cancer than the general population. Certain cancers have been termed 'AIDS Defining Cancers' (ADC):

- Kaposi sarcoma (KS)
- Non-Hodgkin lymphoma (NHL)
- Invasive cervical cancer

With the advent of effective combination antiretroviral therapy (ART), the rates of some of these cancers have declined significantly.

Other cancers have been associated with HIV and the rates of these Non-AIDS Defining Cancers (NADCs) are rising. Sites for these NADCs include:

- Head and neck including squamous conjunctival carcinoma
- GIT including anus
- Lung, liver, Genito-urinary tract and kidney
- Hodgkin lymphoma (HL)
- Glioma
- Leiomyosarcoma in children

The reasons for this increase are poorly understood and may include increased susceptibility to cancers known to be associated with oncogenic viruses, decreased tumour surveillance with HIV-associated immune suppression and the fact that patients with HIV are now living much longer on ART.

Anal, penile, cervical, vaginal, vulva, oral, laryngeal and nasopharyngeal cancers are associated with HPV infection; HL is associated with Epstein-Barr virus (EBV) infection; liver cancer is associated with hepatitis B and C infection.

Patients with HIV and cancers should be treated for the HIV infection and for the cancer. In addition, palliative care with meticulous attention to symptom control from the time of diagnosis is vital, especially in patients with advanced HIV disease.

Overlapping toxicities of ART and chemotherapy medicines or biological agents used to treat cancer may be a problem. Timing of the ART and the cancer treatment is critical as immune reconstitution may be associated with worsening of the cancer. Chemotherapy can deplete the CD4 count by up to

50%. Most patients will require consultation with a specialized referral unit in order to develop a treatment plan.

8.6.1 Kaposi Sarcoma (KS)

KS is a spindle cell tumor, related to infection with human herpesvirus-8 (HHV8) or Kaposi sarcoma herpes virus (KSHV). KS presents with multifocal purplish-red macules, plaques or nodules on the skin. Typical

sites include the tip of the nose, around the ear, antero-medial part of the thigh, instep of the foot, but any part of the skin can be affected.

KS also affects the mouth and the oropharynx; palate disease may indicate lung involvement, although any of the viscera may be affected. KS involves the lymph nodes and may present with lymphoedema, even in the absence of overt cutaneous disease. It can occur at any CD4 count, but most patients have a CD4 <200 cells/μL.

8.6.1.1 Staging

Staging may be Clinical or according to the AIDS Clinical Trials Group (ACTG) system.

I. Clinical Staging:

a. Indolent, local disease, <5 lesions, long history
b. locally aggressive, regional lymphadenopathy
c. generalized cutaneous, generalized lymphadenopathy
d. visceral, palatal, abnormal CXR, positive endoscopy Plus A or B without/with systemic symptoms of significant LOW, fever, sweats

II. AIDS Clinical Trials Group (ACTG) Staging:

Tumor Immune Staging (TIS: systemic illness – poor performance status, prior or current OIs). Staging is recorded as 0 (good prognosis) or 1 (poor prognosis)

a. Extent of tumour (T)

1. T0 'good' prognosis – skin macules, plaques and nodules, minimal oral plaques (flat on palate), lymph nodes
2. T1 'poor' prognosis – lymphoedema, ulceration/fungating nodules, extensive oral disease, visceral disease

- Immune status – I0 > 200 or I1 < 200 cells/μL
- Severity of systemic symptoms – (S)

1. S0 – no symptoms
2. S1 – some symptoms

Diagnosis

This is clinical, preferably confirmed by biopsy.

THE TIMING OF ART INITIATION AND SPECIFIC THERAPY FOR THE KS IS CRITICAL.

Early or trivial KS may respond to ART alone but many patients present late and with a heavy tumour burden. Thus, these patients need chemotherapy to reduce the tumour burden and then ART. Immune reconstitution with ART occurs and may worsen the KS dramatically.

Treatment may be Local or Systemic:

Local therapy can be used for scanty or cosmetically disfiguring skin disease. Local radiotherapy, intra-lesional chemotherapy and cryotherapy are possible alternatives.

Systemic therapy consists of intravenous chemotherapy (first-line is usually a combination of vincristine, bleomycin and doxorubicin, second line chemotherapy is paclitaxel). Other therapies include interferon-α, thalidomide and other biological agents.

Survival

In the pre-ART era, survival was 4%. This has improved markedly although resolution of KS may be a slow, gradual process which invariably requires chemotherapy in addition to ART.

8.7 Lymphomas

HIV positive patients have an increased incidence of high-grade NHL, including primary B-cell lymphoma of the brain. Lymphoid tumours generally have an aggressive course in HIV positive patients. This also applies to HL (often mixed cellularity or lymphocyte depleted) and CNS lymphoma.

