



**AUGUST
2019**

CONSOLIDATED GUIDELINES FOR **HIV CARE** IN GHANA

Test, Treat & Track

National AIDS/STI Control Programme,
Ghana Health Service.

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ABBREVIATIONS/ ACRONYMS



AIDS	-	Acquired Immune Deficiency Syndrome
ANC	-	Antenatal Clinic
ART	-	Antiretroviral Therapy
CHW	-	Community Health Worker
CHN	-	Community Health Nurse
CBTC	-	Community Based Testing and Counselling
DHIMS	-	District Health Information Management System
DMOC	-	Differentiated Models of Care
DTG	-	Dolutegravir
DSD	-	Differentiated Service Delivery
EID	-	Early Infant Diagnosis
EMTCT	-	Elimination of Mother-To-Child Transmission of HIV
FBTC	-	Facility Based Testing and Counselling
GAC	-	Ghana AIDS Commission
FDA	-	Food and Drugs Authority
FDC	-	Fixed Dose Combination
GDHS	-	Ghana Demographic and Health Survey
GFATM	-	Global Fund to Fight AIDS, TB and Malaria
GHS	-	Ghana Health Service
HeFRA	-	Health Facilities Regulatory Authority
HIV	-	Human Immunodeficiency Virus
HTC	-	HIV Testing and Counselling
HTS	-	HIV Testing Services

HSS	-	HIV Sentinel Survey
IBBSS	-	Integrated Biological Behavioural Surveillance Survey
IPT	-	Isoniazid Preventive Therapy
LMIS	-	Logistics Management and Information System
LTFU	-	Loss-To-Follow Up
MOH	-	Ministry of Health
NACP	-	National AIDS/STI Control Programme
NGO	-	Non-Governmental Organization
PEP	-	Post-Exposure Prophylaxis
PITC	-	Provider Initiated Testing and Counselling
PLHIV	-	Persons Living with HIV
PMTCT	-	Prevention of Mother - To -Child- Transmission of HIV
PrEP	-	Pre-Exposure Prophylaxis
PSM	-	Procurement and Supply Management
SI	-	Strategic Information
SOP	-	Standard Operating Procedure
STI	-	Sexually Transmitted Infection
TB	-	Tuberculosis
TLD	-	Tenofovir/Lamivudine/Dolutegravir drug combination
TLE	-	Tenofovir/Lamivudine/Efavirenz drug combination
UNAIDS	-	The Joint United Nations Programme on HIV/AIDS
VL	-	Viral Load
VLSUP	-	Viral Load Scale-up Plan
WHO	-	World Health Organization
WHO/AFRO	-	World Health Organization/ Regional Office for Africa



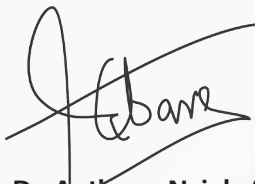
ACKNOWLEDGEMENT

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

The review was based on global evidence and country experiences in the implementation of HIV prevention, treatment services. We wish to acknowledge the monumental role of all Technical contributors to previous editions especially the ART Working Group (TWG) members. The Ghana Health Service is also grateful for all the contributions made to this document by other stakeholders, particularly the WHO, UNICEF, UNAIDS, US Centres for Disease Control and Prevention (CDC), Ghana AIDS Commission and the Global Fund to fight AIDS, TB and Malaria.

I commend all CEOs of respective Ministry of Health agencies, Ghana Health Service Divisional, Regional and District directors for their continued oversight of all disease surveillance, control and prevention activities under the technical guidance of the Director, Public Health.

The development of this first edition of the consolidated HIV Care guideline was made possible through the leadership of the Programme Manager, staff of the NACP and the entire cadre of service providers whose hard work has ensured the progress chalked in the prevention and control of HIV in Ghana till date.

A stylized, handwritten signature in black ink, appearing to read 'Ghana' or a similar word, with a large, sweeping flourish above it.

Dr. Anthony Nsiah-Asare

Director General
Ghana Health Service



FOREWORD

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

This updated National HIV Care Guideline include newly recommended HIV testing and linkage strategies, ARV drug regimens and formulations and diagnostics that are appropriate to the local setting. This version consolidates previous stand-alone guidelines for HTS, PMTCT, EID and ART into one single document for the first time.

The national guideline review process included extensive consultations with various stakeholders through workshops and technical working group meetings. The purpose of consolidating existing guidelines is to establish the linkage from client identification to follow-up care as the standard cascade of HIV care in line with 90/90/90 goals. HIV care must be viewed by all stakeholders as a continuum that is seamless to avoid gaps in implementation by service providers; hence the introduction of a new chapter on linkages.

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



Honourable Kwaku Agyeman Manu (MP)

Minister for Health



INTRODUCTION

Ghana is known to have a low HIV prevalence which is generalized in the population. In 2018, the estimated national prevalence of HIV in Ghana was 1.69% with an estimated 334,713 persons living with HIV (PLHIV) (UNAIDS HIV Estimates, 2018 to 2025). Of these, 65% (217,515) are females in the reproductive age group of 15 to 49 years. The median HIV prevalence in women attending antenatal care in 2018 was 2.4% (HSS Report 2018, NACP/GHS). Mother- to-child transmission of HIV is the second most common mode of transmission, after sexual transmission, and accounts for HIV infections in almost all children under 15 years.

The number of PLHIV who knew their status in Ghana in 2018 was 190,786 which is 57% of the estimated 334,713 PLHIV but the clients enrolled on treatment were 113,171 (34%). Out of the 113,171 on ART, 54,538 had viral load tests done with 66% (36,226) virally suppressed.

Differentiated strategies across the cascade of HIV care therefore have to be adopted to meet the needs of different populations to accelerate progress towards achieving the ambitious 90-90-90 targets of which Ghana is currently at 55-61-66 (2018 UNAIDS, HIV Estimates and Projections Report, GAC).

Provider Initiated Testing and Counselling (PITC) which entails the routine offer of HIV testing and counselling to clients in the health facilities at entry points with high yield is being implemented. These points with high yield include the OPD, DOTS corners, Emergency Room, ANC, PNC, CWC and Nutritional Rehab. PLHIV who are diagnosed with HIV should also be offered family and partner testing as index clients so their contacts are diagnosed as well. Populations like men and key populations who are not coming to the facilities to test need differentiated testing services in the form of targeted outreaches. WHO recommends that for low HIV prevalence countries, a three test algorithm is used to improve the true positivity rate hence the HIV testing algorithm has been updated to reflect current recommendations in this guideline. The Early Infant Diagnosis algorithm has also been updated to include DNA PCR testing at nine months after testing negative in the first six weeks of life. Everyone who tests positive to HIV MUST be linked to care and reported on by the service provider.

Once linked to care, Treat All is the strategy being used to offer ART to all HIV positive clients irrespective of WHO staging of the disease or the CD4 cell count/ml. clients who have been on ART for at least a year qualify to be assessed as stable. If they are stable, they can be given clinic appointments twice a year. This enables health care workers to provide focused and priority attention to the clients who aren't virally suppressed or present to the clinic in a very sick state. CD4 cell count was used to monitor clients on therapy before the era of Treat All. Currently, viral load testing is used to monitor clients on treatment.

Any client whose viral load is not suppressed has to be assessed for adherence and given enhanced adherence counselling. Another change is the ART regimen which was updated by WHO in July, 2019 is the shifting of Dolutegravir from third to first line for adults and adolescents with a caveat for women of child-bearing age to use contraception in order to avoid possible neural tube defects in the first few weeks of pregnancy.

Previously, the HIV testing, PMTCT and ART guidelines were stand-alone documents these have been merged to create a single document that provides comprehensive guidance on HIV care in Ghana.

It is expected that the implementation of these revised national guidelines at all levels of healthcare delivery including community level facilities, private hospitals and maternity homes will lead to the attainment of the 90-90-90 by 2020 and epidemic control.

1.1 PURPOSE

The purpose of this document is to provide guidelines for use by care providers within the continuum of HIV prevention, treatment and care for all age groups and populations in Ghana.

1.2 OBJECTIVES

The objectives of this document are:

- To provide updated guidelines for HIV Testing and Treatment based on current evidence.
- To standardize the provision of comprehensive HIV Care in-country.
- To provide direction on procurement, logistics management and information on HIV and AIDS Commodities.
- To provide guidance on the documentation and reporting of key ART indicators.



HIV TESTING AND COUNSELING SERVICES (HTS)

Differentiated strategies across the cascade of HIV care therefore have to be adopted to meet the needs of different populations to accelerate progress towards achieving the ambitious 90-90-90 targets of which Ghana is currently at 74 - 61 - 41 (2019 HIV Service Data, NACP, GHS).

Provider Initiated Testing and Counselling (PITC) which entails the routine offer of HIV testing and counselling to clients in the health facilities at entry points with high yield is being implemented. These points with high yield include the OPD, DOTS corners, Emergency Room, ANC, PNC, CWC and Nutritional Rehab. PLHIV who are diagnosed with HIV should also be offered family and partner testing as index clients so their contacts are diagnosed as well.

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HIV TESTING AND COUNSELING: GUIDING PRINCIPLES

The guiding principles for HIV Testing and Counseling (HTC) are Confidentiality, Informed consent and Post-test counseling and support services:

1. Confidentiality:

Maintaining confidentiality is an important responsibility of all healthcare providers. Clients should however be informed that their HIV test results may be disclosed to other healthcare providers to ensure they receive appropriate medical care.

2. Informed consent:

Written consent is not required but it is the responsibility of providers to ensure that:

- Clients understand the purpose and benefits of testing.
- Client's decision to refuse testing is respected.

3. Post- test Counseling and Support services:

The result of an HIV test should always be offered to a person with appropriate post-test information, counseling or referral.

LIMITS TO CONFIDENTIALITY

Ethical and legal limits to confidentiality should be discussed with clients. If disclosure is in the best interest of the client or is required by law; clients must first be notified and invited to disclose the information themselves. If the client is unwilling to disclose such information, the counselor must advise the client that he/she is legally obliged to do so. Only relevant information may be shared in these circumstances. Counselors should understand that such decisions should only be made when prior consultation with a supervisor or senior colleague indicate it is absolutely necessary.

CONFIDENTIALITY IN RECORD KEEPING

Clients' records must be stored securely. In a clinical setting only personnel with direct responsibility for a client's medical condition should have access to the records. All personnel with access to medical records on which HIV test results are recorded should be trained in procedures to maintain confidentiality of HIV test results. Where records are taken home, clients should be informed about the risks of breaches in confidentiality.

SHARED CONFIDENTIALITY REFERRALS

When clients are referred for additional services such as Prevention of Mother-To-Child Transmission (PMTCT), Sexually Transmitted Infection (STI) clinic and treatment of Opportunistic Infections including TB, psychological and social services including home-based care etc. it is usually preferable to state the client's name.

The counsellor should ensure that the client understands the reasons for giving his/her name on the referral letter. Referrals to other services should be based on the client's specific needs, life situation and test results. HTC counsellors should ensure that organizations to which they refer and release the client's name and test results are practicing careful procedures for confidentiality of test results. As much as possible, such referral letters should be addressed to a specific facility providing the additional services required.

INFORMED DECISION MAKING

When HTC services are provided within a health facility, it is necessary to distinguish between Client-Initiated Testing and Counseling (CITC) and Provider-Initiated Testing and Counseling (PITC). For CITC, the client shall be offered pre-test counselling. For PITC, it is recommended that adequate information be given to the client before the test is performed.

WRITTEN RESULTS

HTC sites may provide written results which must be dated and signed. Positive test results must be provided to the client. On the other hand, negative test results may be provided when required. In both cases clients must be counselled to keep their status. Clients requesting testing for official reasons such as employment or to obtain a visa where written results are required should be referred to the approval laboratory, hospital or clinic for the type of testing.

LEGAL AND ETHICAL ISSUES

The legal and human rights of HTC clients should be protected at all times in the context of other individual, legal and human rights and public health interest. Clients using HIV Testing Services (HTS) especially those who test HIV positive should not be stigmatized or exposed to discrimination.

RIGHT TO PRIVACY

Privacy is particularly emphasized in the context of HIV/AIDS given the stigma and discrimination associated with HIV/AIDS. Adequate safeguards must be in place at the HTC- sites to ensure that confidentiality is protected and that information about HIV status is not disclosed without the consent of the individual. There is a need to define how privacy should be protected (i.e. during testing, result disclosure, record keeping, etc.) There is a need also to define exceptions to this rule (i.e. immediate impact on the lives of others, rape etc.).

RIGHT TO NON-DISCRIMINATION, EQUAL PROTECTION AND EQUALITY BEFORE THE LAW

Participating in HTC must not constitute a source of discrimination against the individual HTC client; especially those found to be positive should not be denied services or other benefits on the ground of their HIV status.

RIGHT TO MARRY

An HIV Positive client has the right to marry but should ensure that disclosure of his/her HIV status is made to his/her partner before marriage. Non-disclosure to a partner before marriage constitutes a violation of the partner's human rights. Willful infection of a partner with a venereal disease constitutes a criminal offence under the Criminal Code of Ghana.

RIGHT TO INFORMED CONSENT

It is generally recommended in the practice of medicine that for any medical procedure, informed consent be obtained. Given the risks associated with HIV/AIDS, obtaining informed consent must be given special attention; and the risks and benefits of HTC must be fully explained to the client to ensure informed consent. Informed consent may be verbal or written. In adolescents and vulnerable groups, a written consent must be provided. In case of written consent, forms must be signed or thumb printed by the client before testing.

PROTECTING HUMAN RIGHTS WITHIN AN HTS SITE

In addition to information giving, counselling, confidentiality and informed consent, protecting the human rights of HTC clients should be promoted through the adoption of an ethical code of conduct for all those involved in HTC services. Such a code should include a commitment to competence, respect for the rights of individuals, professional conduct and integrity in the discharge of duties.

PRE-TEST INFORMATION AND EDUCATION

All HTS service providers (health worker or lay) shall be trained to offer HTS per the following standards:

- Establish a good relationship between yourself and the client.
- Identify yourself and clarify your role.
- Establish what prompted client to visit Centre.
- Assure confidentiality.
- Obtain client's particulars: name or code name, age; sex; residential address; telephone number, occupation; education; tribe; religion; marital status; economic status.
- Assess client's knowledge of HIV and AIDS, misconceptions, misunderstandings.
- Correct misconceptions/ misunderstandings and give the necessary information on basic facts on HIV and AIDS including the window period.
- Explain what a positive, negative and indeterminate result means.
- Explore who client will like to talk to about test results.
- Explain how long it will take for results to be ready and talk about limitations of test.
- If client decides to undergo test, obtain informed consent before the test is done.
- Provide opportunity for client to ask questions.

POST-TEST COUNSELLING AND EDUCATION

- Congratulate client for waiting for test result.
- Give the test result as soon as possible in a neutral tone of voice.
- For a positive test result, say: Your test result is positive. That means you are infected with HIV.
- For a negative test result, say: Your test result is negative. That means HIV antibodies was not detected in your blood.
- Pause for client to assimilate results communicated.
- Assess understanding by asking client to tell you what the test result means.
- Ask client how he or she feel about results and allow expression of emotional reactions.
- Continue with counseling on behavioral change either to maintain negative status or live positively with positive test results only when client is ready to talk about what he or she is planning to do next.
- Offer to test nuclear family members through the index client.
- Draw a risk reduction plan or other behavior change strategies, depending on the test result and the risk assessment/ client's situation.
- For clients with positive test results, discuss the need for linkage and initiation on ART within 7 days as well as plans for partner notification, and testing.
- Perform a psychosocial support assessment.
- Encourage clients to accept and live positively even if they face S&D and psychological problems.
- Counsel client on positive living (acceptance of status, nutrition, early identification and treatment of infections, avoidance of isolation, exercise, ART etc.).
- All HIV positive clients have to disclose their status to their sexual partner(s). This may be done as passive or assisted notification (see Differentiated Service Delivery (DSD) manual section 3.2 page 22).

HIV TESTING AND COUNSELING APPROACHES

CLIENT INITIATED TESTING AND COUNSELING (CITC)

This is traditionally known as Voluntary Counseling and Testing (VCT). In this type of HTC, the individual of his own accord goes to a counseling center and requests for the HIV test. CITC does not yield adequate coverage in both high-income and resource-constrained settings. Uptake of CITC has been hampered by many of the same factors that limit uptake of other HIV-related services, including stigma and discrimination, limited access to treatment, care and health services delivery in general, as well as gender issues.

PROVIDER INITIATED TESTING AND COUNSELLING (PITC)

The PITC is the offer of HIV tests to all clients who utilize health services. It presents an opportunity to ensure that HIV is more systematically diagnosed in order to facilitate patient access to needed HIV prevention, treatment, care and support services. PITC is recommended for adults, adolescents and children with signs and symptoms or medical conditions that indicate possible HIV infection, including Tuberculosis (TB), HIV-exposed children and symptomatic infants and children, malnourished children, people with Sexually Transmitted Infections (STI), people with hepatitis, all pregnant women attending antenatal care settings, Key Populations (KPs), notably Men who have Sex with Men (MSM), Transgender (TG), Female Sex Workers (FSWs), people who use drugs with a history or current injecting practices, migrant workers and their spouses with history of possible unsafe exposures, people in prison, and all others deemed at high risk of HIV. In order to implement PITC services the following should be taken into consideration. PITC Should be provided by healthcare providers trained to provide PITC services.

PITC should be provided within; OPD, IPD, TB unit, STI clinic, RCH settings, PMTCT sites including referrals to other support services. The first user of the test result is the health care provider who uses the HIV test to make diagnosis and provide appropriate treatment and/or referral. There are three types of PITC. These are: routine offer, diagnostic and mandatory testing.

1. Routine PITC

Routinely offered PITC is when HTC is offered to all clients using the health facility irrespective of their reasons for doing so. Note that routine offer does not mean routine testing.

2. Diagnostic PITC

Diagnostic PITC is where HTC services are offered to clients who have signs and symptoms that are consistent with HIV related disease or AIDS to aid clinical management.