Treatment

Combination chemotherapy is used; there is evidence that the same doses as for HIV negative patients may be used but this requires aggressive supportive measures to be available for complications of treatment such as myelosuppression.

Modified/low dose chemotherapy may be more applicable in low-resource settings though there is no definitive study to guide treatment in terms of chemotherapy medicines, dose intensity and scheduling. There are no guidelines as to timing of ART versus chemotherapy but patients should have proper HIV VL suppression with ART. CNS prophylaxis with intrathecal chemotherapy is standard practice.

8.8 Viral Hepatitis (Refer to the National Hepatitis Guidelines)

Chapter Nine

9.0 Common Non-communicable Diseases (NCDs) among PLHIVs

9.1 Introduction

With effective ART, HIV infection is now largely a chronic, manageable disease, with patients living longer as a result of reduced mortality. However, this positive impact of ART has been accompanied with the emergence of chronic NCDs like cardiovascular disease, diabetes, chronic liver and kidney disease among PLHIV, either as a consequence of aging, due to undesirable effects of ART, as a direct consequence of HIV infection or as a result of the pro-inflammatory (possible question) effects of HIV infection. Increasingly PLIHV will present to health care providers with the dual challenges of treatment of HIV in the setting of multiple co-morbid NCD conditions.

In addition, mental health issues are also highly prevalent among PLHIV, although data on mental health and HIV in The Gambia is still limited.

Because of the direct association of mental illness and poor patient outcomes in HIV-infected patients, it is important that health care providers identify this population and provide them with appropriate treatment.

HIV is becoming a chronic disease now that mortality is being averted with ART. Patients will be living longer and hence are at risk of dying from non- communicable diseases. Apart from assessing patients, for the traditional risk factors for cardiovascular disease such as hypertension, chronic kidney disease, diabetes, obesity and hyper-lipidaemia, there is need to be aware of the risk posed by the antiretroviral medicines themselves. Antiretroviral medicines, in particular, the protease inhibitors (PIs) tend to make patients have hyperglycaemia and hyperlipidaemia (Possible question).

Assess the following parameters:

Monitor the blood pressure (B/P), weight, Body Mass Index (BMI)/ MUAC, glucose, lipid levels and renal function at least annually or more frequently in those who already have abnormalities.

Interventions such as nutrition assessment, dietary counselling and support, smoking cessation, promoting exercise as part of HIV care provide opportunities for reducing the risks of NCDs among PLHIV

Chapter Ten

10.0 Prevention of Malaria

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.

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.**

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 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. 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) and may have important pharmacokinetic interactions (especially artemesinins, lumefantrine, NNRTIs and PIs). For this reason, people receiving treatment for both HIV and malaria should be monitored closely for adverse drug reactions, and people with HIV receiving AZT or EFV should, if possible, avoid amodiaquine-containing artemisinin-based combination regimens because of the increased risk of neutropaenia in combination with AZT and hepatotoxicity in combination with EFV.

Chapter Eleven

11.0 Mental Health

PLHIV and their careers may have a wide range of mental health needs. The most common mental health comorbidities among PLHIV include depression, anxiety, dementia and other cognitive disorders and substance use disorders.

HIV care settings provide an opportunity to ensure the detection and management of mental disorders among PLHIV. Treatment or lack of treatment for these conditions can affect adherence to ARV drugs, retention in care and may involve potential side effects and drug interactions.

Chapter Twelve

12.0 Pre-Exposure (PreP) and Post-Exposure Prophylaxis (PEP)

12.1 Oral Pre-exposure Prophylaxis (PrEP)

12.1.1 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) either TDF or the combination of TDF + 3TC may be considered as a possible additional intervention for the uninfected
- If oral pre-exposure prophylaxis is to be provided for the HIV-negative partner in same-sex, male sero-discordant couples, the combination of TDF + 3TC should be used, as evidence of effectiveness and safety in male-to-male penetrative sex is available for this regimen only.
- People with HIV in sero-discordant couples, who start ART for their own health, should be advised that ART is also recommended to reduce HIV transmission to the uninfected partner.

12.2 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.

The following types of exposures should be considered for occupational post-exposure prophylaxis including rape:

- Needle-stick injury or injury with a sharp object used on a patient
- Mucosal exposure of the mouth or eyes by splashing fluids
- Broken skin exposed to a small volume of blood or secretions such as may occur with sexual abuse
- Sexual assault (rape).

The exposure can be classified as high risk or low risk for HIV infection, as follows:

Low risk:

- Solid, such as surgical needle, superficial exposure on intact skin
- Small volume (e.g., drops of blood) on mucous membranes or non-intact skin
- Source patient asymptomatic or with VL less than 1,500 copies/ml

High risk:

- Large-bore needle, deep injury
- Large-volume splash on mucous membranes or non-intact skin
- Source patient symptomatic or with high VL levels

12.2.1 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 infective 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 care 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.

12.2.2 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 water.
2. Start the ARVs recommended for post-exposure prophylaxis immediately—these should be started within 1 hour 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 counseling:

a. The standard rapid HIV antibody tests and Hepatitis should be used and the results of tests obtained as quickly as possible.
b. Offer viral DNA or RNA testing, if source is suspected to be in the window period.
c. Depending on the results of the HIV and Hepatitis tests, the following actions should be taken:
d. If the source patient is HIV-negative, no further post-exposure prophylaxis is necessary for the exposed health worker. There will be need to consider exposure to other infections such as hepatitis B.
e. If the exposed health worker is HIV-positive, no further post- exposure prophylaxis is necessary for the health worker. The health worker should be referred for further counseling and the long-term management of his or her HIV infection, which would have occurred prior to the exposure.
f. 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.
g. If the health worker should seroconvert during this time, provide appropriate care and counseling and refer for expert opinion and long-term treatment.
h. If the health worker declines to be tested for HIV and Hepatitis, reinforcement counseling on the benefits of knowing his or her HIV status and may have no claim for possible future compensation.
i. 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.
j. 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 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.

12.2.3. PEP with Hepatitis B immune globulin (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 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 OIC, Hospital Administrator and RHT.

12.2.4 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 the survivor is provided with the treatment as listed in the preceding section including comprehensive STIs management and pregnancy test (management of a verified rape case, Gambia HIV treatment and training manual). Refer the client to the nearest support centre for sexual assault survivors.

12.2.5 ARVs to be used in PEP

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

- TDF/3TC /DTG 300mg/300mg/50 mg orally daily

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

> 30 kg and/ or > 6 yrs: TDF/3TC/DTG

< 30 kg and/ or < 6 yrs: AZT/3TC+ LPV/r

The exposed individuals should be counseled regarding side effects prior to receiving the medicines. If the source is HIV-negative, medicine administration should be discontinued.

12.3 Key Populations

Key populations include both vulnerable and most-at-risk populations. Most-at-risk populations include men who have sex with men, transgender people, people who inject drugs and sex workers.

The use of ART in key populations should follow the same general principles and recommendations as for adults. There is one recommendation on community-based HIV testing, that is specific to key populations which will include self-testing and index-testing.

Chapter Thirteen

13.0 Monitoring, Evaluation and Pharmaco-Vigilance

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 in the transition period (Dolutegravir DTG). 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 seen weekly for the first month, then monthly for another three months at the referred health centre, and six-monthly review at the ART Centre that initiated the treatment.

Figure 1: The HIV treatment and care cascade

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

- **Head of the Team**
- **Pre-ARV Nurse**
- **Assistant to the Pre-ARV Nurse**

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 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 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.

Appendix 1: ARV Paediatric Dosing Table

Medicine	Strength of tablet or sprinkle sachet or capsule	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/NVP	60mg/30mg/	1	1	1.5	1.5	2	2	2.5	2.5	3	3	4	4
LPV/r sprinkles	40mg/10mg	2	2	3	3	4	4	5	5	6	6		
ABC/3TC/LPV/r	30mg/15mg/	2	2	3	3	4	4	5	5	6	6		
AZT/3TC/LPV/r	30mg/15mg/	2	2	3	3	4	4	5	5	6	6		
DRV/r	240/40mg	-	-	-	-	1	1	1	1	2	1		
ATV/r	100/33mg	-		-		1		1		2			
ABC/3TC	120/60mg	1		1.5		2		2.5		3			
TDF/3TC	75mg/75mg					1.5		2		2.5		3-3.5	
TDF/3TC/EFV	75mg/75mg/1					1.5		2		2.5		3-3.5	
TDF/3TC adult double	300mg/300mg					One third		One half		Two thirds		1	
TDF/3TC/EFV adult double scored	300mg/300mg/					One third		One half		Two thirds		1	

3 tablets for 25-29.9kg and 3.5 tablets for 30-34.9kg

TDF tablets are scored to break into half or third

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 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 ▪ Chronic Isosporiasis ▪ Disseminated nontuberculous mycobacteria infection