3. Mandatory PITC

Mandatory testing is the situation in which HIV testing is ordered for specific purposes and situations. Mandatory testing is not permitted unless under the following situations as stipulated in the Ghana HIV and AIDS policy:

1. By court order.
2. Screening of all donated blood before transfusion or donation of body organs.
3. Sexual offenders.
4. Person is unconscious and unable to give consent.
5. A medical practitioner reasonably believes that such a test is clinically necessary or desirable in the interest of that person.

PROVISION OF HTC SERVICES IN GHANA

To increase access to HIV diagnosis and detection of persons living with HIV, HTC shall be provided in both public and private health care facilities: Facility-Based Testing (FBT) as well as through a range of Community-Based Testing (CBT) approaches in Ghana. The FBT takes place in a health facility, whereas the CBT is available in the community.

FACILITY-BASED PROVISION OF HIV TESTING AND COUNSELLING SERVICES

Facility-based HTS are available either at general health service sites or at stand-alone sites for HIV testing. These health facilities follow two approaches: Client-Initiated Testing and Counselling (CITC) and Provider-Initiated Testing and Counselling (PITC). Both approaches are voluntary, where the client gives verbal consent for HIV testing. HIV testing will be routinely offered by health workers to all patients at the OPD/IPD, STI, TB, ART clinics, emergency settings and across all entry points where feasible in all health facilities. Children will access HTS through Early Infant Diagnosis (EID), index testing and PITC based on risk after applying the screening tool at both outpatient and inpatient departments.

COMMUNITY-BASED PROVISION OF HIV TESTING AND COUNSELLING SERVICES

Community-based HTS refers to a situation where an HTC provider visits a community and offers HTC services to individuals, couples, and families within the community setting. This may include a number of approaches: door-to-door/home-based testing, - and testing at the workplace, schools, universities, special testing campaigns and events. Alternatively, clients or patients currently enrolled on treatment may request HTC providers to visit their communities or homes to conduct HTC for them or their family members.

The trained health care professionals or HTC providers visit the home with their consent, and offer HTC services to their partner(s), spouse(s), or family member(s). Thus, community HTC includes aspects of both PITC and CITC.

COUPLE AND PARTNER HIV COUNSELING AND TESTING

Couple and partner HIV testing and counseling including disclosure should be encouraged, supported and offered in all settings where HIV testing and counseling is provided, including antenatal, TB clinics, STI clinics, hospitals, Primary Health Care; health posts, community-led HTS. Couple/partner testing and counseling can identify sero-concordant couples who can be linked to services for HIV prevention and treatment. Such HTS need to be offered to married and cohabiting couples, premarital couples and other sex partners. When found positive, mutual disclosure needs to be encouraged. Service providers must be aware of potential intimate partner-based aggression and violence and need to support individuals who do not want to test with their partners and/or do not agree to mutual disclosure. Such clients can be encouraged and HIV testing offered for sex partners, children and other family members, which can be done individually, through couple testing, index case testing, family testing or partner notification, intimate partner notification by provider, with permission, if feasible. As with all HIV testing and counselling approaches, couple HIV testing and counselling should be voluntary but freely promoted or offered by the service providers. Partner consent is not mandatory for HIV testing and counseling.

TESTING AMONG INFANTS AND CHILDREN

In the paediatric setting, the entry points into HIV care are mainly through PITC. Health-care workers should see every patient encounter as an opportunity for providing PITC. Parents and caregivers should be encouraged to know their status, as well as that of their children and family members. Where PITC is practiced, more children are tested for and diagnosed with HIV, and can therefore access treatment services.

PITC should apply to all children attending the health care setting. In most instances, the parent/caregiver gives consent for an HIV test. Under some circumstances and depending on national legal requirements, a child considered to be sufficiently mature may give consent for an HIV test.

Infants and children should be tested in the following circumstances:

1. To identify the HIV status of all exposed infants for the purpose of appropriate follow-up, which includes provision of co-trimoxazole prophylaxis, antiretroviral prophylaxis and/or treatment;
2. Within 6 weeks of birth or soon thereafter for infants known to be exposed to HIV through mother-to-child transmission to enable early diagnosis of HIV with virologic testing;
3. For diagnosing all HIV-exposed infants who initially tested negative in the first six weeks of life with virologic testing at nine months;
4. To confirm the HIV infection status of children born to HIV-positive mothers six weeks after exposure to HIV has ceased or at eighteen months, whichever is sooner;
5. For the purpose of individual diagnosis in a child who is ill (e.g. presenting with an HIV-associated illness, such as tuberculosis or malnutrition, or other recurrent common childhood illnesses such as pneumonia or diarrhoea);
6. For the purpose of individual diagnosis where another sibling or parent has been diagnosed with HIV or where there is a history that the parents have died as a result of AIDS or other undiagnosed debilitating illness in the family;
7. In cases where a child has been exposed or potentially exposed to HIV.
 - o Through sexual abuse or
 - o Through contaminated needle sticks or receipt of potentially infectious blood or blood products (or through other routes, e.g. wet nursing).

DISCLOSURE OF HIV STATUS TO A CHILD

Disclosure refers to the process of informing the child about their HIV status. It also refers to person telling others of their HIV status. In HTC with infants and children, disclosure is an ongoing process continuing as the child matures. The parents/care givers, must be involved although the support of health care worker is also required. It is important for the child to be able to participate in their own health care. Many parents/care givers are reluctant to disclose the HIV test result and status to their young children and often seek to postpone the discussion well into the teens. Health care providers should ensure that;

- Disclosure of the HIV status to the child should be discussed with the parents or guardians from the beginning.
- The process of disclosure should be done over time; beginning as early as possible. Usually, one can start mentioning to a 4 – 6 years old HIV-infected child that they have a chronic disease that requires regular clinic visits and medicines every day. Usually when the child starts asking questions about the disease or the medication he/she is taking or when acting in a way that suggests that he/she is feeling isolated from other children because of the disease. Close coordination with the guardian/parent of the child in question is crucial.
- At about 8 – 10 years it is recommended that full disclosure of HIV and AIDS be offered but in a caring and supportive manner and environment. Before their early teen years HIV-infected children should know that they are infected with HIV, learn how it is spread and how to stay healthy.

It has been shown that children cope better with their HIV status when properly counselled. It is particularly important that adolescents be informed of their HIV status so that they can become active participants in their own care. Following challenges in disclosure, close coordination with the guardian/parent of the child is crucial.

Parents/guardians should be offered disclosure counseling to prepare and enable them to support disclosure in their children. Health care workers should be equipped with knowledge and skill on disclosure counseling.

HIV TESTING AND COUNSELING AMONG ADOLESCENTS

Adolescents above 16 years of age can give consent for HIV testing without parental permission. For adolescents younger than 16 years, parents or guardians or related institutions, and especially for adolescents from KP, older peers can give consent to receive HTS. Counseling of adolescents requires a non-judgmental attitude and assurance of confidentiality. It is preferable if the client is accompanied by a trusted adult able to provide support and assimilate information. Information should be appropriate for the adolescent patient's level of understanding and education. Adolescents may have concerns about sex, current and future relationships, fear of rejection and having a family in the future. All these fears can be addressed during post-test counselling and at subsequent visits. Often, people need some time alone to assimilate a positive HIV test result, and formulate questions and concerns. The role of post-test counselling is to contain any anxieties, provide support and reassurance, and to initiate plans with respect to disclosure, and follow-up visits for treatment and counselling.

Children and adolescents who test HIV negative must be counselled and advised on how to protect themselves to stay negative, as well as the importance of re-testing and testing with any current or future sexual partners. HTS for adolescents offers many important benefits. Adolescents who learn that they have been diagnosed with HIV are more likely to obtain emotional support and practise preventive behaviours to reduce the risk of transmitting HIV to others, and are more likely to receive HIV treatment and care.

HIV TESTING AND COUNSELING AMONG BLOOD DONORS

Blood donors and donated blood units shall be screened for HIV according to national algorithms. Under specific emergency life-or-death conditions, mainly where fresh blood transfusion is required, blood donors shall be screened for HIV using a rapid HIV test. All blood donors are required to complete a donor screening questionnaire prior to donating blood. When the donated blood unit is found reactive for HIV, it should be discarded, and the donor referred for confirmatory testing and further management for HIV.

HIV TESTING AND COUNSELLING AMONG KEY POPULATIONS

Key Populations will also access HTS through lay providers (peer-led) models at HTS sites and mobile outreach to hotspots and KP friendly locations and through the use of social network-based approaches, moonlight testing during evening hours in high risk settings and focused outreach to specific workplaces for military personnel, truckers, miners and prison guard peers in an effort to reach high risk men.

HIV SELF-TESTING FOR HIV (HIVST)

HIV self-testing (HIVST) is a process in which a person collects his/her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he/she trusts. HIV self-testing is an empowering and innovative way to reach more people with HIV and help achieve aspirational targets. Expanded use of HIVST can contribute to these global targets by reaching the first-time testers, people with undiagnosed HIV or those at ongoing risk who need frequent retesting. HIVST reduces the number of visits to facilities for frequent testers, and eliminating travel distances or long waiting to access HIV testing due to the convenience it offers. HIVST is recommended as a triaging and complementary test in Ghana in accordance with HIV LI under the Ghana AIDS Commission act 938, 2016.

The following guidance shall be followed by all persons eligible for promoting or undertaking HIVST;

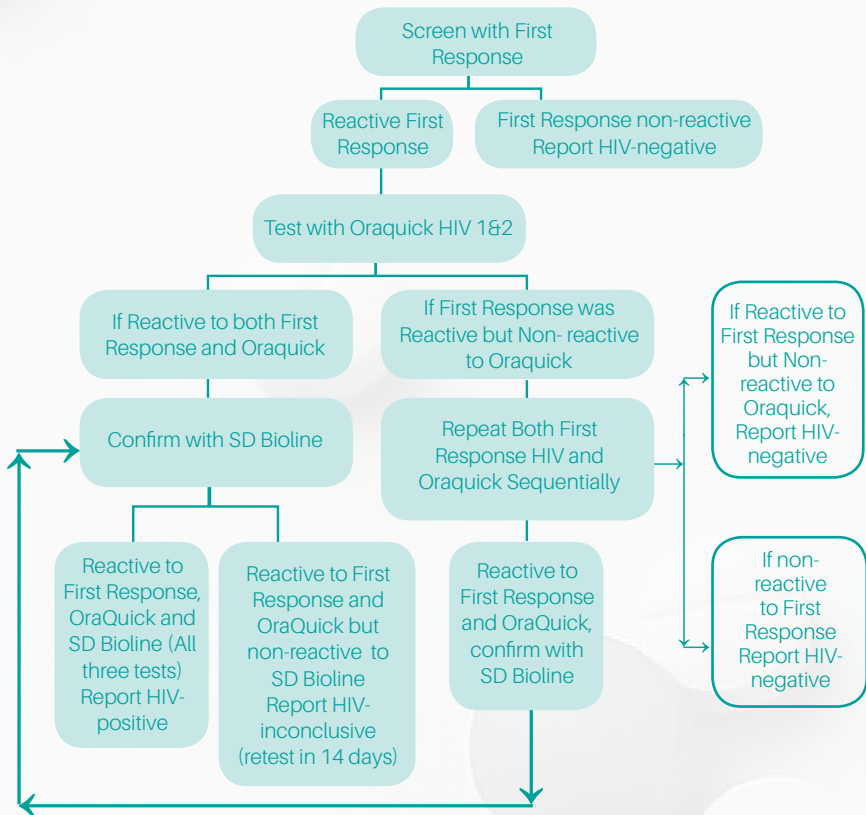
1. The result of a single RDT is not sufficient for HIV positive diagnosis. HIVST requires self-testers with a reactive result to receive further testing from a trained provider using a validated national testing algorithm.
2. To facilitate the point above all service providers offering HIVST kits shall provide pretest HIV information, explain the procedure for use of HIVST kits including interpretation of test results and post-test counselling and linkage information to client.
3. Assisted HIVST is recommended for adolescents: the adolescent is issued with the Self-Test kits and guided by a trained tester through the process of taking the test and interpreting the results and then assisted with linkage to prevention and or treatment services.
4. All self-testers with a non-reactive test result should re-test for exposure to HIV in the succeeding six weeks or if they are at high HIV risk again prior to sixth week.
5. HIVST is not recommended for people taking antiretroviral drugs as this may cause a false non-reactive result and false assumption of cure.
6. HIV RDT for self-testing, either oral or blood, shall be periodically evaluated and recommended for use in-country by the Ministry of Health and National AIDS/STI Control Programme of the Ghana Health Service.
7. All HIVST RDTs recommended for use in Ghana shall have the relevant international (WHO) product quality pre-certification and valid Ghana FDA registration.
8. The procurement and distribution of approved HIVST kits will be by both public and private health sector in line with national procurement laws. Key private pharmacy outlets will be engaged and oriented to facilitate access in accordance with national guidelines.

9. HIVST kits may be procured and offered to the public by only MOH/GHS-NACP recognized health institutions and pharmacies accredited by Health Facility Regulatory Authority (HeFRA) to all persons who meet age criteria for voluntary HIV testing in Ghana.
10. All approved HIVST RDT must retain clear instructions and procedure for use disposal and reporting of the kits.
11. All facilities accredited to procure and distribute HIVST RDTs shall be required to routinely report through the national health data repository (DHIS 2 of Ghana Health Service) for timely collation and reporting.
12. The country will also test other innovative approaches to increase HIV testing, which includes the use of mobile technologies, using standard computer applications, etc.

HIV TESTING ALGORITHM FOR GHANA

The national testing algorithm for establishing the sero-status of a person shall be a three-step process for all eligible populations irrespective of prior use of a preliminary test such as an HIVST. A positive status shall thus be established by the use of three rapid diagnostic tests as indicated in figure 1. Currently the only kits recommended for use in Ghana are First Response HIV 1&2 (first test), Oraquick HIV 1&2 (Second test) and SD Bioline HIV 1&2 (Third test) for the General Population. For Pregnant women the first test is First response HIV/Syphilis duo, Oraquick HIV 1&2 (Second test) and SD Bioline HIV 1&2 (Third test).

Figure 1: National HIV testing algorithm for Non-pregnant women and general population



DIAGNOSING HIV INFECTION IN CHILDREN UNDER 18 MONTHS

Diagnosis of HIV infection in babies born to HIV-infected mothers cannot be confirmed by conventional antibody tests due to the presence of residual maternal antibodies. These maternal antibodies may persist in the infant for as long as 18 months. Hence, virological assays such as HIV DNA-PCR or total nucleic acid-based assays represent the gold standard for diagnosing of HIV infection in children younger than 18 months.

ALGORITHMS FOR EARLY INFANT DIAGNOSIS (EID)

a. Diagnosis of HIV in first six weeks of life: Samples from HIV-Exposed Infants (HEIs) will be collected at any time within the first six weeks of life. All infants with non-reactive DNA PCR at birth will be retested at nine months. Infants with reactive test results should be put on ART as soon as possible.

Samples for HEIs can still be collected for clients who missed being tested in the first 6 weeks of life anytime they report to the health facility.

b. Diagnosing HIV infection in babies at 9 months of age: HEIs who tested negative in the first 6 weeks of life should be retested at 9 months of age for HIV using DNA PCR. Those exposed babies who test PCR negative six weeks after complete cessation of breast feeding are deemed negative whilst those who test positive are deemed to be HIV infected; and must initiate ART.



2

LINKAGE TO CARE AND OTHER SERVICE

Linkage is defined as a process of actions and activities that support people testing for HIV and people diagnosed with HIV in engaging with appropriate prevention, care and treatment services for their HIV status. In reference to PLHIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment. Special efforts should be made to link people who have a reactive test result in a community setting to facility-based services for additional testing and HIV diagnosis. For those diagnosed HIV positive in a facility, immediate linkage to clinical care is critical to ensure ART initiation and follow-up.

HTS must be accompanied by assured linkages to prevention, treatment, care and support services, including services for ART, TB, STI, RCH e.g. family planning, Psycho-social and judicial services. This will enable early enrolment in treatment, as well as access to services to prevent further transmission of HIV, prevent other OIs and co-morbidities.

This is especially important to prevent client from being lost to follow-up. Establishing these linkages is the responsibility of HTS providers. This may include assisting with transportation of the client; involving community in-reach workers; identifying and finding people lost to follow-up; ensuring support from peers or experienced patients; and using new technologies such a social, medical, and mobile phone reminder text messaging.

LINKAGE STEPS

- All HIV-positive clients testing positive at a facility should be escorted (with their consent) to the point for ART registration and clinical assessment. This should ideally be done by the HCW who has performed the test or by a lay worker (Model of Hope).
- All clients who have tested HIV positive in the community should be linked, with their consent, with a community health nurse or other community-based lay worker for further clinical assessment and care. The person who has performed community testing should link the client to their ART site of choice and, within a month, follow up to ensure that linkage has occurred.
- All linkages must be documented in a simple linkage register or booklet to facilitate client monitoring and reporting.
- If not linked, tracing should be performed by the community-based HCW.

Detailed guidelines on linkage and initiation into HIV care can be found in the Operational Manual for Differentiated Service delivery for HIV in Ghana (Page 26).

REFERRALS AND LINKAGES TO OTHER SERVICES

ART is only a part of the continuum of care in the comprehensive care package for PLHIV. Strong linkages within and outside the health system with other providers of care and support will further strengthen the effective management of clients. ART sites should have linkages with other comprehensive care services such as HTS, eMTCT, DOTS Centres, Management of Opportunistic Infections, Nutritional Support, Home-Based Care, Care for Orphans and Vulnerable Children, Psychosocial Support and STI services.

Referrals should follow the normal health system channels and in addition there should be networking with other stakeholders such as those in the community e.g. PLHIV associations, Models of Hope, Home-Based Care providers, Social workers and Legal Workers.

ART sites should form linkages with one another to facilitate referral and exchange of information and resources.



INITIATION INTO HIV CARE

HIV infection is a chronic condition that requires lifelong therapy. It is therefore important that the team should ascertain that the client is willing, ready and able to sustain therapy as interruption of treatment will be detrimental to the health of the client. Interruption could lead to development of drug resistance and increase the likelihood of transmission of a resistant virus which would have further public health implications.

CLINICAL EVALUATION

A comprehensive Clinical Evaluation (medical and social history, a complete physical examination) and laboratory evaluation are required before ART can be initiated. This is aimed at:

- Confirming HIV infection.
- Identifying past HIV-related illnesses.
- Identifying current HIV-related illnesses requiring treatment.

- Identifying co-existing medical conditions and pregnancy. This may influence the choice of therapy.
- Assessing nutritional status.
- Assessing capacity to adhere to treatment.
- Assessing clinical stage.

These can be achieved by:

1. Taking a detailed medical and social history.
2. Carrying out a complete physical examination.
3. Conducting appropriate laboratory investigations.

The Medical History should include:

- Date of initial HIV diagnosis and type of HIV infection.
- Current symptoms and concerns including a symptom screen for tuberculosis (See Appendix 4 for TB screening algorithm) and Hepatitis B and C.
- Past Medical History including diagnosis of tuberculosis.
- Drug history including treatment for TB and Hepatitis B.
- Previous ARV exposure.
- Sexual history and past symptoms of STI.
- Obstetrics and Gynaecological history including family planning.
- Social history including family support systems and income.
- History of drug use.

The physical examination should have the following components:

- Client's weight and height.
- Skin- looking out for the following: Herpes Zoster (old scars and new lesions), Herpes simplex, Molluscum contagiosum, Kaposi's sarcoma, Pruritic Papular Dermatitis or Eruptions or Prurigo and Plane warts.
- Mouth- Oropharyngeal mucosa, Candidiasis, Oral hairy Leukoplakia, Gingivitis, Mouth ulcers and Kaposi sarcoma.
- Lymphadenitis/lymphadenopathy

- Respiratory (sinusitis, Otitis, pneumonia, TB) and Cardiovascular system (Cardiomyopathy)
- Genito-urinary system
- Gastrointestinal system (Oesophagitis, Diarrhoea etc.).
- Anorectal area for discharge, ulcers, enlarged glands and growths.
- Nervous and musculo-skeletal systems including mental status, motor and sensory deficits.
- Fundoscopy whenever possible for retinitis or papilloedema and Cytomegalovirus (CMV) retinitis.
- Detailed examination of Genital Tract for discharge, ulcers, enlarged glands and growths.

LABORATORY EVALUATION

The reasons for investigations are:

- Confirmation of HIV infection and type (HIV1, HIV2, HIV1 and 2).
- Whether female clients are pregnant.
- The presence of opportunistic infections.
- The presence of co-morbid diseases.

Further information on the client's baseline laboratory tests are as in the Table 3.1. Within the context of Good Clinical Practice, these baseline tests should not be a barrier to ART initiation. ART can be initiated while the lab tests are done after ART. Where a lab test is essential to guide decision for ART initiation, it must be secured by all means prior to ART initiation in line with Good Clinical Practice Principles. Where a client is found to have any opportunistic infection, it should be treated and ART initiated when the client is stabilised.

Table 3.1: Baseline Laboratory Investigations

Haematological test	Full blood count
Biochemical test	Blood Urea Electrolytes and Creatinine Liver Function tests Fasting Blood Sugar Cholesterol and lipid profile
Routine examinations	Urinalysis (Urine R/E) Stool R/E
Respiratory examinations	TB screening Gene Xpert Chest X-ray
Serological Test	Hepatitis B Surface antigen
Immunological Test	CD4
These tests are performed depending on signs and symptoms	Histology on skin and lymph node Biopsy Kidney biopsy Screening for STIs Pap smear, HPV DNA Abdominal Ultrasound



ANTIRETROVIRAL THERAPY

The current National HIV Strategic Plan and Health Sector Strategic framework 2016-2020 has a goal of enrolling at least 90% of persons living with HIV on ART and achieve viral load suppression in 90% by 2020 in accordance with new UNAIDS 90/90/90 targets. Antiretroviral therapy is a lifelong activity and distinctive strategies are necessary to ensure its effectiveness and prevent development of drug resistance.

The proven effectiveness of Antiretroviral medications (ARVs), the simplicity or complexity of the regimen, the need for careful monitoring and adherence to therapy were considered in the formulation of ART regimen outlined in this guideline. It is essential that specific services and facilities be in place before considering the introduction of ART into any health care setting. Sites shall undergo assessment, and be assisted to meet a set of national criteria before accreditation to provide ART is given.

However, accreditation may be suspended or withdrawn if a facility consistently fails to adhere to national standards. The management of PLHIV is best achieved using a multidisciplinary team approach. The team should ideally comprise the following categories of individuals;

- Clinician/Prescriber
- Nurse
- Pharmacy staff
- Counsellor
- Nutritionist/dietician
- Social worker
- Laboratory staff
- Psychosocial support provider

GOAL

The provision of comprehensive HIV care and the administering of ART aim at attaining the following goals.

1. The suppression of HIV replication, as reflected in plasma HIV concentration, to as low as possible and for as long as possible.
2. The enhancement or preservation of the immune function (CD4 restoration), thereby preventing or delaying the clinical progression of HIV disease.
3. Improvement in quality of life.
4. Reduction in HIV related morbidity and mortality.
5. Promotion of growth and neurological development in children.

RECOMMENDED ANTIRETROVIRALS (ARVS) IN GHANA

The approach to antiretroviral treatment and the design of therapeutic regimens have been influenced by the following key findings from studies on the pathogenesis of HIV infection.

- Demonstration that a continuous high-level of replication of HIV is present from the early stages of infection.
- Demonstration that the measured concentration of plasma viral load is predictive of the subsequent risk of disease progression and death.
- Proof that combination antiretroviral treatment is able to consistently suppress HIV replication and also able to significantly delay disease progression to AIDS.
- Since on-going replication of HIV drives the disease process, the ideal target of antiretroviral treatment is to obtain timely and sustained suppression of viral replication.
- It should be made known to the patient that ART is not a cure. It only suppresses viral replication and makes the patient clinically better.
- Transmission of HIV can occur while on ART and so preventive measures should still be applied including safe sex such as male and female condom use.
- Once the patient starts ART, treatment should continue for the lifetime of the patient. Stopping treatment leads to a sudden increase in the viral load and increases the emergence of resistant strains of the virus.
- The patient who interrupts treatment needs to be reassessed before the reintroduction of ART.

Table 4.1: Recommended ARVs In Ghana

Nucleoside Reverse Transcriptase Inhibitors (NRTI)	Nucleotide Reverse Transcriptase Inhibitor (NtRTI)	Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)	Protease Inhibitors (PI)	Integrase strand transfer inhibitors INSTI
Zidovudine (AZT/ZDV)	Tenofovir Disoproxil Fumarate (TDF)	Nevirapine (NVP)	Ritonavir boosted Lopinavir (LPV/r)	Raltegravir (RAL)
Lamivudine (3TC)		Efavirenz (EFV)	Ritonavir boosted Atazanavir (ATV/r)	Dolutegravir (DTG)
Abacavir (ABC)			Darunavir/r (DRV/r)	
Emtricitabine (FTC)				

Fixed dose combinations of these drugs are preferred to single dose preparations because they improve adherence to treatment. In Ghana the preferred formulations shall be the triple fixed dose forms. Using simplified less toxic and more convenient regimens as Fixed Dose Combinations (FDC) is recommended for first line ART in Ghana. Mono therapy or dual therapy (treatment with one or two drugs only) is contraindicated for treatment of PLHIV.

Tables 4.2, show the recommended drug combinations used in Ghana. The first line regimen is the first option for treatment of all patients who fit the treatment criteria.

The second line regimen is used when there is evidence of treatment failure with the first line regimen.

This should be confirmed preferably by viral load monitoring. In this case the whole regimen should be changed.

Dosages of the regimen will be found in drug information attached in Appendix 5. A third line or salvage therapy is recommended for those who have failed second line treatment. Baseline investigation for such patients should include viral load and drug resistance testing. This must be done in consultation with a specialist.

ART REGIMEN FOR ADULTS (20 YEARS AND ABOVE) AND ADOLESCENTS (10 TO 19 YEARS)

Adults including pregnant women (>20years); Adolescents including pregnant adolescents (10-19 years); HIV-1, Dual HIV-1 and HIV-2 infection; HIV-2 infection

Table 4.2: First Line ART Regimen for Adults and Adolescents (Including Pregnant Women)

DRUGS	CAUTION	COMMENTS
PREFERRED REGIMEN		
Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Caution with TDF in renal dysfunction. DTG cannot be used with some anticonvulsants (such as carbamazepine) and should not be simultaneously administered with antacids, laxatives and multivitamin supplements because of the risk of chelation	Monitor renal function including urinalysis. ABC can replace TDF in renal impairment. Women of childbearing potential who intend to become pregnant or who are not otherwise using contraception should be informed of the potential increase in the risk of neural tube defects (at conception and up to the end of first trimester) before being offered DTG. DTG can be taken with or without food.

ALTERNATIVE REGIMEN		
<p>Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)</p>	<p>Caution with TDF in renal dysfunction</p> <p>Caution with EFV in liver disease</p> <p>Discontinue EFV if severe agitation or psychosis occurs.</p>	<p>Monitor renal function including urinalysis</p> <p>ABC can replace TDF in renal impairment.</p> <p>Monitor liver function tests before and during treatment in patients with underlying hepatic disease, including hepatitis B or C co-infection, marked transaminase elevations, or who are taking medications associated with liver toxicity. If AST/ALT more than 5 times upper limit of normal (ULN) or if elevation of serum transaminases is accompanied by clinical signs or symptoms of hepatitis or hepatic decompensation, discontinue therapy.</p> <p>Nervous system symptoms are frequent and usually begin 1-2 days after initiating therapy and resolve in 2-4 weeks; dosing at bedtime may improve tolerability.</p>
<p>Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)</p>	<p>ABC is contraindicated in ABC hypersensitivity</p>	<p>TDF can be used in place of ABC.</p> <p>Use ABC if client not eligible for TDF or ZDV.</p>

Table 4.3: Second Line ART Regimen for Adults and Adolescents
(Including Pregnant Women)

	DRUGS	COMMENTS
First Alternative	Zidovudine (AZT/ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir/r, ATV/r)	Use ABC if client not eligible for ZDV due to Hb <8g/dL or client had a TDF-based first line If Hb is <8g/dL or drops >25% from the baseline value for a client started on ZDV as second line, use ABC Use ZDV for clients who had ABC as first line Use PI for clients who were on DTG as first line
Second Alternative	Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Use DTG for clients who were on EFV as first line ZDV can be used in place of TDF for clients who had ABC as first line or have renal impairment so cannot use TDF.
	Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir/r (A)	Consider ABC if client has used TDF in first line and ZDV is contraindicated due to Hb is <8g/dL or Hb drops >25% from the baseline value for a client started on ZDV as second line

Table 4.4: Third Line ART Regimen for Adults and Adolescents
(Including Pregnant Women)

	DRUGS	COMMENTS
First Alternative	Darunavir/r (DRV/r) + Raltegravir (RAL) + 1 or 2 NRTI	<p>If possible, consider optimization using genotyping before selecting 3rd line regimen.</p> <p>DRV/r must be taken with food.</p> <p>RAL can be taken with or without food For PI-experienced people, the recommended DRV/r dose should be 600 mg/100 mg twice daily.</p> <p>DTG can be used as 3rd line in place of RAL but should be taken twice daily</p>
Second Alternative	DRV/r +2NRTIs ±NNRTI	<p>DRV/r must be taken with food in PI-experienced patients. DRV/r should be given 600mg/100mg twice daily</p> <p>DTG can be used as 3rd line in place of RAL but should be taken twice daily</p>

ART REGIMEN FOR CHILDREN

Table 4.5: First Line ART Regimen for Neonates (First 28 Days Of Life)

DRUGS	CONTRA-INDICATIONS/ CAUTION	COMMENTS
PREFERRED REGIMEN		
Zidovudine (ZDV) + Lamivudine (3TC)(or Emtricitabine (FTC)) + Raltegravir (RAL)	ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	Replace ZDV with ABC Raltegravir to be replaced with LPV/r after two weeks.
ALTERNATIVE REGIMEN		
Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Nevirapine (NVP)	ZDV is contraindicated in severe anaemia (Hb < 8g/dL) NVP is contraindicated in Liver dysfunction and hypersensitivity	Replace ZDV with ABC Replace NVP with LPV/r

Table 4.6: First Line ART Regimen for Children from Post-Neonates (>4 Weeks) to 9 Years

WEIGHT BAND	DRUGS	CONTRA-INDICATIONS/ CAUTION	COMMENTS
PREFERRED REGIMEN			
≥ 30Kg	Tenofovir (TDF) + Lamivudine (3TC)(or Emtricitabine (FTC)) + Dolutegravir (DTG)	TDF is contraindicated in renal impairment. DTG is contraindicated in children who weigh less than 20kg	Give TDF every 48 hours if Creatinine Clearance is less than 50ml/min
20 to 29.9Kg	Abacavir (ABC) + Lamivudine (3TC)(or Emtricitabine (FTC)) + Dolutegravir (DTG)	ABC is contraindicated in ABC hypersensitivity DTG is contraindicated in children who weigh less than 20kg	Replace ABC with ZDV
3- 19.9Kg	Abacavir (ABC) + Lamivudine (3TC)(or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	Abacavir is contraindicated in Abacavir hypersensitivity	Replace ABC with ZDV
ALTERNATE REGIMEN			
≥30Kg	Zidovudine (ZDV) + Lamivudine (3TC)(or Emtricitabine (FTC)) + Dolutegravir (DTG)	DTG is contraindicated in children who weigh less than 20kg	Where TDF is contraindicated, ZDV or ABC can be used
	Abacavir (ABC) + Lamivudine (3TC)(or Emtricitabine (FTC)) + Dolutegravir (DTG)	ABC is contraindicated in ABC hypersensitivity EFV is an option but DTG is preferred	ABC can be used where client is not eligible for TDF or ZDV If ABC is contraindicated, ZDV or can be used

WEIGHT BAND	DRUGS	CONTRA-INDICATIONS/ CAUTION	COMMENTS
ALTERNATE REGIMEN			
20 to 29.9Kg	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	Zidovudine is contraindicated in severe anaemia (<8g/dL)	ABC can replace ZDV
	Zidovudine (ZDV) + Lamivudine (3TC) (or emtricitabine) + Nevirapine (NVP)	Zidovudine is contraindicated in severe anaemia (<8g/dL) Nevirapine is contraindicated in Liver dysfunction or hypersensitivity	ABC can replace ZDV NVP can be replaced by EFV
3 to 19.9Kg	Zidovudine (ZDV) (or Abacavir (ABC)) + Lamivudine (3TC) + Lopinavir LPV/r	Zidovudine is contraindicated in severe anaemia (<8g/dL) ABC is contraindicated in ABC hypersensitivity	ZDV can replace ABC
	Abacavir (ABC) (or Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)	ABC is contraindicated in ABC hypersensitivity EFV should not be given to children less than 3 years old or less than 10Kg. EFV is contraindicated in EFV-related persistent CNS toxicity	ABC can replace ZDV Replace EFV with LPV/r

Table 4.7: Second Line ART Regimen for Children from Post-Neonates (>4 Weeks) to 9 Years

WEIGHT BAND	INITIAL FIRST-LINE REGIMEN	PREFERRED SECOND LINE REGIMEN	CONTRAINDICATIONS/ CAUTION	COMMENTS
≥30Kg	Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir/r (ATV/r))	ZDV is contraindicated in severe anaemia (Hb < 8g/dL) Pancreatitis, hepatotoxicity and metabolic disorders are some adverse effects of LPV/r	LPV/r can be taken with or without food. Monitor GIT complaints if on LPV/r
	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Abacavir (ABC) + Lamivudine (3TC) + Lopinavir/r (LPV/r) (or Atazanavir/r (ATV/r))	ABC is contraindicated in ABC hypersensitivity Pancreatitis, hepatotoxicity and metabolic disorders are some adverse effects of LPV/r	Monitor GIT complaints if on LPV/r
	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir/r (ATV/r))	ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	Maintain ABC if ZDV is contraindicated

WEIGHT BAND	INITIAL FIRST-LINE REGIMEN	PREFERRED SECOND LINE REGIMEN	CONTRAINDICATIONS/ CAUTION	COMMENTS
20 to 29.9Kg	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir/r (ATV/r))	ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	Monitor GIT complaints if on LPV/r
	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	TDF is contraindicated in renal impairment	Give TDF every 48 hours if Creatinine Clearance is less than 50ml/min TDF can be given to children weighing 10Kg or more and at least 2 years old
	Zidovudine (ZDV) + Lamivudine (3TC) (or emtricitabine) + Nevirapine (NVP)	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir	ABC is contraindicated in ABC hypersensitivity DTG is contraindicated in children who weigh less than 20kg	

WEIGHT BAND	INITIAL FIRST-LINE REGIMEN	PREFERRED SECOND LINE REGIMEN	CONTRAINDICATIONS/ CAUTION	COMMENTS
3 to 19.9Kg	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Raltegravir (RAL)	ABC is contraindicated in ABC hypersensitivity ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	RAL is preferred to DTG as second line for children who weigh less than 20kg
	Zidovudine (ZDV) (or Abacavir (ABC)) + Lamivudine (3TC) + Lopinavir (LPV/r)	Abacavir (ABC) (or Zidovudine (ZDV)) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Raltegravir (RAL)	ABC is contraindicated in ABC hypersensitivity	RAL is preferred as second line to DTG, which is contraindicated in children who weigh less than 20kg
	Abacavir (ABC) (or Zidovudine (ZDV)) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)	Zidovudine (ZDV) (or Abacavir (ABC)) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir (ATV/r))	ZDV is contraindicated in severe anaemia (Hb < 8g/dL) DTG is contraindicated in children who weigh less than 20kg	EFV is contraindicated if less than 3 years old or weighs less than 10Kg.

Table 4.8: Third Line ART Regimen for Children from Post-Neonates (>4 Weeks) to 9 Years

RECOMMENDED THIRD-LINE REGIMEN	DRUGS	COMMENTS
Darunavir/r (DRV/r) + Dolutegravir (DTG) ± 1-2 NRTIs	Severe hypersensitivity reactions with DRV/r can occur, DRV/r can worsen hepatic dysfunction if there is underlying liver disease	DRV/r should be given with food. In PI-experienced patients DRV/r should be given BID. If DTG or RAL (INSTI) has been used before, when added as a 3rd line, DTG must be administered twice daily. Where possible consider optimization using genotyping.