Appendix 3: Revised WHO clinical staging of HIV and AIDS for infants and children with established HIV infection (Adapted from WHO, 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 ▪ 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, or meningitis, but excluding pneumonia). ▪ 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 ▪ Chronic Isosporiasis ▪ Disseminated nontuberculous mycobacteria infection ▪ Acquired HIV-associated rectal fistula ▪ Cerebral or B-cell non-Hodgkin's lymphoma ▪ Progressive multifocal leukoencephalopathy

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 (3)

Classification of HIV associated immune deficiency	Age-related CD4 values			
	<11 months (%)	12-35 months (%)	36-59 months (%)	≥5 yrs (cells/mm3)
Not Significant	>35	>30	>25	>500
Mild	30-35	25-30	22-25	350-499
Advanced	25-30	20-25	15-20	200 - 349
Severe	<25	<20	<15	<200 or <15%

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 20: 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)
90	0.5 ml
120	5 ml
150	480 mg tablet
180	Start full prophylactic or therapeutic dose.

Table 21: Opportunistic Infections, their prophylaxis and recommended Treatment

OIs (PROPHYLAXIS OF OPPORTUNISTIC INFECTIONS)	
Co-trimoxazole 480mg	
Co-trimoxazole 240mg/5mls	
Dapsone 100mg	
Isoniazid 300mg/100mg	
OPPORTUNISTIC INFECTIONS	**TREATMENT**
Diarrhoea	Oral Rehydration Salts
	Loperamide Hcl 2mg
	Co-trimoxazole 480mg BD
	Zinc
	Metronidazole 250mg tds (PO) for 7/7
Respiratory Tract Infection	Amoxicillin 250mg(1000tabs)
	Azithromycin 250mg (6 tabs)
	Erythromycin 250mg (1000tabs)
Urinary tract infection	Ciprofloxacin500mg (100)
	Doxycycline cap 100mg (500pcs)
Herpes Simplex	Acyclovir 200mg
	Gentian violet
Oral thrush	Nystatin oral suspension
	Miconazole
	Fluconazole
Scabies	25% Benzyl benzoate
	25% Sulphur ointment
Eczema	Zinc oxide
	Hydrocortisone cream/ointment
Cerebral toxoplasmosis	Pyrimethamine 50mg
Cryptococcal Meningitis	Fluconazole 100mg/kg
	Fluconazole 5-6mg/kg
Ring worm	Benzoic acid with salicylic acid (Whitfield's)
Herpes zoster	Acyclovir
REGIMENS FOR STI (SYNDROMIC APPROACH)	
Gonorrhea (Urethral/Vaginal discharges)	Ciprofloxacin 500mg
	Doxycycline cap 100mg
	Metronidazole 250mg
Syphilis (Genital Ulcers)	Benzathine Penicillin 2.4 mu
	Water for injection 5mls
	Doxycycline cap 100mg

Appendix 7: Checklist for Tuberculosis (TB) screening of all HIV positive clients/patients

1. Do you have cough that has lasted for more than 2 weeks? YES [ ] NO [ ]
2. Do you have fever? YES [ ] NO [ ]
3. Have you lost significant weight recently? YES [ ] NO [ ]
4. Do you have night sweats? YES [ ] NO [ ]
5. Have you had TB or had contact with a TB patient at least 3 months back? YES [ ] NO [ ]

Appendix 8: Some Important Medicine Interaction

Avoid giving the following Medicines together

Medicines Involved	Effects of the Interaction
Avoid giving Nevirapine and Ketoconazole together.	Both medicines are toxic to the liver. The level of Nevirapine is increased while that of ketoconazole is reduced.
Use alternative contraception with Nevirapine.	ARVs can make oral contraceptives less effective. Encourage dual methods of contraception (including using condoms).
Avoid giving Dolutegravir and Diazepam together except in an emergency that requires diazepam.	Dolutegravir increases the levels of diazepam in the blood.
Avoid giving Stavudine and Zidovudine together.	Both medicines work to prevent the virus from entering the CD4 lymphocyte. They antagonize each other when given together.

Appendix 9: 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	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

Developmental milestones (cont.)