RECOMMENDATIONS FOR SPECIAL CONDITIONS

HEPATITIS B/HIV CO-INFECTION

For children born after 2002, it is anticipated that PENTAVALENT vaccine in Ghana will cover all immunized children.

For children above 3 years of age with hepatitis B, the preferred regimen is Tenofovir (TDF) + (Emtricitabine (FTC) or Lamivudine (3TC) + Efavirenz. Adult and adolescent clients who are co-infected with Hepatitis B will take TDF + 3TC as first line backbone which may be combined with DTG or EFV as the guidelines state above in Table 2.3. When they fail first line, the recommended second line is AZT + TDF + 3TC + PI.

TB/HIV CO-INFECTION

All HIV positive clients with TB shall be treated in accordance with the National Tuberculosis Programme Guidelines. (See Guidelines for Clinical Management of TB and HIV co-infection in Ghana). The regimen consists of initiation phase of Rifampicin, Isoniazid, Pyrazinamide and Ethambutol for 2 months and a continuation phase of Rifampicin and Isoniazid for 4 months. In the treatment of tuberculosis some important interactions should be considered. Rifampicin, PIs and NNRTIs are metabolised by the same liver enzyme system (cytochrome P450). Thus, Rifampicin, which stimulates the enzyme, can lead to a reduction in the blood levels of the PIs and NNRTIs. PIs and NNRTIs may also inhibit or enhance this enzyme system to different extents and can lead to altered blood levels of Rifampicin. These drug-drug interactions may result in ineffective antiretroviral or anti-tuberculous therapy or drug toxicity. To reduce the effect of drug-drug interactions, the following options must be followed in the treatment of HIV positive clients with TB co-infection.

ADULTS

Clients co-infected with HIV and Tuberculosis will be treated in accordance with the National Tuberculosis Programme Guidelines. Preferred first line in this case is TDF + 3TC (or FTC) + EFV but where EFV is not tolerated or contraindicated due to adverse effects like agitation or psychosis, the following options apply for the duration of TB treatment. Revert to standard first line upon completion of TB treatment. These combinations are weak as they contain triple NRTIs or triple nukes – TDF + 3TC (or FTC) + AZT OR ABC + 3TC (or FTC) + AZT. For clients who are on DTG-based regimen, they have to receive an additional 50 mg of DTG 12 hours after taking their main DTG-based ARV drug regimen (DTG is taken twice daily in TB management on Rifampicin-containing TB therapy).

CHILDREN

Any child with active TB disease should begin TB treatment immediately, and start ART, as soon as tolerated, but not later than 8 weeks after starting TB therapy if possible. For infants and children on LPV/r based regimen (2NRTIs + Lopinavir/ritonavir) who have to take a rifampicin-containing regimen for TB, LPV/r has to be super-boosted with additional Ritonavir or change to triple NRTIs for the duration of TB treatment. The usual ratio of Lopinavir to Ritonavir is 4:1 but in super-boosting the ratio becomes 1:1.

CLIENTS NOT ON ART

Start ART in all HIV/TB co-infected individuals. The ART must be started as soon as practicable within two weeks but not later than 8 weeks of starting TB treatment. In clients with MDR TB and HIV co-infection, ART regimen is the same as above.

CLIENTS ALREADY ON ART

Maintain client on ART, but replace Nevirapine with Efavirenz if client was on Nevirapine. Start TB treatment as soon as possible.

DRUG TOXICITY

This refers to the inability of the patient to tolerate the side effects of the medication and/or significant organ dysfunction. See table below for some common ARV Toxicities

Table 4.9: Common ARV Toxicities

HAEMATOLOGICAL TOXICITY	Drug-induced bone marrow suppression, most commonly seen with AZT (anaemia, neutropenia).
MITOCHONDRIAL DYSFUNCTION	Primarily seen with the NRTI drugs, including lactic acidosis, hepatic toxicity, pancreatitis, peripheral neuropathy, lipodystrophy, myopathy.
RENAL TOXICITY	Renal tubular dysfunction is associated with Tenofovir (TDF). ATV/r can also cause nephrolithiasis.

OTHER METABOLIC ABNORMALITIES	<p>More common with PIs. Include hyperlipidaemia, fat accumulation, insulin resistance, diabetes and osteopenia.</p> <p>Lipodystrophy is also associated with Zidovudine. The risk of cardiovascular events with Abacavir (ABC) is still debatable.</p>
ALLERGIC REACTIONS	<p>Skin rashes and hypersensitivity reactions, more common with the NNRTI drugs but also seen with certain NRTI drugs, such as ABC and some PIs.</p>
HEPATIC TOXICITY	<p>Liver enzyme elevation with DTG especially in patients with HBV or HCV co-infection. DRV/r also causes liver enzyme elevation</p>
MUSCULAR TOXICITY	<p>Muscle weakness and sometimes rhabdomyolysis seen with RAL</p>

DRUG-DRUG INTERACTIONS

Drug interactions may occur between any medications taken by an individual. For a PLHIV, drugs may be taken for prophylaxis and treatment of opportunistic infections, and diseases. Drug interactions may occur between:

- Different antiretroviral drugs.
- Medicines used for the management of Opportunistic Infections and Antiretroviral drugs
- Prescription and non-prescription medication or alternative medicine
- Between medicines and food
- Certain recreational drugs and prescribed medications

Some important drug interactions:

- Trimethoprim-sulfamethoxazole, ganciclovir, acyclovir and hydroxyurea can have potentially additive haematologic toxicity when given together with Zidovudine. Careful haematologic monitoring is necessary.
- Dapsone may lead to additive neurotoxicity with Zidovudine.
- Ketoconazole and Fluconazole may inhibit the metabolism of Protease Inhibitors and may result in PI toxicity.

GRADING OF ADVERSE EVENTS

Table 4.10: Grading of Adverse Events

GRADE	SEVERITY	ACTION
1	Mild	Transient or mild discomfort: no limitation in activity; no medical intervention/ therapy required
2	Moderate	Limitation in activity- some assistance may be needed; minimal or no medical intervention required
3	Severe	Marked limitation in activity- some assistance usually required; medical intervention/therapy required- Hospitalization possible
4	Severe Life-Threatening	Extreme limitation in activity - significant assistance required; significant medical intervention/ therapy required; hospitalization and home-based care

GUIDING PRINCIPLES IN THE MANAGEMENT OF ARVS ADVERSE EVENTS

1. Evaluate concurrent medications and establish whether the toxicity is attributable to an ARV drug or to a non-ARV medication taken at the same time.
2. Consider other disease processes (e.g. viral hepatitis in an individual on ARV drugs who develops jaundice) because not all problems that arise during treatment are caused by ARV drugs.
3. Manage the adverse event according to severity:
 - **Grade 4 (severe life-threatening reactions):** Immediately discontinue all ARVS drugs, manage the medical event (i.e. symptomatic and supportive therapy) and reintroduce ARV drugs using a modified regimen (i.e. with an ARV substitution for the offending drug) when the client is stabilized.
 - **Grade 3 (severe reactions):** Substitute the offending drug without stopping ART.
 - **Grade 2 (moderate reactions):** Consider continuation of ART as long as feasible. If the client does not improve on symptomatic therapy, consider single-drug substitutions.
 - **Grade 1 (mild reactions)** are bothersome but do not require changes in therapy.
4. Stress the maintenance of adherence despite toxicity for mild and moderate reactions.
5. If there is a need to discontinue ART because of life-threatening toxicity, all ARV drugs should be stopped until the client is stabilized.



ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION (EMTCT)

5.1 EMTCT GUIDING PRINCIPLES

The EMTCT guidelines are developed in line with the following guiding principles recommended by the WHO as a public health approach for increasing access to EMTCT services. This approach involves the EMTCT programme being built around standardized regimens and protocols according to national guidelines, and delivering a comprehensive package of services based on the UN strategic approach to the prevention of HIV infection in infants and young children.

The EMTCT programme in Ghana is also based on the WHO promoted comprehensive strategic approach to the prevention of

HIV infection in infants and young children and includes:

1. Integrated delivery of interventions for EMTCT within maternal, newborn and child health services including links between the services which is key. Programmes to prevent MTCT shall be implemented and scaled up both as important prevention interventions and as access points for care, treatment and support for women living with HIV, their children and families. For this to happen, interventions to prevent MTCT need to be integrated into reproductive and child health services and programmes for HIV and care.
2. Women's health is the overarching priority in decisions about ARV treatment during pregnancy to improve maternal and child survival. For HIV positive pregnant women, treatment reduces maternal mortality and morbidity. It is the most effective method of preventing MTCT of HIV by securing the health and improving the chances of survival of her child.
3. Necessity for highly effective ARV regimens and simple formulations for eliminating HIV infection in infants and young children.
4. Task sharing to remove all barriers to initiation of therapy within EMTCT and ANC settings.
5. Urgent need to scale up services to achieve equitable national coverage and universal access aiming for impact and equity.
6. Emphasizing partnerships and participation of people living with HIV and communities including male involvement.

GOAL OF EMTCT IN GHANA

The goal of EMTCT is to provide a comprehensive family centered continuum of promotive, preventive, clinical and supportive services in conjunction with other public health interventions to maintain the health of the mother and prevent the transmission of HIV from a mother to her infant(s).

THE STRATEGY FOR EMTCT IN GHANA

The components of the strategy are:

1. Primary prevention of HIV infection in women of child bearing age.
2. Prevention of unintended pregnancies among women infected with HIV.
3. Prevention of HIV transmission from women infected with HIV to their infants.
4. Provision of treatment, care and support to women infected with HIV, their infants and their families.

The first 2 components are addressed in other documents such as the Reproductive Health Policy and Standards and Adolescent Reproductive Health Policy. The rest of this EMTCT policy document focuses on components 3 and 4 of the strategy.

APPROACH FOR THE PROVISION OF EMTCT SERVICES IN GHANA

EMTCT services shall be provided in both public and private health care settings in Ghana where antenatal, delivery and postnatal services are conducted. The national strategies for providing services for the prevention of mother-to-child transmission of HIV have two main approaches:

Facility-based care

It comprises clinical and public health interventions in health care settings both public and private which reduce the transmission of HIV from a pregnant woman to the new-born. These consist of the provision of:

- IEC and BCC on the transmission of HIV and STI.
- Both client and provider-initiated testing and counselling strategies.
- Antiretroviral therapy.
- Continued supportive counselling for all HIV positive mothers.
- Counselling on and support for infant feeding.

Outreach/community-based services

- Psychosocial care and community support.
- Outreach maternity services.
- Child Welfare Clinic.
- Nutritional counselling and support for safer infant feeding practices.
- Home visits by Community Health Officers and others.
- Linkages of families and household members to care.
- Mother, child and adolescent support groups.

COST OF CARE

Subject to any policy directive or law to the contrary that shall subsequently be made or enacted, every mother accessing EMTCT service interventions shall be provided services free of charge; and this shall include ante-natal care, labour and delivery, as well as postnatal care up to 18 months.

5.2 GUIDING PRINCIPLES FOR HIV TESTING IN EMTCT

The guiding principles for HIV testing in EMTCT setting are the same as for general HTS. They include Confidentiality, Informed consent and Post-test Counselling and support services as detailed in Chapter One under HTS. In brief;

Confidentiality: Maintaining confidentiality is an important responsibility of all healthcare providers. Clients should however be informed that their HIV test results may be disclosed to other healthcare providers to ensure they receive appropriate medical care.

Informed consent: In the context of EMTCT, written consent is not required but it is the responsibility of providers to ensure that: Clients understand the purpose and benefits of testing and Client's decision to refuse testing is respected.

Post- test Counselling and Support services: The result of an HIV test should always be offered to a person with appropriate post-test information, counselling or referral.

5.3 HIV TESTING STRATEGIES FOR EMTCT

HIV testing is a process that determines whether a person is infected with HIV or not. HIV testing detects antibodies or antigens associated with HIV in blood and other body fluids.

5.3.1 FRAMEWORK FOR TESTING

In the context of MTCT prevention, HIV testing shall be integrated into Reproductive and Child Health (RCH) services. All pregnant women accessing RCH services shall receive information on HIV testing. All HIV testing and counseling shall be performed by trained counselors and nurses.

5.3.2 ADVANTAGES OF TESTING AND COUNSELLING FOR EMTCT

After testing, HIV negative pregnant women are to be counselled to enable them remain uninfected. For pregnant women who test positive, counselling shall be undertaken to help them:

1. Make informed decisions about their pregnancy
2. Receive appropriate and timely interventions to reduce MTCT including:
 - a. Follow up and on-going health care for themselves, their HIV exposed infants and family.

- b. Antiretroviral treatment.
- c. Infant feeding counselling and support.
- d. Information and counselling on family planning.

5.3.3 Routine Offer of HIV Testing

Irrespective of the types of testing strategies indicated in Chapter One (HTS), the main mode of testing for EMTCT in Ghana shall be the provider-initiated testing strategy. Consequently, HIV Testing and Counselling shall be routinely offered to all pregnant women as part of initial and subsequent ANC services as early as possible in the pregnancy. All women after an initial negative HIV test result shall be encouraged to have the test repeated in the third trimester. The minimum amount of information that should be provided to clients includes the following:

- 1. Clinical and prevention benefits of testing.
- 2. Right to refuse.
- 3. Follow-up services offered.

In the event of a positive test result, anticipating the need to inform partners and other family members who may be at risk of exposure to HIV infection is necessary.

5.3.4 WHEN A CLIENT DECLINES TO TEST

Some women may initially decline an HIV test as a result of some concerns. They might accept at a later date, especially if their reasons for declining are discussed and addressed. It is therefore important to continue routine offer of testing during subsequent visits. Certain women will continue to decline testing and their decisions shall be respected and documented in the medical record. Their refusal shall not compromise the quality of care they receive.

5.4 OTHER OPPORTUNITIES FOR HIV TESTING AND COUNSELLING

5.4.1 HIV Testing during Labour

Any woman with undocumented HIV status at the time of labour shall be offered HIV testing and counseling. Testing shall not however be done during the active stage of labour or in the second stage of labour. Immediate initiation of appropriate antiretroviral treatment shall be recommended to women in labour in the event of a positive test.

5.4.2 Post-partum and Newborn Testing

A woman whose HIV status is unknown postpartum shall be offered HIV testing and counseling. In the situation where the mother's HIV status is unknown postpartum and she is unavailable to be counseled and tested, rapid testing of the newborn as soon as possible after birth (within 48 hours postpartum) is recommended. In all of the above, a positive HIV test indicates the baby is HIV exposed and shall be offered the recommended antiretroviral prophylaxis and care as early as possible until their status is confirmed with DNA PCR testing within the first six weeks of life.

In case of an indeterminate result, the infant should be put on antiretroviral prophylaxis and then followed up with further testing to confirm the status of the child.

5.4.3 Couple and Partner HIV Counseling and Testing

Couple and partner HIV testing and counseling including disclosure should be encouraged, supported and offered. Partner consent is not mandatory for HIV testing and counseling.

HIV TESTING ALGORITHMS FOR EMTCT

Serial testing with three rapid HIV testing kits shall be used. The first test is for dual HIV/Syphilis detection and the subsequent two rapid tests for confirmation of HIV reactivity.

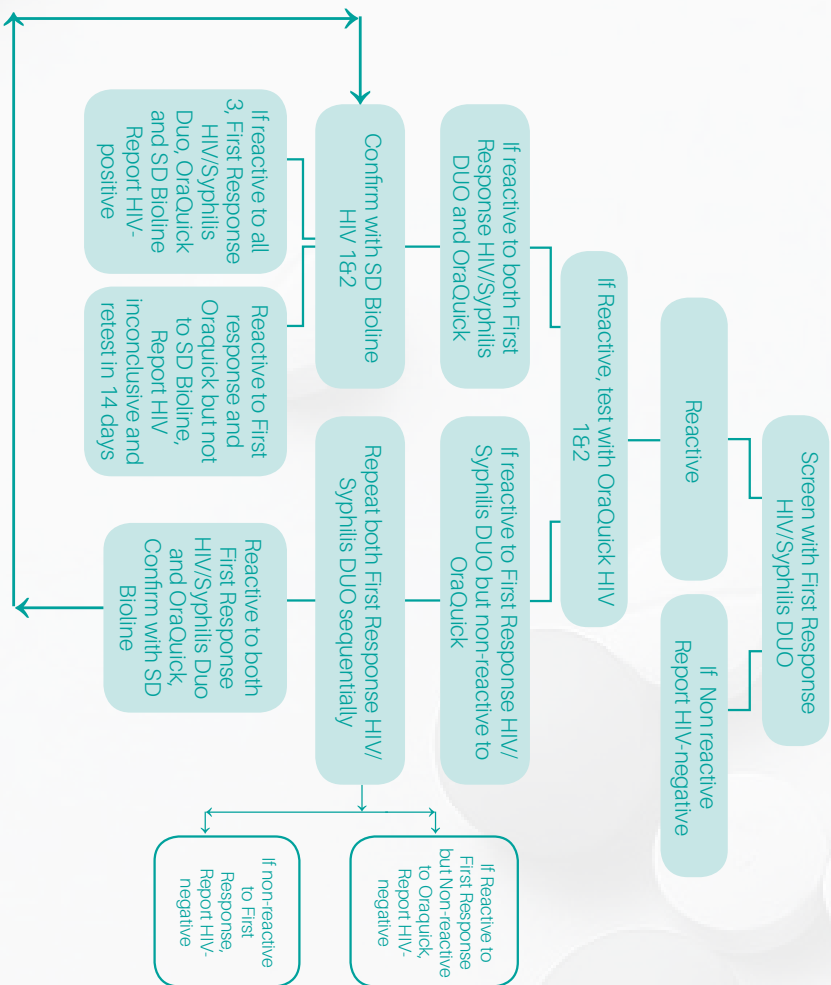


Figure 5.5. 2 National Algorithm for Antenatal clients

5.5 RECOMMENDED ANTIRETROVIRAL PROTOCOLS FOR PMTCT.

Antiretroviral therapy shall be given to all HIV positive pregnant and breastfeeding women for treatment and prevention of mother to child transmission of HIV regardless of their stage or immune status. This reflects a reinforcement in policy to offer lifelong treatment of all HIV positive mothers for EMTCT.

5.5.1 PREFERRED ART REGIMEN FOR EMTCT

All pregnant women should be put on the preferred ART regimen. The preferred treatment regimen is a triple fixed-dose formulation of:

TDF+ 3TC (or FTC) + EFV (or DTG). (Inform HIV positive woman of family planning options due to potential CNS risk).

The alternate regimen for EMTCT are

a. TDF + 3TC (or FTC) + EFV or b. ABC + 3TC (or FTC) + EFV.

5.5.2 ARV PROPHYLAXIS FOR THE HIV-EXPOSED INFANT

All HIV- exposed infants irrespective of feeding option are to be provided within 48 hours of birth with: AZT 12 hourly + NVP daily for 12 weeks.

Where AZT is contraindicated (e.g. anaemia or bleeding disorder), NVP daily for twelve weeks should be given. Breast feeding must be up to 12 months; with first 6 months being exclusive breastfeeding. (Refer to Annex D).

NB:

AZT: Zidovudine; 3TC: Lamivudine; NVP: Nevirapine; EFV: Efavirenz; TDF: Tenofovir; FTC: Emtricitabine; DTG: Dolutegravir; ABC: Abacavir.

5.6 CARE FOR HIV INFECTED WOMEN AND WOMEN OF UNKNOWN STATUS

Clients identified as having HIV infection during pregnancy require active follow-up counselling and support services to facilitate the acceptance of their sero-status and linkage to treatment and care services. Women with unknown HIV status shall be routinely offered HIV testing and counseling any time they access maternity services and be given the necessary care and interventions to reduce the possible risk of MTCT. The comprehensive care of persons living with HIV require both acute (immediate) and chronic (long term) care at the health facility and at home. Care providers caring for HIV positive pregnant women will be required to provide management for acute care problems and illnesses associated with HIV infection such as opportunistic infections which include bacterial, skin, neurologic, and mental health problems, whilst also addressing the long term needs associated with chronic diseases. This calls for planned management and good client-provider partnership.

Pregnancy provides a unique opportunity for such a long term relationship between the care provider and the HIV positive client. Principles of chronic care must guide this relationship. These principles focus on clients' concerns and priorities, as well as supporting client's self-management. Care providers must be guided by the 5 'As' of ASSESS, ADVISE, AGREE, ASSIST, and ARRANGE, in their dealings with their clients. Follow-up of the HIV pregnant woman must be proactive but also according to their emotional, physical, and psychosocial needs.

A team approach to care is important and must include linkages to the Paediatrician, Obstetrician, Physician, Psychologist, medical social worker, ART centers, family planning services, and community based support services.

Good documentation and communication are important to support such continuum of care.

Care providers must understand that the socio-cultural milieu, gender issues, economic situations can affect the HIV-positive mother's behaviour and adherence to advice and treatment. This understanding is necessary for the provision of optimum care.

The midwife shall remain the primary care provider until after the post-partum period. Thereafter, the mother-baby pair shall be seen at the RCH/Child Welfare Clinic.

5.6.1 DURING PREGNANCY

The essential antenatal care package shall include, but not be limited to the following:

- Health Information and Education
- Birth preparedness and complication readiness.
- Maternal nutrition.
- Health problems in pregnancy associated with HIV infection.
- Safer sex practices.
- Family planning.
- HIV Testing and Counselling
 - Routine Offer (Provider-Initiated TC),
 - Partner(s) HIV Testing and Counselling.
 - Repeat HIV TC at 34 weeks for a woman who tested negative in the early stages of pregnancy.
 - Women of unknown HIV status shall routinely be offered HIV TC at all ANC visits.
- Follow up counseling on subsequent visits.
- Intermittent preventive therapy (IPT) for malaria.
- Screening for and treatment of anemia.
- Tetanus Toxoid Immunization
- De-worming
- Prevention, Screening and management of STIs (including syphilis).

- Provision of information on early recognition and treatment of STIs
- Follow up care and treatment of HIV positive women
- Viral Load Assessment (see Appendix 7)
- Clinical assessment (WHO staging; see Appendix 1)
- Prevention, Screening, TPT, and Treatment of TB
- Initiation of ART for PMTCT
- Co-trimoxazole prophylaxis (***Do not give SP/IPT to clients on Co-trimoxazole prophylaxis**).
- Nutritional support and counselling
 - Initiation of micronutrient supplementation for the mother (vitamin, folic acid and iron)
 - Counselling and support on infant feeding choices
 - A woman who is HIV-positive shall be supported to make an informed decision between breastfeeding and replacement feeding (Refer to: National Breastfeeding Policy (See PMTCT Training Manual).

5.6.2 DURING LABOUR AND DELIVERY

Safe delivery services

Vaginal delivery is still the safest mode of delivery. Caesarean section shall be considered on obstetric grounds rather than solely for PMTCT. Where Caesarean section is indicated this must be performed promptly.

Minimise the risk of postpartum haemorrhage by active management of third stage of labour and use safe blood transfusion practices.

Interventions that can reduce MTCT include the following:

1. Administration of ARV treatment during labour in accordance with national protocols.
2. Routinely offering TC during latent phase of labour where feasible for women of unknown HIV status.

3. Use of good infection prevention practices for all client care.
4. Performing vaginal examinations as per partograph protocols and /or when absolutely necessary and with appropriate clean technique.
5. Avoiding prolonged labour (use a partograph to measure the progress of labour).
6. Avoiding routine artificial rupture of membranes.
7. Avoiding unnecessary invasive procedures during and after delivery e.g. routine episiotomy, vacuum delivery, milking of umbilical cord and routine suctioning of baby.

5.7 POST PARTUM CARE OF HIV INFECTED WOMEN, WOMEN OF UNKNOWN STATUS AND THE NEWBORN

5.7.1 CARE FOR MOTHER

Though not limited to the following, post-partum care for the mother shall include:

- Women of unknown HIV status shall be routinely offered HTC.
- Information Education and Counseling (IEC) on for example danger signs, self-care, nutrition and postpartum clinic attendance.
- Screening for health problems associated with HIV infection in postpartum period e.g. puerperal sepsis and anaemia.
- Screening and treatment for STIs.
- Counselling on breast and cervical cancer screening.
- On-going counseling and support.
- Provision of medical and psychosocial supportive care.
- Prophylaxis with Co-trimoxazole and treatment for OIs and other infections for HIV positive symptomatic mothers.
- All HIV positive mothers and exposed infants shall be linked to care and follow up.

5.7.2 NEWBORN CARE

- Provide standard newborn care.
- Initiate and support infant feeding choice.
- Initiate ARV prophylaxis in infants of HIV positive mothers.
- Provide immunization (BCG and OPV).
- Take Dried Blood Spot (DBS) sample for Early Infant Diagnosis (EID).

5.7.3 DISCHARGE AFTER DELIVERY

The mother and baby shall be followed up after delivery to ensure continuity of care started in the antenatal period. As much as possible appointments for mother and baby shall be synchronised.

Checklist for Discharge after Delivery

- ✓ Give counselling and support on method of infant feeding chosen by mother (see below) and on maternal nutrition including micronutrient supplementation.
- ✓ General physical examination of infant to exclude birth injuries and congenital abnormalities.
- ✓ Physical examination of mother for anaemia and sepsis or signs of other opportunistic infections.
- ✓ Supply drugs and explain dosage, timing, adherence and duration of ARV treatment for mother and ARV prophylaxis for baby.
- ✓ OI prophylaxis for mother.
- ✓ Educate on recognition of ill health in mother and new-born and appropriate actions to be taken.
- ✓ Advice and support on preventive measures such as hygienic practices, malaria prevention.
- ✓ Ensure BCG/OPV immunisation for infant has been given.
- ✓ Record infant weight, length and head circumference in Child Health Record booklet.
- ✓ Psychosocial /Community support.
- ✓ Give appointment for first Post-natal clinic visit (3-7 days).

5.7.4 POST-NATAL FOLLOW-UP

Clinic visit

Follow up visits for healthy mothers at the Post-natal clinic shall be within 3-7 days and at 6weeks postpartum. Women who delivered at home shall be encouraged to report to the postnatal clinic within 48 hours after delivery. The HIV positive mother and baby shall be linked to both the RCH/Child Welfare Clinics. Mothers with HIV-related complications should be seen more frequently as needed.

3 -7 Days postnatal clinic visit:

MOTHER

- ✓ History and physical exam to exclude complications such as pallor, complications related to genital tract and breasts (engorgement, cracked nipples, infection) etc.
- ✓ Discuss chosen infant feeding option and challenges.
- ✓ Discuss Safe Sex and Family Planning.
- ✓ Provide OI prophylaxis.
- ✓ Emphasize ART adherence.
- ✓ Provide adequate supply of ART until six weeks visit. Give 6week appointment for Post-natal clinic.
- ✓ Assess Nutritional/ Psychosocial /Community support.
- ✓ Women of unknown HIV status shall be routinely offered HIV TC.

NEW-BORN

- ✓ History and physical exam including assessment for pallor, jaundice, weight, length, head circumference, birth injuries and congenital abnormalities. Refer for clinical care if indicated.
- ✓ Assess adherence to feeding choice, provide counselling and support (see below).
- ✓ BCG/OPV if not already given.
- ✓ Assess adherence to infant ARV prophylaxis and ensure adequate supply until next scheduled visit at 6 weeks.

- ✓ Educate on recognition of ill health (especially for anaemia) in new-born and appropriate actions to be taken.
- ✓ Schedule appointment to see the child at Maternal New-born, Child and Adolescent Health (MNCH)/Child Welfare clinic at age six weeks.
- ✓ Where mother is not available to be offered testing and counselling, a serological test shall be offered to establish whether the baby is HIV exposed or not.
- ✓ Take Dried Blood Spot (DBS) for Early Infant Diagnosis (EID) if not already taken.

6week postnatal clinic visit:

MOTHER

- ✓ Fulfil all relevant actions as at 3-7 days postnatal visit;
- ✓ Provide Comprehensive HIV care and treatment.
- ✓ Supply ART drugs until next scheduled follow-up visit.

INFANT

- ✓ History and physical exam including assessment for pallor, jaundice, weight, length, head circumference and development. Refer for clinical care if indicated.
- ✓ Assess adherence to feeding choice, provide counselling and support (see below).
- ✓ Pentavalent/OPV immunisation.
- ✓ Assess adherence to ARV prophylaxis and continue till twelve weeks.
- ✓ If first EID test is positive, provide Comprehensive HIV care and treatment.
- ✓ Start Co-trimoxazole prophylaxis once daily for all HIV exposed babies from six weeks onwards.
- ✓ If EID has not been done already, take Dried Blood Spot (DBS) for EID.

Maternal, Neonatal and Child Health (MNCH)/Child Welfare Clinic

Beyond the six weeks post natal period, HIV positive mothers and their new babies will require continuing care. Such comprehensive care is best provided through linkage of maternal and child health care services to the ART Clinics. As much as possible appointments for mother and baby shall be synchronised.

Schedule monthly follow-up visits for healthy mothers and babies until 12 months of age then every 3 months. For mothers/babies with problems, schedule more frequent visits as needed.

MOTHER

- ✓ Assess for general wellbeing (including childcare and support).
- ✓ Assess for opportunistic infections and manage accordingly.
- ✓ Inquire about adherence to ART.
- ✓ Inquire about adherence to agreed infant feeding plan.
- ✓ Provide counselling and support as needed.
- ✓ Monitor viral load according to adult ART protocol.

INFANT

Whenever the mother brings the child to the clinic, the baby should be monitored for adherence to co-trimoxazole prophylaxis, weight gain, development and evidence of OI. Additional sessions may be required during special high-risk periods, such as when the:

- Child is sick.
- Mother returns to work.
- Mother decides to change feeding methods.

Duration of follow-up depends on when HIV infection status is determined and on feeding method. At each visit the following activities should take place:

- ✓ DNA PCR test if not yet done.
- ✓ Initiate ART in all HIV infected infants and children under five regardless of CD4 count or WHO staging.

- ✓ History and physical exam including assessment for pallor, weight, length, head circumference, development and features of HIV-associated illnesses.
- ✓ Counselling and support on feeding.
- ✓ Immunisations according to national immunization schedule. Symptomatic infants (Stage 4) should not be given yellow fever immunisation.
- ✓ Continue Co-trimoxazole prophylaxis once daily in all infants who are at risk or are HIV positive.
- ✓ Early and aggressive treatment of opportunistic infections (OIs).
- ✓ Nutrition intervention.
- ✓ Vitamin A supplementation.
- ✓ Regular 6 monthly de-worming.

BREASTFED INFANT

- ✓ HIV status should be determined within 6 weeks with DNA PCR test:
 - If the baby tests positive, then the infant is HIV infected and shall be provided comprehensive HIV care including the initiation of ART.
 - If the initial HIV DNA PCR test is negative, it shall be repeated 6 weeks after complete cessation of breastfeeding.
 - If DNA PCR testing at 6 weeks after stoppage of breastfeeding is negative, discharge from follow up and refer to child welfare clinic for continuing child care.
 - At 9months, all initial negative HIV exposed babies should be screened again using DNA PCR
 - Serological HIV testing (Rapid test) shall be used in infants older than 18 months.
- For children less than 18 months, where DNA PCR testing is not available:
- Children less than 18months who tested positive by a previous serological test should have the serological test repeated at 18months.

- A child whose serologic test is still positive at 18 months has HIV infection and should continue to receive comprehensive HIV care and treatment for life.

5.7.5 INFANT FEEDING

Mothers known to be HIV-infected will be provided with lifelong ART interventions to reduce HIV transmission through breastfeeding. In view of this, mothers who are HIV-positive shall be counseled on infant feeding over the course of several sessions during the antenatal period. At least three counseling sessions shall take place sometime during ANC after post-test counseling.

Mothers shall be counselled to exclusively breastfeed their infants for the first 6 months of life introducing appropriate complementary foods thereafter and continuing breastfeeding for the first 12 months of life. Breastfeeding should be stopped only when a nutritionally adequate diet can be provided. Avoidance of mixed feeding during the first 6 months should be emphasized.

Mothers and their infants shall be seen regularly to monitor wellbeing and infant feeding progress.

The following recommendations are made:

1. Mothers known to be HIV-infected who decide to stop breastfeeding at any time before 12 months should be supported to stop gradually within one month.
2. Mothers must continue their ART throughout the breastfeeding period and for life.
3. When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development.

4. Mothers known to be HIV-infected should only give commercial infant formula milk as a replacement feed to their HIV-exposed infants or infants who are of unknown HIV status, when the following specific conditions are met:
 - a. safe water and sanitation are assured at the household level and in the community; and
 - b. the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant; and
 - c. the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition; and the mother or caregiver can, in the first six months, exclusively give infant formula milk; and
 - d. the family is supportive of this practice; and the mother or caregiver can access health care that offers comprehensive child health services.
5. If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first six months of life and continue breastfeeding as per the recommendations for the general population, that is, up to two years or beyond.

Counselling should emphasise the following:

- ✓ Information about the risk of HIV transmission through breastfeeding.
- ✓ Reduction of risk of transmission of HIV through breast milk by ARVs.
- ✓ Advantages and disadvantages of breastfeeding.
- ✓ Consideration for local customs, practices, and beliefs when helping a mother to make infant-feeding choices.
- ✓ Disadvantages of practising mixed feeding during the first 6 months.
- ✓ Skilled counselling and support for appropriate infant feeding practices and ARV interventions shall be provided to all pregnant women and mothers.

Note: Mixed feeding should always be avoided in the first 6 months.

EVALUATION OF CHILD AT 18 MONTHS

At 18 months the definitive HIV infection status of all HIV-exposed children should be determined using both PCR and Antibody test. Some would have been proven to have a negative infection status by DNA PCR testing earlier on or by negative serologic test result at least 12 weeks after cessation of breastfeeding.

- ✓ All HIV-exposed children whether positive or negative, should have serologic testing at 18 months.
- ✓ A negative serological HIV test result means the child is not infected (if breastfeeding had been stopped at least 12 weeks prior to the test).
- ✓ A positive serological test at 18 months means the child is infected provided breastfeeding had been stopped at least 12 weeks prior to the test).
- ✓ A child whose serologic test is positive should receive comprehensive HIV care and ART for life.
- ✓ Co-trimoxazole prophylaxis should be stopped in non-infected child.
- ✓ The serologically negative child should be discharged from follow up at ART clinic back to MNCH clinic.

5.7.6 DIAGNOSTIC TESTING OF INFANTS AND CHILDREN EXPOSED TO HIV

ARV treatment for the mother and ARV prophylaxis for the infant significantly reduces but does not completely eliminate the risk of MTCT. A test may be necessary at any stage in the development of an infant to determine status.

USING ANTIBODY TESTS

- ✓ For children older than 18 months, antibody tests shall be used for HIV diagnosis, as shown in the algorithm on page 29.
- ✓ If the child is still breastfeeding, the antibody test shall be repeated 12 weeks after the child stops breastfeeding.
- ✓ A negative HIV test result for a child 18 months and above indicates the child is not infected with HIV.
- ✓ A positive HIV antibody test result at 18 months and above indicates that the child is infected with HIV.

USING HIV VIRAL ASSAYS (DNA PCR)

These assays could be used for detection of HIV infection in children 18 months and less. Early detection allows for initiation of counselling for infant feeding methods and early clinical care for infected infants. See Appendix 8 for viral assay testing algorithm.

5.7.7 PSYCHOSOCIAL AND COMMUNITY SUPPORT

Women shall be supported and encouraged to undergo pre-marital and couple counseling and testing for HIV. Women who test positive shall be provided with follow-up counseling and support and encouraged to disclose test results to their partners and families.