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	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	Runs without Falling	Looks at pictures in a book; imitates drawing a vertical line	Combines 2 different Words

Appendix 10: Developmental Red Flags

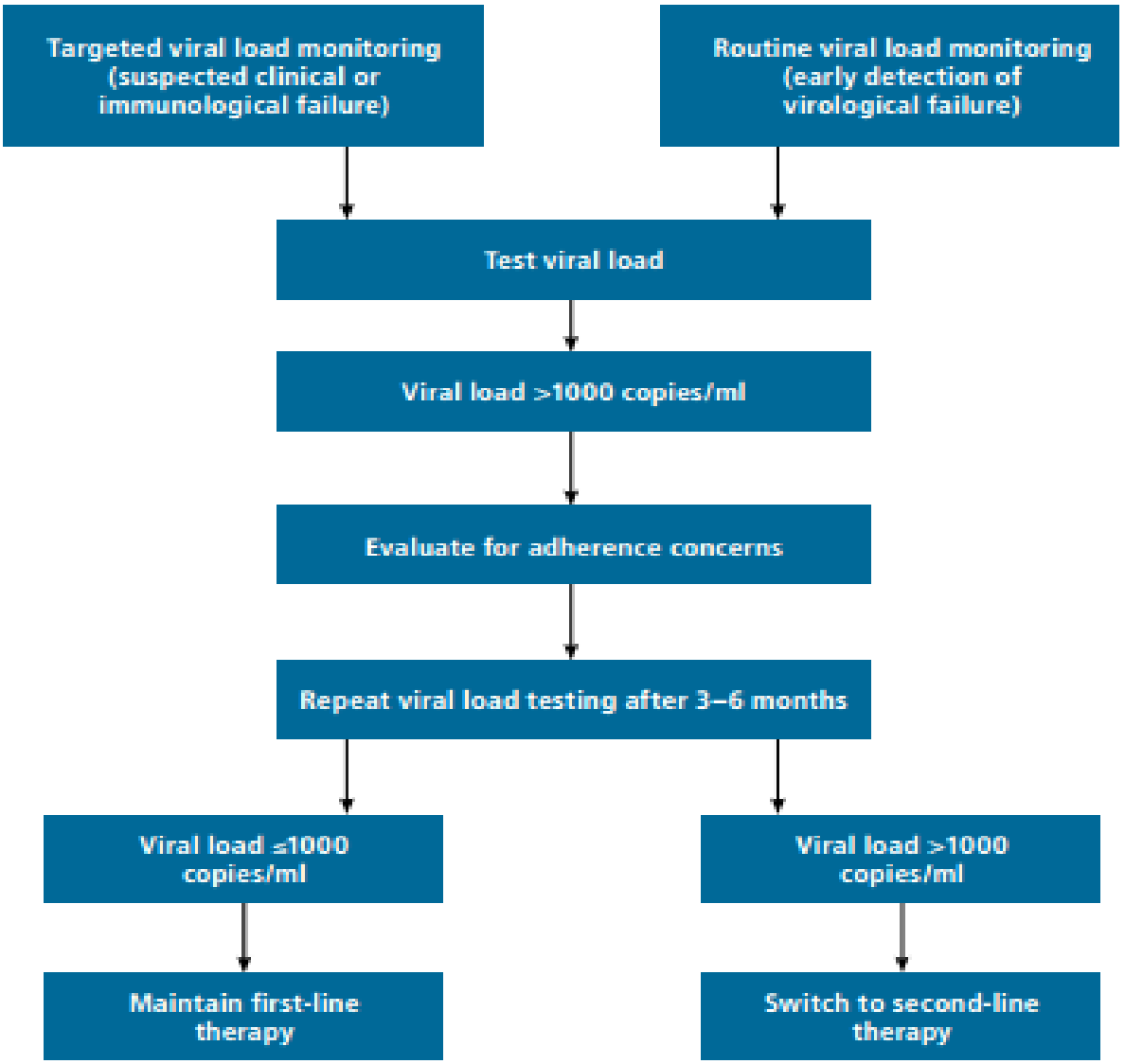
Birth to 3 months	• Failure to alert to environmental stimuli • Rolling over before 2 months (hypertonia)
4 to 6 months	• Poor head control • Failure to smile
6 to 12 months	• No baby sounds or babbling
12 to 24 months	• Lack of consonant production • Hand dominance prior to 18 months (contralateral weakness)
Any age	• Loss of previously attained milestones