By disclosing her HIV status to her partner and family, the woman would be in a better position to:

- ✓ Access EMTCT interventions.
- ✓ Receive support from her partner (s) and family when accessing EMTCT and HIV treatment, care, and support services.
- ✓ Encourage the partner(s) to go for HIV testing and counselling.
- ✓ Prevent the spread of HIV to her partner(s).

- ✓ Have other children tested. The family shall be encouraged to support the woman in making and adhering to the infant feeding choice that works best for her. Mothers and their newborn babies should be linked to social support systems. After delivery and before discharge from the health facility, the mother, partner and/or family shall be given specific information on care and support; this will include the names of social support organizations, their addresses, and the kind of service they provide and their work schedule.

PROVIDING PSYCHOSOCIAL SUPPORT

Midwives and other care givers providing care for HIV positive mothers can provide support to these clients by:

- ✓ Providing continuing counseling support throughout pregnancy, childbirth, postpartum and postnatal periods.
- ✓ Helping mothers identify confidants and other support persons.
- ✓ Counselling identified confidants/support persons on their expected roles and responsibilities.
- ✓ Linking them to other support groups and institutions such as social welfare, PLHIV etc.
- ✓ Linking them to family planning services.

5.8 EMTCT LOGISTICS MANAGEMENT

All ARVs and rapid diagnostic kits shall be procured solely by Ministry of Health (MOH) in Ghana. All facilities accredited for EMTCT shall be supplied ARV in line with the supply chain management of MOH.

The pharmacy staff at the facility level shall ensure that all:

1. The medications required for EMTCT are available and adequately stored at the facility.

2. Logistics Management Information System (LMIS) reporting forms are sent to the next level in a timely manner.

5.9 MONITORING AND EVALUATION

This shall be done using standard indicators from data capture registers, reports and monitoring visits. EMTCT indicators shall be integrated with reproductive and child health records to facilitate easy collation and reporting. Day to day (Transactional) ART/ EMTCT data should be captured using the ART e-tracker. Monthly data on EMTCT shall be validated and reported through the District Health Information Management System. Periodic assessment of the EMTCT service quality and data shall be carried out to evaluate its effectiveness and efficiency. Facilities providing EMTCT services shall also be enrolled into an HIV proficiency testing programme to assure valid test results for quality service. This will be complemented by periodic laboratory quality assurance support for all HCWs providing rapid serological HIV testing within EMTCT and other service settings in accordance with national algorithms and protocols.



MONITORING OF CLIENTS ON ART

6.1 CLINICAL MONITORING

Clients on ART should be closely followed-up to assess adherence to therapy as well as tolerance and efficacy of the treatment. Regular laboratory monitoring after start of ART is necessary to identify side effects, toxicity, viral suppression and drug resistance. Intensive follow up should be done in the first few weeks of management. Management of the PLHIV should be a team approach between the clinician, nurse, counsellor, pharmacist, laboratory personnel, any other service provider and confidante who will support the client with his/her management. The client should be seen a few days (not more than 14 days) after initiation of therapy.

After the first few weeks, follow up can be at monthly intervals for the first 3 months, then at intervals of 2 – 3 months as necessary and later adjusted to fit a differentiated care approach.

6.1.1 MONITORING OF ADHERENCE

Adherence to ART is essential and more than 95% adherence is required for effectiveness of therapy. To improve adherence, the initial counselling sessions should be comprehensive and should result in well informed decisions and commitment by the client. Disclosure to and the use of adherence monitors has been found to be effective in improving adherence. In addition, there should be available information and a committed supporting medical team. Adherence to treatment should be discussed in-depth at each follow-up visit.

MEASUREMENT OF ADHERENCE

Adherence should be monitored using one of the following methods:

- Self-reports
- Pill counts
- Pharmacy records

MONITORING OF ADVERSE EFFECTS

Causes of any new symptoms and signs should be identified after initiation of ART. New symptoms may be due to;

- Intercurrent illnesses,
- Adverse reactions to antiretroviral drugs and other drugs and
- Opportunistic infections becoming clinically apparent as a result of immune reconstitution.

Where opportunistic infections become clinically apparent as a result of immune reconstitution syndrome (IRS), these need to be diagnosed and treated. Clients should be observed at each clinic visit for opportunistic infections and screened for TB at every visit.

Adverse effects of drugs should be explained to clients and appropriate measures taken. Antiretroviral agents are responsible for a broad range of adverse effects from low grade self-limiting to life-threatening side-effects. Differentiating between complications of HIV disease and ART toxicity is sometimes difficult. Alternative explanations for a client's presenting symptoms should be considered before it is concluded that toxicity is ART-related. Regardless of their severity, adverse events may affect adherence to therapy. Drug toxicity refers to the inability of the client to tolerate the side effects of the medication and/or significant organ dysfunction as in Table 4.9. A proactive approach to managing toxicity is recommended. Ancillary laboratory tests should be done to confirm adverse effects such as anaemia, neutropenia among others (see laboratory monitoring).

MONITORING OF EFFICACY

Indicators for improvement in the client's condition are:

- Gain in body weight.
- Decrease in frequency or severity of opportunistic infections.
- Increase in CD4 count.
- Improvement in full blood counts.
- Sustained suppression of viral load.

Important clinical signs of response to ARV therapy in children include:

- Improvement in growth of children previously failing to grow.
- Improvement in neurological symptoms.
- Development in children with delayed developmental milestones or encephalopathy.
- Decreased frequency of infections (oral thrush, bacterial and other opportunistic infections).

In addition to the clinical assessment recommended in adults, clinical monitoring of treatment in children should include:

- Nutritional status: mid-upper arm circumference (children 6months -5years).

- Height, weight and head circumference.
- Weight for height Z-score.
- Developmental milestones.
- Neurological symptoms and signs.

6.2 LABORATORY MONITORING

Regular laboratory monitoring after start of ART is necessary to identify side effects, toxicity, viral suppression and drug resistance of the client. TB screening should be done at each visit to the clinic using the TB screening algorithm (Appendix 3). Clients with a positive screening test must be evaluated for active TB disease.

6.2.1 HIV VIRAL LOAD AND RESISTANCE TESTING GUIDE

WHAT IS VIRAL LOAD (VL)?

HIV Viral Load is the quantity of HIV (specific HIV RNA) present in the blood (plasma) at a given time. This does not include HIV outside the bloodstream such as those in the brain and other tissues. The levels of Viral Load can be a predictor of disease progression to AIDS and for those on Antiretrovirals (ARVS) an indicator of response to Antiretroviral Therapy (ART).

MEASUREMENT OF VIRAL LOAD

Viral Load measurement is done using the Polymerase Chain Reaction (PCR) method which allows for measuring viral RNA. The results are reported as copies of HIV RNA per milliliter of plasma (copies/ml), as for example 270,000 copies/ml or 100 copies/ml or 50 copies/ml or <50 copies/ml (which is usually reported as undetectable).

INTERPRETATION OF HIV VIRAL LOAD TESTING RESULTS

Viral load measurements must always be interpreted bearing in mind that results are affected by laboratory variation and assay fluctuations that may lead to 10-30 percent variation in a test result if the same sample is repeated on the same assay in the same laboratory. For example, 100,000copies/ml is not significantly different from 130,000copies/ml, and 1,100copies/ml is not significantly different from 990copies/ml. The results are also affected by patient variables such as acute illness, and recent vaccinations which may require deferral of viral load testing for at least 4 weeks, or a repeat after 4 weeks for proper appreciation of results. In-patients who have been on ART for more than 6 months, there is said to be treatment failure, where viral loads of more than 1,000 copies/ml are obtained for 2 viral loads at least 3 months apart indicating a need to change antiretroviral regimen.

INDICATIONS FOR VIRAL LOAD TESTING (WHEN TO REQUEST FOR VIRAL LOAD)

For the purpose of Monitoring of HIV treatment (ART),

- a. Routine viral load testing should be conducted at 6 months after ART initiation and repeated at 12 months and every 12 months thereafter.
- b. Diagnosis of Treatment Failure.
- c. Prior to HIV Drug Resistance Testing.

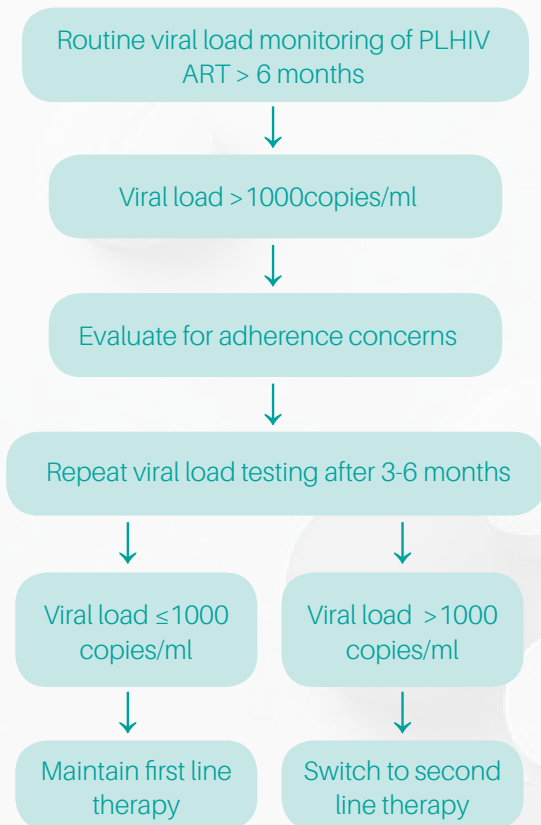
USE OF VIRAL LOAD TESTING RESULTS

- a. To determine the efficacy of Treatment Regimen.
- b. To determine adherence to treatment.
- c. To diagnose Treatment Failure.

DIAGNOSIS OF VIROLOGICAL FAILURE

Virologic failure is defined as the situation where a PLHIV having been on ART for more than 6 months is found to have persistently detectable viral load exceeding 1000 copies/ml on two consecutive viral load measurements conducted at least 3 months apart while

the patient remains on same ART regimen with adherence support. Virological rebound after a formerly successful regimen without complicating factors such as vaccination or opportunistic infection. A person should have been on ART for at least 6 to 9 months before it can be determined by successive viral loads that the ART regimen has failed.



Note: Switching to second line must be done after consultation.

HIV DRUG-RESISTANCE TESTING

HIV Drug-resistance testing is used to determine changes in the virus (mutations) that will make the virus not responsive to particular anti-retrovirals. In Ghana, our standard resistance test is the genotypic test which enables detections of mutations in the different drug classes, e.g. NRTI, NNRTI and PI. Phenotypic tests can also be applied but these are not routine in Ghana.

INDICATIONS FOR HIV DRUG RESISTANCE TESTING

- a. Virological failure in patients on treatment.
- b. Monitoring of emergence of HIV Drug-resistance (usually as a survey or follow-up in a cohort of patients on treatment).
- c. Establishment of threshold of resistance in PLHIV population at initiation of ART (usually done as a study).
- d. Assessment of efficacy of new ARVS about to be introduced or those which have been in use for some time.

INTERPRETATION OF HIV DRUG RESISTANCE TESTING RESULTS

Interpretation is dependent on the purpose for which the test was conducted. As a sequel to virologic failure, the resistance test will give an indication as to which class of ARVS and which particular ARVS the virus had become resistant to in that particular patient. In the case of emergence and threshold study type resistance testing, the result would give an indication of the levels of emergence of resistance in the population on treatment over time and the levels of resistance amongst population of PLHIV at the initiation of treatment respectively. Resistance testing for assessing the efficacy of ARVS provides that baseline information required for decision making.

REQUESTING DRUG-RESISTANCE TESTING IN GHANA

HIV Drug-Resistance testing is conducted in Ghana by the Noguchi Memorial Institute for Medical Research at the University of Ghana, Legon.

The information to be provided on blood samples for resistance testing are as follows:

The following ancillary tests should be done at 6 month intervals at least:

- Full blood count (clients on Zidovudine may require frequent Hb monitoring).
- Urine R/E.
- Fasting Blood Sugar and Lipid profile (if the client is on PIs).
- BUE and Creatinine.
- Liver function tests (ALT, AST).



CHANGING OR INTERRUPTING THERAPY

7.1 INTERRUPTION OF THERAPY

Interruption of therapy refers to the temporary or permanent discontinuation of all drugs at the same time. The administration of one or two drugs only should not be done for any reason as this may result in the development of resistant viruses. Interruption of therapy should be done by the clinician in consultation with the client under the following circumstances:

- Intolerable side effects
- Severe drug interactions
- Poor adherence

7.2 TREATMENT CHANGES

Therapy changes are similar for adults and children. Changes to antiretroviral therapy may be done under the following circumstances:

- Drug toxicity
- Treatment Failure.

In children, important clinical signs of treatment failure include:

- A lack of growth among children who show an initial growth response to therapy;
- A loss of neurodevelopment milestones
- Development of encephalopathy
- Recurrence of infections, such as oral candidiasis refractory to treatment.

Before an ARV regimen is thought to be failing, based on clinical criteria, the child should have had a reasonable time on the ART (i.e. must have received the ART for at least 6months). A switch to a second line regimen is recommended when virological failure is recognized.

7.2.1 CRITERIA FOR CHANGING THERAPY

The clinician in consultation with the other team members and the client may change antiretroviral therapy under the following circumstances:

- Drug toxicity (This has been dealt with earlier in chapter 4).
- Treatment Failure.

7.2.1.1 TREATMENT FAILURE

This can be defined clinically by disease progression, immunologically by a decrease in CD4 count or virologically by an increase in viral load.

Treatment failure may occur soon after initiation as may be in a case of transmitted resistance viruses or may occur sometime after treatment.

Virological failure is defined as plasma HIV RNA >1000 copies/ml 6 months after initiating therapy in persons that are adherent to ART. This should be confirmed with a repeat test at 3 to 6 months before a switch to second line. However in children the viral load results in the first 6 months after initiating ART must be interpreted carefully as infants and young children may take longer to achieve viral suppression because of high baseline viral load.

Immunological failure is defined as persistent CD4+ levels below 200 cells/mm³ or <10% in children younger than 5 years and CD4+ levels below 100 cells/mm³ in children older than 5 years.

Clinical failure is defined as the appearance or reappearance of WHO clinical stage 3 or stage 4 events signifying clinical disease progression after at least 6 months on ART in a treatment-adherent Client.

Note: under no circumstances should a client be switched to second line based solely on clinical failure. If clinical failure is evident, do viral load for confirmation.

The main reasons for treatment failure are;

1. Poor prescribing practices.
2. Poor adherence.
3. Pre-existing viral drug resistance.
4. Insufficient drug levels (serum and cellular).
5. Insufficient ARVS potency.
6. Unreliable drug supply

Table 7.1 Clinical Events Indicating Possible Treatment Failure

NEW OR RECURRENT CLINICAL EVENT DEVELOPS AFTER AT LEAST 6 MONTHS ON ART	MANAGEMENT OPTIONS
No new events or Stage 1 events	<ul style="list-style-type: none"> • Do not switch to new regimen • Maintain regular follow-up • Reinforce adherence to therapy
Stage 2 events	<ul style="list-style-type: none"> • Treat and manage event • Do not switch to a new regimen • Assess adherence and offer support • Assess nutritional status and offer support • Schedule earlier visit for clinical review and viral load measurement.
Stage 3 events	<ul style="list-style-type: none"> • Treat and manage event and monitor response • Check if on treatment 6 months or more • Assess adherence and offer support • Assess nutritional status and offer support • Check viral load • Institute early follow-up
Stage 4 events	<ul style="list-style-type: none"> • Treat and manage event • Check if on treatment 6 months or more • Assess adherence and offer support • Assess nutritional status and offer support • Check viral load • Consider switching regimen if adherence is optimal and viral load is persistently higher than 1,000 copies/ml after three VL tests.



8

OPPORTUNISTIC INFECTION MANAGEMENT & PROPHYLAXIS FOR HIV-RELATED INFECTIONS AMONG ADULTS, ADOLESCENTS & CHILDREN

8.1 MANAGEMENT OF OPPORTUNISTIC INFECTIONS

This should follow established protocols for the management of opportunistic infections. (See Guidelines for Management of Opportunistic infections and other related diseases). Opportunistic infections need to be treated as much as possible before the initiation of ART.

8.2 PROPHYLAXIS FOR HIV-RELATED INFECTIONS AMONG ADULTS, ADOLESCENTS AND CHILDREN

8.2.1 CO-TRIMOXAZOLE PROPHYLAXIS

Co-trimoxazole is a fixed-dose combination of two anti-microbial drugs (sulfamethoxazole and trimethoprim) that covers a variety of bacterial, fungal and protozoan infections. It has advantages of being an off-patent drug that is widely available everywhere. Since 2006 WHO has recommended the use of Co-trimoxazole as a preventive therapy for people living with HIV to reduce HIV-related morbidity and mortality particularly those associated with *Pneumocystis jirovecii* pneumonia, toxoplasmosis, malaria, pneumonia and diarrhoea.

Its use has proven to be an effective, well tolerated and inexpensive intervention particularly in low resource settings where HIV related morbidity and mortality from infections are high. The use of Co-trimoxazole prophylaxis should therefore be considered an integral component of HIV and AIDS patient care.

8.2.1.1 ELIGIBLE PATIENTS

Co-trimoxazole prophylaxis is recommended for:

- ✓ Adults (including pregnant women) with severe or advanced HIV clinical disease (WHO stage 3 or 4) and/or with a CD4+ count of ≤ 350 cells/mm³.
- ✓ Co-trimoxazole prophylaxis is also recommended for PLHIV in countries where malaria and severe bacterial infections are endemic.
- ✓ HIV-infected people with active TB disease regardless of CD4+ cell counts.

- ✓ Infants, children and adolescents with HIV, irrespective of clinical and immune conditions. Priority should be given to all children younger than 5 years old regardless of CD4 cell count or clinical stage and children with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and/or those with a CD4 count of ≤ 350 cells/mm³. HIV-exposed infants 4–6 weeks of age and should be continued until HIV infection has been excluded by an age-appropriate HIV test to establish final diagnosis after complete cessation of breastfeeding.