Appendix 11: Monitoring Patients on ART

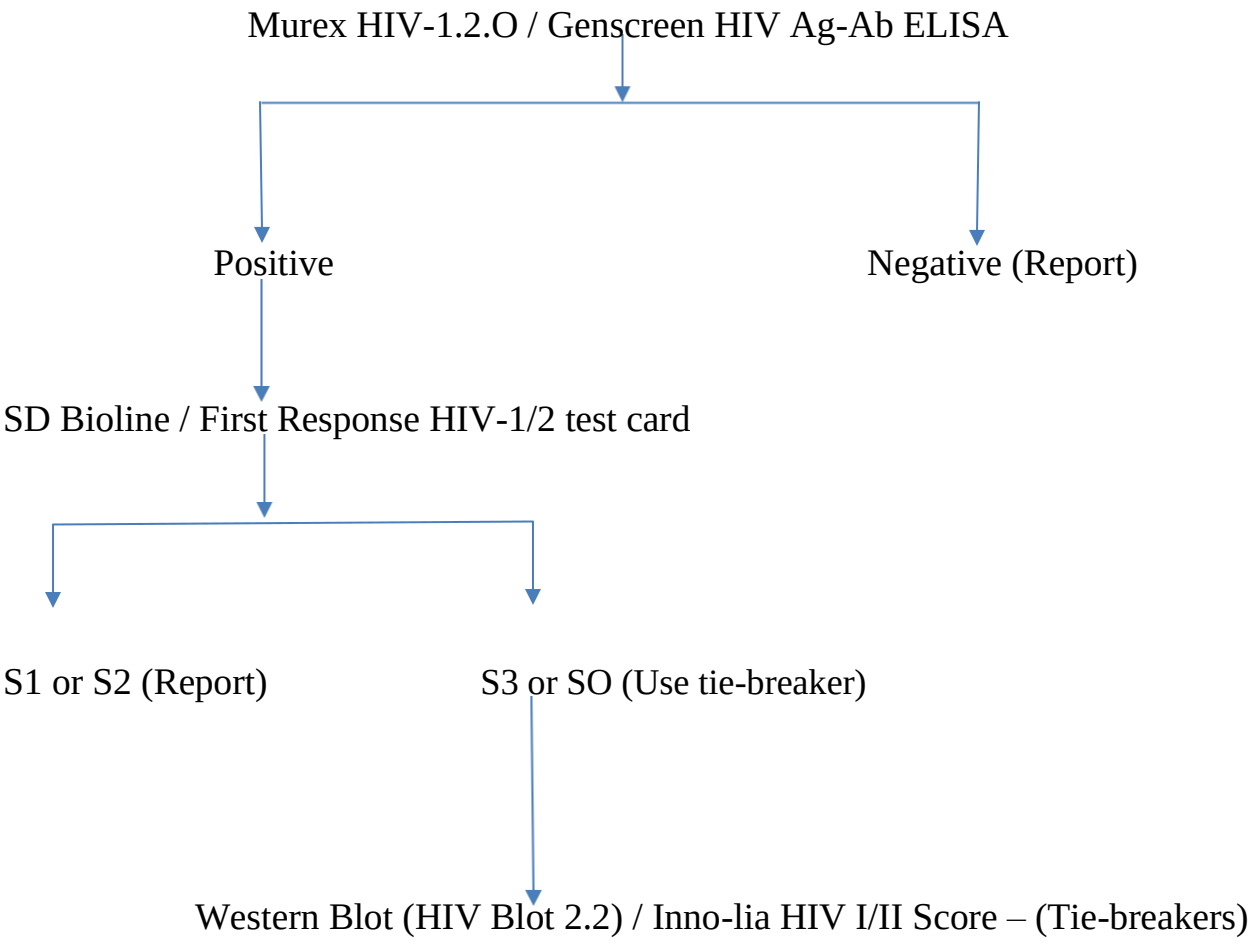
	Week		Month								
Appointment	0	2	1	2	3	4	5	6	8	12	Stable
Clinical evaluation, Wt, Ht[1], ADRs	+	+	+	+	+	+	+	+	+	+	Every visit
TB screening	+	+	+	+	+	+	+	+	+	+	Every visit
Adherence check	+	+	+	+	+	+	+	+	+	+	Every visit
Hb	+		+[2]		+[2]	Symptom directed					
ALT	+		+[3,4]		+[3,4]	Symptom directed					
Creatinine[5]	+	Symptom directed									
Pregnancy test[6] (PT)	+	If indicated									
Urinalysis	+	Symptom directed									
Fasting lipid profile & glucose[7]	+	Annually for patients on PIs									
CD4 count	+							+		+	Every 6 months
Viral load[8]		Targeted									

[1] Weight and height should be measured in children regularly and in adults for BMI calculation at initial assessment
[2] Schedule when AZT is used
[3] Schedule when NVP is used
[4] Schedule in pregnant women: ALT should be done at baseline, 2, 4 weeks then monthly until the woman delivers; especially important in women with CD4 >250 cells/mm³ at ART initiation on NVP-based regimen
[5] All pts should have creatinine measured if available. NRTI doses may need adjustment if renal function (RF) abnormal. TDF should be avoided if RF abnormal (See Table 20.11-20.14).
[6] PT should be done at baseline if EFV is to be used; thereafter PRN
[7] Schedule if PIs used
[8] Currently viral load is indicated for suspected treatment failure cases and before substituting d4T in cases of toxicity where d4T has been used for more than 6 months.