8.2.1.2 NON ELIGIBLE PATIENTS

- ✓ Patients with partial or complete G6PD defects.
- ✓ Patients with blood Dyscrasias such as Porphyria.
- ✓ With known allergies to Sulphur
- ✓ It should also be used with caution in patients with severe liver and renal disease.

8.2.1.3 INITIATING TREATMENT OF CO-TRIMOXAZOLE

- ✓ Screen patient for any contraindications to Co-Trimoxazole use e.g. known allergies to Sulphur or history of Haemolytic blood diseases e.g. G6PD.
- ✓ Initiate treatment if client meets criteria for prophylaxis as described in Table 8.1.

Table 8.1: Recommended criteria for initiating and discontinuing Co-trimoxazole Prophylaxis

HIV POPULATION GROUP	RECOMMENDATION	
	CRITERIA FOR INITIATION	CRITERIA FOR DISCONTINUING
Adults (including pregnant mothers)	Severe or advanced HIV clinical disease (WHO stage 3 or 4) and/or with a CD4 count of ≤ 350 cells/mm ³ .	Adults (including pregnant women) with HIV infection who are clinically stable* on ART, with evidence of immune recovery and viral suppression.
Children and Adolescents	Infants, children and adolescents with HIV, irrespective of clinical and immune conditions. Priority should be given to all children younger than 5 years old regardless of CD4 cell count or clinical stage and children with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and/or those with a CD4 count of ≤ 350 cells/mm ³ .	
HIV exposed but uninfected infants	HIV-exposed infants 4–6 weeks of age.	When risk of transmission ends (e.g. complete cessation of breastfeeding) or HIV infection is excluded by an age-appropriate HIV test to establish final diagnosis.
TB infected	HIV-infected people with active TB disease.	

**Clinically stable adults are defined as individuals receiving ART for at least 1 year without any new WHO clinical stage 2, 3 or 4 events, CD4 count >350 cells/mm³, with viral load suppression, are considered to have immune recovery. Parameter for immune recovery among children >5 years old: CD4 count >350 cells/mm³, with viral load suppression.*

8.2.1.4 CO-TRIMOXAZOLE DOSAGE

ADULTS AND ADOLESCENTS:

The recommended dose of Co-trimoxazole for adults living with HIV is:

- 960 mg daily (800 mg sulfamethoxazole + 160 mg trimethoprim, either as a 960-mg double-strength tablet or two 480-mg single-strength tablets).

NOTE: Intermittent preventive treatment of malaria (SP/IPT) should not be provided in addition to Co-trimoxazole prophylaxis for pregnant women with HIV.

INFANTS AND CHILDREN

- The dosing of Co-trimoxazole prophylaxis for children is optimized based on body weight. See table below

Table 8.2 Optimal Co-trimoxazole dosing for children

Strength of Co-trimoxazole Tablet (mg) or Suspension mg/5ml	Number of tablets or ml/wt. (Kg)					
	3.0-8.9	6.0-9.9	10.0-13.9	14.0-19.9	20.0-24.9	25.0-34.9
Suspension 200/40 mg/ml	2.5 ml	5.0 ml	5.0 ml	10.0 ml	10.0 ml	-
Dispersible tablets 100/20 mg	1	2	2	3	4	-
Tablets (scored) 400/80 mg	-	0.5	0.5	1	1	2
Tablets (scored) 800/160 mg	-	-	-	0.5	0.5	1

8.2.1.5 CLIENT FOLLOW UP AND MONITORING

All clients on Co-trimoxazole treatment must be counselled about the medication and followed up closely. All patients must be advised:

- To take adequate amounts of fluid daily.
- To discontinue medication and report back immediately if they develop any adverse effects such as skin rashes, jaundice, mental confusion, vomiting etc.
- To include folate rich foods (e.g. green leafy vegetables like cocoyam leaves ('nkontonmire'), cassava leaves, jute leaves ('ad&m&g')) in their diets as Trimethoprim is a folate antagonist. If pregnant, she must also be encouraged to take her daily folic acid 5mg supplement.
- Micronutrient supplementation which includes Selenium has been found to suppress disease progression and provide direct improvement of CD4+ count. (*The country will explore complementary immune boosters*).

Monitor all clients on Co-trimoxazole via Laboratory tests such as;

- Full blood counts 6 monthly if feasible.
- Liver function tests 3 - 6 monthly especially for patients with concurrent Hepatitis B or C infection.

Discontinue Co-trimoxazole:

- If patients develop severe adverse side effects such as Stevens Johnson's Syndrome.
- When risk of HIV-related infectious morbidities no longer exist as spelled out in the criteria above (Table 8.1).

8.3 FLUCONAZOLE PROPHYLAXIS

Fluconazole is an azole antifungal that stops growth of certain types of fungus and yeast infections like oral and oesophageal candidiasis, vaginal candidiasis, Cryptococcal meningitis and Coccidioidomycosis. After appropriate treatment for Cryptococcal and Coccidioidomycosis infections, secondary prophylaxis with fluconazole is given to prevent relapse.

Precaution: Use with caution in: Liver disease, Kidney disease and Heart Disease.

Contraindications: Pregnancy, Concurrent use with QT-prolonging drugs and Infants less than 6 months old.

Dosage:

Adults: The recommended dose of Fluconazole for secondary prophylaxis in adults and adolescents living with HIV is: 150 to 200mg daily.

Children and Adolescents: The dose is optimized based on body weight: 6 to 12mg/kg body weight daily.

Discontinue if rash develops or when viral suppression is achieved.



PRE AND POST EXPOSURE PROPHYLAXIS (PEP)

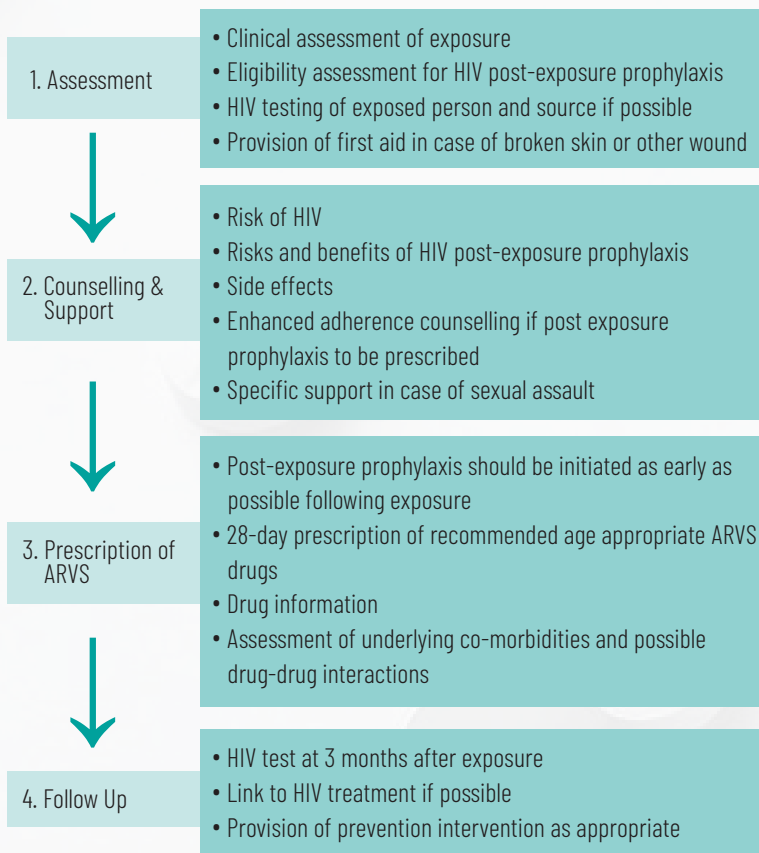
9.1 POST EXPOSURE PROPHYLAXIS

The use of Antiretroviral drugs for post-exposure prevention of HIV infection following occupational exposure to HIV for health workers has been ongoing since the early 1990s. The provision of HIV post-exposure prophylaxis has in recent years been extended to other non-occupational exposures, including unprotected sexual exposure, injecting drug use and exposure following sexual assault. The clinical management guidance outlined in this section provides current evidence-based recommendations for providing post-exposure prophylaxis for all individuals (adults, adolescents and children) exposed to a potential HIV source.

STANDARD OF CARE FOR INDIVIDUALS EXPOSED TO HIV

Every individual exposed to potential HIV source should be assessed by a trained health-care worker. Essential components of post-exposure care should include assessing the mechanism of exposure and eligibility for post-exposure prophylaxis, examination of any wound and initial first-aid treatment. Baseline and post prophylaxis treatment testing for HIV should be offered however denial of consent or lack of access to test should not delay initiating post-exposure prophylaxis where warranted. Any prescription of post-exposure prophylaxis should follow consent based on an understanding of the risks and benefits, including discussion of possible side effects and the importance of full adherence to post-exposure prophylaxis. In cases that do not require post-exposure prophylaxis, the exposed person should still be counselled about limiting future exposure risk. HIV testing may be provided to such individuals if desired.

Care pathway for people exposed to HIV



9.1.1 ELIGIBILITY FOR POST-EXPOSURE PROPHYLAXIS: RISK ASSESSMENT

Post-exposure prophylaxis should be offered, and initiated as early as possible, to all individuals with exposure that has the potential for HIV transmission, and ideally within 72 hours. Assessment for eligibility should be based on the HIV status of the source whenever possible and may include consideration of local population and risk group prevalence.

Exposures that may warrant post-exposure prophylaxis include:

- Parenteral or mucous membrane exposure (sexual exposure and splashes to the eye, nose or oral cavity).
- Contact with the following bodily fluids: blood, blood-stained saliva, breast-milk, genital secretions and cerebrospinal, amniotic, rectal, peritoneal, synovial, pericardial or pleural fluids.

The risk of infection appears higher after:

- Exposure to a large quantity of blood or to other infectious fluids
- Exposure to the blood of a patient in an advanced HIV disease stage
- A deep percutaneous injury
- An injury with a hollow bore, blood filled needle.

Exposure to HIV may be classified in three categories as described below:

Very Low Risk Exposure

Exposure of potentially infectious material to intact skin.

Low risk exposure

1. Exposure to a small volume of blood or body fluids contaminated with blood from asymptomatic HIV-positive patients.
2. An injury with a solid needle.
3. Any superficial injury or mucocutaneous exposure.

High-risk exposure

1. Exposure to a large volume of blood or potentially infectious fluids.
2. Exposure to blood or body fluids contaminated with blood from a patient with a high viral load. i.e. patients in the AIDS phase or early sero-conversion phase of HIV infection.

3. Injury with a hollow bore needle
4. Deep and extensive injury from a contaminated sharp instrument.
5. Exposure to blood from an HIV Drug resistant patient.

Exposures that do not require post-exposure prophylaxis include:

1. Exposure of potentially infectious material to intact skin,
2. When the exposed individual is already HIV positive,
3. When the source is established to be HIV negative and
4. Exposure to bodily fluids that does not pose a significant risk i.e. tears, non-blood-stained saliva, urine and sweat.

9.1.2 COUNSELLING, TESTING AND SUPPORT

The exposed individual accessing PEP must be offered counselling and testing immediately from a trained counsellor. The risks and benefits of testing should be sufficiently explained to the individual so that an informed decision can be made. Testing must also be repeated after the PEP treatment period. Where an exposed individual declines testing for HIV infection after counselling, this must be documented. He or she must not be denied access to PEP on account of refusal to test or lack of access to testing services.

All known source-patients shall also be counselled and tested for HIV infection if this is not known. Where the source tests negative, they should be encouraged to repeat the test after 3 months. Counselling and support should continue throughout the PEP period and thereafter if necessary. Counsellor must emphasize safe sex including condom use.

9.1.3 PRESCRIBING AND DISPENSING POST-EXPOSURE PROPHYLAXIS MEDICINE

If therapy is necessary, it should be initiated promptly, preferably within 1-2 hours post-exposure and not more than 72 hours after exposure. A 28-day course of ARVS drugs should be offered and prescribed. (See Table 9.1)

All Individuals receiving PEP should be educated about risks and benefits of post-exposure prophylaxis, and consent should be obtained. They should be informed of potential drug–drug interactions and possible side effects and toxicity. The importance of adherence to treatment must be stressed upon as critical for optimum outcome.

9.1.4 BASELINE LABORATORY TESTS INCLUDING

Full blood count, Liver and renal function tests, Hepatitis B Surface Antigen, HIV serology or PCR should be done if available.

Table 9.1: Recommended ARVs for PEP

AGE GROUP	RECOMMENDED PROPHYLAXIS
Children (<10 years old)	AZT + 3TC (or FTC) + LPV/r OR ABC + 3TC (or FTC) + LPV/r OR TDF + 3TC (or FTC) + LPV/r can be considered as alternative regimen. Other alternatives for the third option include ATV/r, RAL and DRV/r depending on availability.
Adults and Adolescents (including pregnant and lactating mothers)	TDF + 3TC+ DTG (or LPV/r). Other alternatives to DTG or LPV/r include ATV/r, RAL and DRV/r depending on availability.

9.1.5 FOLLOW UP

A follow-up appointment for people prescribed post-exposure prophylaxis should be scheduled for a repeat HIV test 3 months following HIV exposure. Review of an individual during the 28-day period is not essential, but individuals should be encouraged to seek assistance if they experience side effects that interfere with taking ARVS drugs or adherence problems.

Any further contact with a person prescribed post-exposure prophylaxis should emphasize the importance of completing the full 28-day course, and reducing future risk of HIV infection.

If the source is established to be HIV negative during the course of post-exposure prophylaxis, ARVS drugs may be discontinued.

During the period of prophylaxis a number of base-line and follow-up investigations may need to be done to determine HIV sero-status, and to monitor the level of drug toxicity.

TABLE 9.2: Recommended monitoring of drug toxicity and HIV serology of exposed individuals

AGE GROUP	RECOMMENDED PROPHYLAXIS
Baseline tests:	Full blood count Liver and renal function tests, Hepatitis B Surface Antigen HIV serology or PCR if available
Two weeks:	Full blood count Liver and renal function tests
Six weeks:	HIV serology
Three months:	HIV serology
Six months:	HIV serology

Individuals who sero-convert should be linked to comprehensive care and ART services. For further information, refer to Chapter 2.

PEP FOR HEALTH CARE WORKERS

The risk of exposure to blood and blood borne pathogens is slightly greater for health care personnel than people who do not work in health care settings. Workplace accidents or injuries that expose the health worker to body fluids of a patient may occur. Post-Exposure Prophylaxis (PEP) reduces the likelihood of HIV infection after exposure. PEP may either prevent the establishment of infection or prevent new infection while allowing clearance of already infected cells. PEP is particularly effective within 1–2 hours and not more than 72 hours after exposure.

Exposures that create risk for health workers may be defined as an exposure from infected blood, tissue or other body fluids through:

- A percutaneous injury (e.g. a needle stick or cut with a sharp object), or
- A mucocutaneous membrane or non-intact skin (e.g. skin that is chapped, abraded, or affected by dermatitis) contact.

The risk of infection for HIV after a percutaneous injury is approximately 0.3%. Transmission rates after exposures of mucous membrane or non-intact skin are lower (0.1%) than from percutaneous injuries.

9.2.1 REDUCING RISKS OF EXPOSURE

- Infection prevention programmes should be in place in all health care settings and health workers should follow Standard Infection Prevention and Control Precautions at all times to prevent exposure.
- Hands should be washed properly and frequently before and after handling all patients.
- Gloves must be worn before any kind of invasive procedure or when venous or arterial access is being performed.
- Personal Protective Equipment (Gloves, gowns, boots eye wear and masks) should be used appropriately for patient care.
- Sharps should be used with caution in all patients. Sharps should be disposed of in a puncture proof receptacle immediately after use. These should be available nearby.

In the event of possible exposure to HIV the incident should be documented and the following actions taken:

1: Treatment of exposure site

The wound site should be cleaned with soap and water. In the case of mucous membranes, exposed area should be flushed with plenty of water. Eyes should be flushed with water or saline.

2: Assess the level of risk

The risk of exposure should be assessed in terms of possible transmission of HIV infection as described above.

3: Counsel and Test

The health care workers accessing PEP must receive counselling and testing immediately from a trained counsellor. This should continue throughout the PEP period and thereafter if necessary. Where an exposed individual declines to test for HIV infection after counselling, this must be documented.

4. Prescribe PEP (See guidelines for ARVS in Table 9.1)

Note however that in the health care settings, in addition to risks for HIV transmission, the risks for HBV and HCV transmission are even higher. Measures to address these risks should also be considered. They include routine vaccination against HBV and HBV immunoglobulin where appropriate following exposure.

The health worker should be counselled and supported to complete his/her PEP per the above stated guidelines. Health workers who sero-convert should have access to comprehensive care and ART services as spelt out in the “Workplace HIV and AIDS Policy and Technical Guidelines for the Health Sector”

9.2.2 REPORTING AND DOCUMENTING OCCUPATIONAL EXPOSURE TO HIV

All occupational exposures should be reported immediately to the supervisor; circumstances of the exposure and PEP management should be recorded. Details should include:

- Date and time of exposure.
- Where and how the exposure occurred, exposure site on the body and type of sharp device.
- Type and estimated amount of exposure fluid, severity (depth/extent) of the exposure.

- Source of exposure and whether the source material contained HIV or blood.
- Clinical status of source patient.
- Relevant information about exposed health care worker (medical conditions, vaccination including Hepatitis B, and medications, pregnancy or breast-feeding).
- Document counselling, post exposure management and follow up.

Note that the health workers privacy should be respected and confidentiality maintained. Reporting and recordkeeping should be in accordance with the national occupational health policies.

PEP FOR SURVIVORS OF SEXUAL VIOLENCE

Ghana has in recent times seen an upsurge of violent crime including sexual violence of various forms such as rape and defilement. Rape and defilement are violent traumatic experiences for the survivors who are affected physically, emotionally and socially. Survivors may react in different ways to such traumatic experiences and they may have to be handled and managed cautiously in order not to aggravate their psychological trauma. Survivors could be women or men, boys or girls; but most often, women and girls are the victims and the perpetrators are usually men. It is important to recognize that rape and defilement are criminal offences in Ghana. Survivors and the general public should be encouraged to report such occurrences to law enforcement agencies. The healthcare provider must therefore be abreast with the legal requirements regarding the management of the survivor. This includes documentation and reporting as well as the provision of emergency contraception, abortion, counselling, testing and prevention of STIs such as HIV infection. Healthcare workers must understand that their duty is to provide basic medical and psychological intervention to survivors and referral to relevant agencies for other needed services.