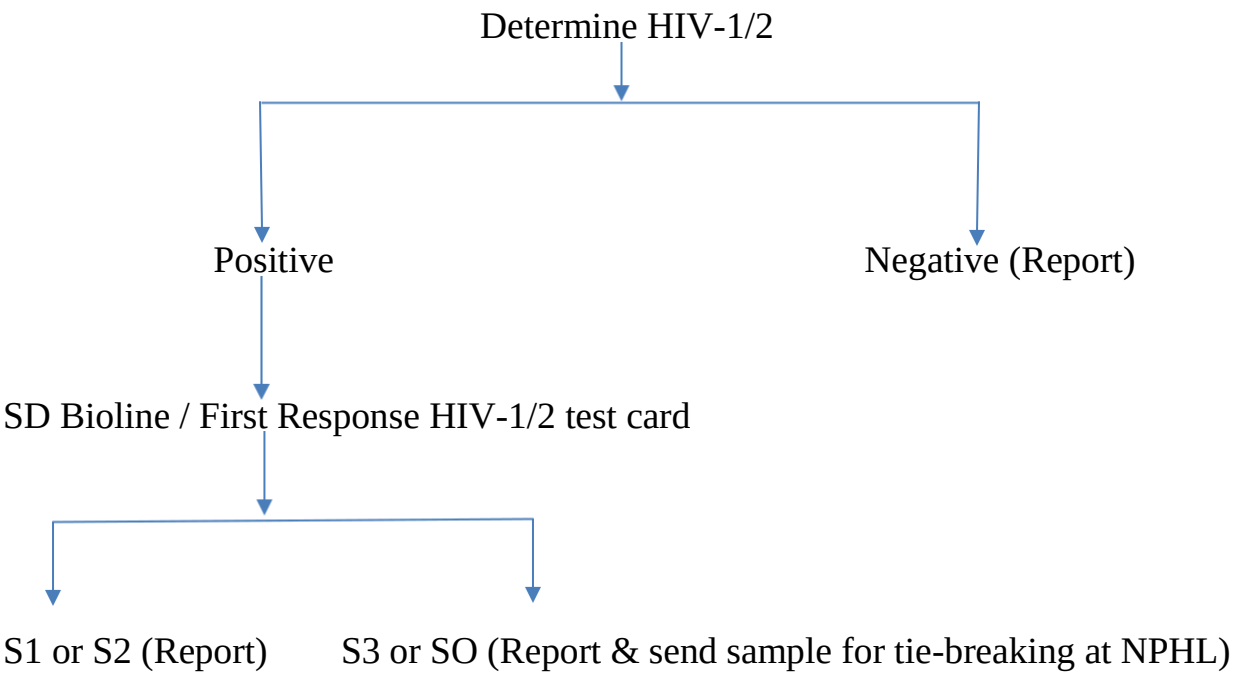
Appendix 12: Viral load testing strategies to detect or confirm treatment failure and switch ART regimen in adults, adolescents and children



Appendix 13: Reference serology laboratory – HIV 1/2 testing algorithm

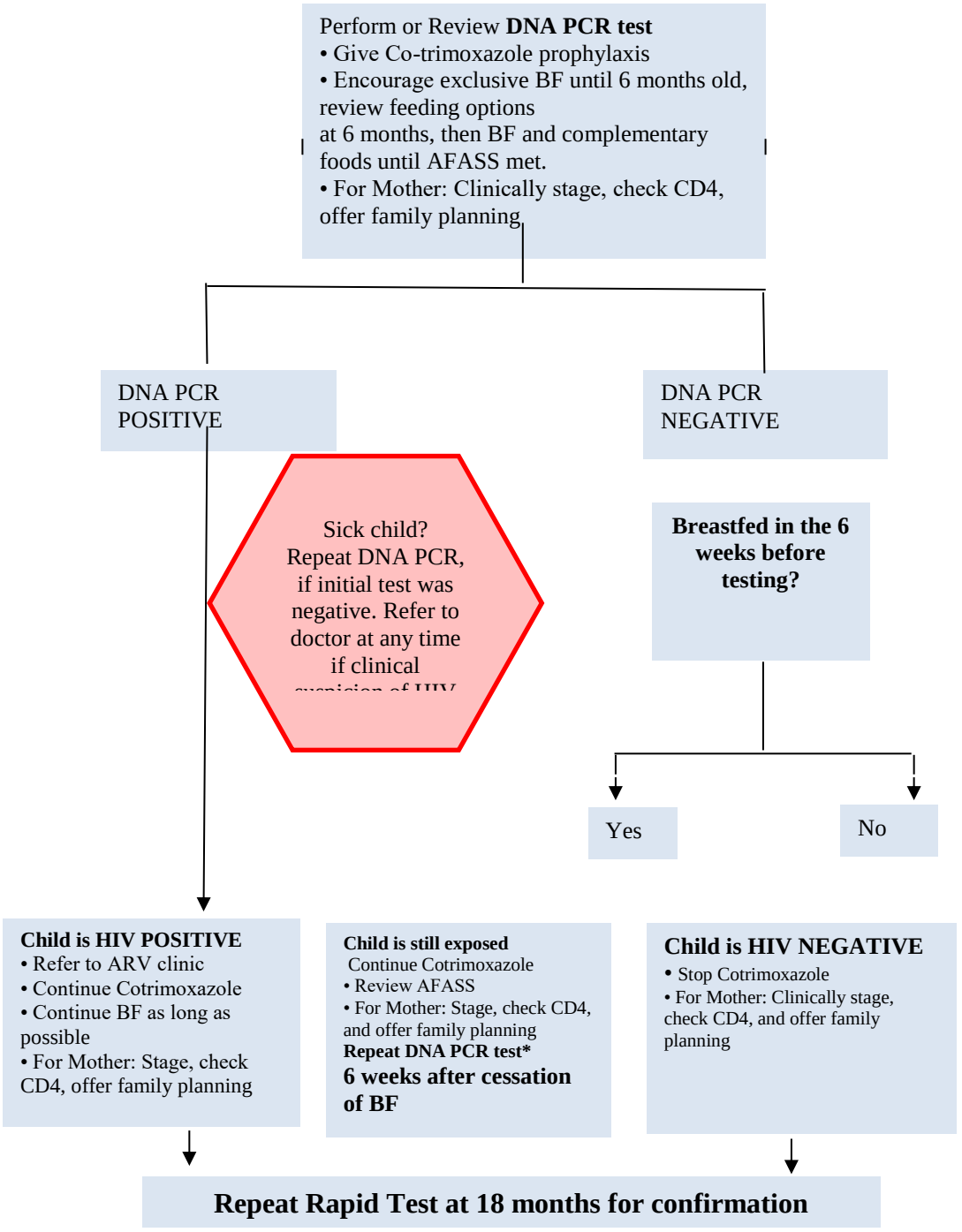


Appendix 14: Peripheral laboratory HIV-1/2 testing algorithm



NB: All HIV positives plus 10% of negatives from each health facility are sent to the Reference Laboratory for further testing and confirmation.

Appendix 15: Algorithm for DNA PCR of HIV-exposed infant aged 6-8 weeks (EID)



Annexes

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

MEDICINES CONTROL AGENCY, THE GAMBIA

Medicines Control Agency
54 Kairaba Avenue
TEL: (+220) 9946188 /4380632/3515273

Reporting Form for Suspected Adverse Drug Reactions (STRICTLY CONFIDENTIAL)

1	*PATIENT'S DETAILS			
	Full Name or Initials: _____ Patient Record No: _____ AGE/DATE OF BIRTH: _____ SEX: M☐ F☐ WEIGHT (Kg): _____ Pregnant Yes ☐ No ☐ Not applicable ☐ HOSPITAL/ Treatment Center: _____			
2	*ADVERSE DRUG REACTION (ADR)/ADVERSE EVENT			
A	DESCRIPTION		C. OUTCOME OF REACTION TICK AS APPROPRIATE Recovered fully ☐ Recovered with disability ☐ (Specify)_____ _____ Congenital Abnormality ☐ (Specify) _____ Life Threatening ☐ (Specify) _____ Death ☐ Others ☐ (Specify)_____	
	DATE Reaction Started	DATE Reaction Stopped		
B	Was Patient Admitted Due to ADR Yes ☐ No ☐ If Already Hospitalized, Was It Prolonged Due to ADR Yes ☐ No ☐ Duration of Admission (days) _____ Treatment of Reaction: _____			
3	*SUSPECTED DRUG (including Biologicals, Traditional/Herbal medicines)			
A	DRUG DETAILS (state name and other details if available/ attach product label/ Sample (available) Brand Name: _____ Generic Name: _____ Batch No._____ MCA No: _____ Expiry Date: _____ 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

References

1. Kenya MoMSo. Guidelines for Antiretroviral Therapy in Kenya, 4th edition. 2011.
2. Lancet Infect Dis, 2012, New England Journal of Medicine, 2013)
3. Service NHASCPMoHGH. GUIDELINES FOR ANTIRETROVIRAL THERAPY IN GHANA. 2010.
4. WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, June 2013/ 2014.