These guidelines are to be used in the context of the clinical management of survivors of sexual assault within the regular health care setting.

This includes:

- Screening for prevention/management of pregnancy.
- Screening for and treatment of Sexually Transmitted Infections (STIs).
- Provision of PEP for HIV.
- Collection of evidence for possible future prosecution*.
- Rendering of psychological support.
- These guidelines focus on female victims of sexual assault but the principles are the same in the management of male victims as well as for minors.
- There are no conclusive data on the effectiveness of PEP in preventing transmission of HIV after the occurrence of rape.
- Experience with prophylaxis relating to occupational exposure and prevention of mother-to-child transmission (PMTCT) however suggest that starting PEP as soon as possible and indeed within 72 hours after the rape is most beneficial.

MEDICO-LEGAL CONSIDERATIONS*

Healthcare providers must appreciate that the establishment of the case of rape is a legal matter to be determined by a court of competent jurisdiction and not a decision for the healthcare worker to make. The healthcare worker is providing a service with the presumption that there has been an alleged case of rape or defilement which may or may not be proven.

For the purpose of these guidelines, the term “rape” means “rape, defilement or non-consensual carnal knowledge”.

This document should not to be used as an absolute guide for a forensic examination and the collection of specimens for prosecution. Such a requirement will need a referral to a gynaecologist, a clinician trained in forensic medicine, or other specialist.

Although only a small percentage of alleged rape cases actually go on trial, it is important that the healthcare worker keeps detailed and accurate documentation in the event of the need to testify in court.

9.3.2 SURVIVOR CARE AND REFERRAL

Care of survivors of sexual violence must be undertaken by a team of care providers including clinicians, obstetrician gynaecologist, PEP focal person psychologist and forensic pathologist. Survivors reporting for care may include individuals who report directly following the alleged incident, client referred later with resulting complications such as pregnancy or STI. Occasionally clients may be referred by the courts after criminal procedures have been initiated.

Where a client is referred from another service provider for PEP or the courts, the attending PEP care provider must be satisfied the client has already received or receives all other relevant care components for such survivors of sexual assault as described above.

All Clients reporting directly to a facility following an alleged incident of rape should be assessed comprehensively by a clinician and counselled appropriately for the administration of needed interventions. The client should be referred for further care and action as needed with the relevant experts.

Survivors/families should be counselled to also report the matter to the police if not already done. In cases of minors, the care provider is required by law to notify law enforcement agencies and social welfare offices of the incident.

9.3.3 CLINICAL ASSESSMENT OF SURVIVOR

- I. Take accurate and detailed history, considering the fact that this could be very sensitive and emotionally traumatic for the client.

- II. Ensure right to privacy, confidentiality, information and non-discrimination.
- III. Clarify the kind of sexual assault and orifices involved in the assault.
- IV. Determine whether the perpetrator constitutes a high risk or otherwise.
- V. Find out the sexual history of the client both before and after the assault. Assess the overall risk of client.
- VI. Perform all relevant physical and genital examinations, and collect forensic evidence as may be required by law if you are the clinician primarily responsible for the case. (See Appendix).
- VII. Offer counselling and testing for HIV and screen for other STIs including Syphilis, Hepatitis B where screening tests are available.
- VIII. Where client is found to be HIV positive, she/he must be counselled and referred to an ART centre for comprehensive HIV care and support services.
- IX. Treat any STIs found or suspected on screening.
- X. In the case of a child survivor:
 - a. History should be taken from both the minor and the parent or legal guardian. It is preferable to have the parent or guardian wait outside during the interview and have an independent trusted person/chaperone present. Avoid asking leading questions.
 - b. For the examination either a parent and/or chaperone must be present.
- XI. Document all findings of the assessment and interventions including the outcome of the HIV test, STI and Hepatitis B screening.
- XII. Where the client declines to undertake the HIV test, document this refusal and make client fill and sign the National PEP and Management Record Form for Rape Survivors indicating the refusal.

9.3.4 ASSESSMENT OF EXPOSURE RISK

The following factors must be considered in the assessment of risk:

- Perpetrator is unknown or HIV status of perpetrator is unknown.
- Perpetrator's HIV status is known to be positive.
- Perpetrator is an injection drug user or armed robber.
- Whether the alleged sexual violation involved anal penetration.
- Whether the survivor was allegedly raped by more than one person.
- Vaginal penetration with associated genital injuries.
- Whether survivor is a minor.

9.3.5 PROTOCOL FOR PEP AND PREVENTIVE TREATMENT OF STI

I. If survivor presents within 72 Hours of the Incident

- a) Prevent HIV Transmission through the provision of PEP using three ARVS according to national protocol and as spelt out under Appendix.
- b) Treat STIs according to national guidelines.
- c) If HBsAg result is negative prevent Hepatitis B infection by initiating the appropriate vaccination protocol.
- d) Pregnancy can be prevented by providing emergency contraception in accordance with the National Reproductive Health Service Policy. Pregnancy test must be done to first exclude an existing pregnancy.
- e) Clean and treat any tears, cuts, abrasions and other injuries. If there are major contaminated wounds consider giving antibiotic cover.
- f) Tetanus prophylaxis (tetanus toxoid – TT) may also be indicated where there are wounds or break in mucosa.

II. If survivor presents more than 72 Hours after the Incident

- a) PEP may not be beneficial when started after 72 hours but decision to start should be made on case by case basis.

Client should be offered TC and appropriate follow up instituted.

- b) Assess and examine for STIs and provide treatment according to national STI treatment guidelines.
- c) If HBsAg test result is negative recommend vaccination against Hepatitis B infection, using the appropriate protocol.
- d) If the survivor presents after 72 hours but within 120 hours (5 days) provide emergency contraception in accordance with the National Reproductive Health Service Policy and Standards.
- e) Pregnancy test must be done to exclude an existing pregnancy.
- f) Treat or refer all wounds, abscesses and other injuries and complications. Vaccinate against tetanus if client has not been fully vaccinated.

9.3.6 FOLLOW-UP CARE

I. For Survivors who received PEP.

- a. One-week follow-up visit:
 - i. Evaluate PEP, STI and other treatment.
 - ii. Evaluate for STI and provide treatment as appropriate.
 - iii. Discuss TC for future HIV testing.
- b. Six-week and three-month follow-up visits:
 - i. Offer TC for HIV.
 - ii. Evaluate for STIs and treat as appropriate.
 - iii. Evaluate for pregnancy and provide counselling

II. For Survivors who do not receive PEP.

- a. Two-week follow-up visit:
 - i. Check if STI and/or other treatment have been adhered to.
 - ii. Evaluate for pregnancy and provide counselling.
 - iii. Discuss TC for future HIV testing.
- b. Three-month follow-up visit:
 - i. Offer TC for HIV.
 - ii. Evaluate for STIs and treat as appropriate.
 - iii. Assess pregnancy status.

In all cases evaluate mental and emotional status at every visit, and refer or manage as needed. For minors assess the safety of their environment (Place of residence and school etc.) for possible re-location.

Documentations and other Potential Forensic Evidence

1. All information gathered from history, referral notes, assessments, and from physical and genital examination must be clearly documented, dated, signed and appropriately filed under strict confidentiality.
2. All laboratory test results must be acknowledged and stored with patient records.
3. Document all referrals to and from or within your facility.
4. Fill all forms required under these guidelines and according to national policies and guidelines.
5. Note that proper documentation will facilitate testimony in a court of law.

9.2 ORAL PRE-EXPOSURE PROPHYLAXIS (PrEP)

INTRODUCTION

Pre-Exposure Prophylaxis (PrEP) with oral Tenofovir (TDF) or TDF co-formulated with Emtricitabine (TDF/FTC) demonstrated substantial HIV prevention benefits in clinical trials. With strong evidence for the efficacy and effectiveness of daily oral PrEP across multiple studies; WHO issued guidance on PrEP use in high HIV incidence settings to people having substantial risk of HIV acquisition (WHO, 2015). PrEP is defined by WHO as the use of antiretroviral drugs before HIV exposure by people who are not infected with HIV in order to block or prevent the acquisition of HIV.

Oral PrEP should be offered as part of the 'Combination Prevention' package that includes HIV Testing Services (HTS), male and female condoms, lubricants, ART for HIV-positive partners in sero-discordant couples, voluntary medical male circumcision (VMMC) and STI prevention and management.

ELIGIBILITY CRITERIA FOR PrEP

Any sexually active HIV-negative person at substantial risk of acquiring HIV. Those at high risk include but not limited to the following:

1. HIV negative people in sero-discordant relationships with a partner who is not confirmed as virologically suppressed (VL <40 copies/ml).
2. All HIV negative people in sero-discordant relationships, regardless of VL of the partner, who want to conceive.
3. Partner(s) of unknown HIV status.
4. Recent/ recurrent STIs.
5. Multiple and/ or concurrent sexual partners.
6. History of inconsistent or no condom use.
7. Recurrent PEP users.
8. History of sex whilst under the influence of alcohol or recreational drugs.

Note: PrEP should always be taken as an additional prevention strategy in combination with a comprehensive prevention package such as condoms.

CONTRAINDICATIONS

The following are contraindications of PrEP:

1. HIV positive status: Evidence or suspicion of HIV primary infection (characterized by flu-like symptoms) and suspicion that person might be in window period following potential exposure.
2. Adolescents <35kg or <15 years who are not Tanner stage 3 or greater (should not get TDF)

3. Abnormal Creatinine Clearance rate <60ml/min.
4. TDF for PrEP should not be co-administered with other nephrotoxic drugs, for example, aminoglycosides.
5. Unwilling or unable to return for 3-monthly HIV testing, counselling and safety monitoring visits.
6. Known allergies to any of the PrEP drugs.
7. Unwilling to get tested for HIV.

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

PrEP ARV REGIMEN

Daily oral Tenofovir/Emtricitabine (TDF/FTC 300mg/200mg) or TDF/3TC 300mg/300mg with the following considerations:

- Oral PrEP may be used intermittently during periods of perceived HIV acquisition risk, rather than continually and lifelong, as is the case with antiretroviral treatment.
- It is important to bear in mind that it takes 7 days of daily dosing PrEP to reach adequate anal/rectal tissue levels and up to 20 days of daily dosing to achieve protective vaginal tissue. During this period, other protective precautions must be used, such as abstinence or condoms.
- PrEP medications should be continued for 28 days after the last potential HIV exposure in those wanting to stop taking PrEP. These should also be borne in mind in users who stop and start PrEP according to their periods of risk.

SUMMARY OF PRE-EXPOSURE PROPHYLAXIS VISITS AND PROCEDURES

- Assess risk and eligibility --thorough history (sexual) and physical examination.
- Educate about the risks and benefits of PrEP and Contraceptive counselling.

- Conduct relevant laboratory tests—HIV test, Creatinine Clearance and HBsAg and Confirm eligibility (including investigation results and creatinine clearance (CrCl-calculation)).
- Provide STI treatment if indicated. •
- Educate client about PrEP side-effects and management.
- Educate client about signs and symptoms of acute HIV infection.
- Discuss with client on the adoption of healthy life-styles such as avoiding alcohol, tobacco and recreational drugs.
- Provide condoms and lubricants.
- Provide one-month TDF/FTC (FDC) prescription and follow-up date.
- Arrange follow up visit: Same as at PrEP initiation visit PLUS: Assess tolerability, side effects and effective use (adherence). Actively manage side effects, Contraceptive services review test results—HIV test, CrCl etc.
 - Provide 3 months prescription and follow up date Four-month follow-up and 3-monthly maintenance visits.
 - Repeat procedures done at one-month follow-up i.e. Tests:
 - 4th Month—HIV test, STI symptom screening, CrCl,
 - 3 monthly afterwards—HIV test, Pregnancy test, HBsAg (at 6 months only).
 - 6 monthly afterwards—CrCl, STI symptom screening, rapid syphilis test and HIV test.

Note: Condoms and condom-compatible lubrication should be provided, and arrangements made for follow-up.

SIDE EFFECTS OF PREP MEDICINES

PrEP is usually safe, with no side-effects for 90% of users. Minor side effects: About 10% of people who start PrEP will have some short-term mild side-effects. These may include gastrointestinal symptoms (diarrhoea, nausea, decreased appetite, abdominal cramping, or flatulence).

Dizziness or headaches have also been experienced. Such side-effects are usually mild and resolve without stopping PrEP. Typically, these symptoms start in the first few days or weeks of PrEP use and last a few days and almost always less than 1 month.

STOPPING PrEP

PrEP should be stopped:

1. Whenever an HIV test is positive. If a client tests HIV positive, discontinue PrEP and refer for enrolment into HIV care.
2. At client's request.
3. For safety concerns/ side effects (CrCl<60ml/Min).
4. If risks of PrEP outweigh benefits.

ADDITIONAL NOTES FOR IMPLEMENTING PrEP

Medical officers and nurses trained to provide ART can provide PrEP. The PrEP initiation visit should preferably take place on the same day of screening.

Also all clients offered PrEP must be registered and clinical records well documented.

PrEP data must be summarized and reported monthly per the following indicators:

1. Number of HIV negative clients given PrEP disaggregated by age and gender.
2. Number of clients taking PrEP who tested HIV positive at follow-up visit month 1,3,6 and 12.
3. Number of clients who discontinued PrEP disaggregated by gender, age and reason.
4. Number of clients who developed STI during PrEP.
5. Number of PrEP clients who received treatment for STI.
6. Number of clients given condoms at initiation of PrEP.



SUPPLY CHAIN MANAGEMENT AND RATIONAL USE OF HIV COMMODITIES

10.1 SUPPLY CHAIN MANAGEMENT

The ultimate purpose of public health supply chain systems is to serve the clients with appropriate commodities in the right quantity, at the right time, place and cost. In the context of HIV and AIDS programmes, this means ensuring an uninterrupted supply of HIV and AIDS commodities to all people living with HIV and AIDS (PLHIV). This is because more than 95 percent adherence to ART is required for treatment regimens to be effective over the long term. A comprehensive HIV/AIDS programme requires a wide range of commodities to support a range of interventions that encompass prevention, care and treatment.

A key objective of the National HIV/AIDS response is to ensure all people living with HIV/AIDS will be initiated on ART. This requires a strong procurement and supply management (PSM) system. Supply chain managers and ART programme managers should collaborate to ensure that the national supply system functions properly. The key components of procurement and supply management cycle includes:

- Product selection.
- Forecasting and supply planning.
- Procurement.
- Storage and distribution.
- Logistics Management Information System (LMIS).
- Use or dispensing to clients.
- Quality monitoring.
- Policy.

Management support is integral to each component. This includes a variety of activities at all levels of the health care delivery system from the national programme level to the facilities where medicines are dispensed, and diagnostics are used. The main activities include managing the information system (LMIS), ensuring timely information flow between stakeholders at different levels and securing financial and other resources for procurement, storage and distribution of medicines and diagnostics required for the programme.

10.1.1 SELECTION OF PHARMACEUTICALS AND DIAGNOSTICS

The World Health Organization (WHO) has developed and updated guidelines for scaling up antiretroviral therapy in resource-limited settings. The treatment guidelines for a public health approach act as guidance for countries to facilitate the proper management and scale up of antiretroviral therapy (ART).

The public health approach is geared towards universal access, standardization, and simplification of antiretroviral (ARV) drug regimens to support the implementation of evidence-based treatment programmes in resource-limited settings. The goal is to avoid the use of substandard treatment protocols and to reduce the potential for the emergence of drug-resistant virus strains. This updated national HIV Care guideline include newly recommended ARV drug regimens and formulations and diagnostics that are appropriate to the local setting.

The detailed guidelines in chapter 4 provide recommendations for managing toxicity or treatment failure and recommends formulations for weight and age that can help to standardize prescribing and dispensing practices and facilitate forecasting for ARV drugs. It also provides clear criteria for first, second and third-line regimens; for the management of patients experiencing toxicity or treatment failure; and for the treatment of specific subgroups, such as patients with tuberculosis, pregnant women, children and health workers who require post-exposure prophylaxis.

10.1.2 RATIONAL USE OF MEDICINES (RUM)

Rational use of medicines requires that patients receive medications appropriate for their clinical needs, in doses that meet their own individual requirements for an adequate period and at the lowest cost to the patient and the community. ART is a complex undertaking that involves a large variety and quantity of highly active drugs. It is a lifelong treatment that is regularly reviewed with the addition of new molecules. It is therefore very important to use ART medicines rationally since inappropriate use may have unwanted consequences at both the individual and the population levels. Irrational use of HIV medicines may lead to:

- Treatment failure.
- Rapid development of drug resistance.
- Increase in the risk of toxicity.
- Increased cost of treatment.
- Spread of new HIV infections.

To promote rational use of medicines:

1. Only trained and authorized persons in certified health care facilities are allowed to prescribe ARVs.
2. Prescriptions for ARVs should clearly indicate the name/ Patient ID number, age, sex, body weight, medicines, dosage, and should include the name and signature.
3. ARVs should only be dispensed to treatment-ready patients with clear instructions and advice.
4. The dispenser should ensure that ARV prescriptions are appropriately written and signed by an authorized prescriber before dispensing.
5. ARVs should only be given to the named patient or appointed adherence assistant.
6. Adequate time should be scheduled for antiretroviral dispensing and counselling.
7. The dispenser should make sure that the patient understands the dosage and drug intake schedule as well as instructions regarding the storage and food requirements.
8. The dispenser should also caution patients about possible side effects and drug-drug interactions and respond to specific questions and problems related to ARV treatment encountered by patients.
9. The dispenser should advise patients on measures to be taken to reduce the side effects, including immediate return to the clinic when they experience serious adverse effects.

10.1.3 FORECASTING AND SUPPLY PLANNING (QUANTIFICATION)

The NACP will work with the national quantification team and key stakeholders to conduct annual quantification of HIV/AIDS commodities. Medium-term forecasts which normally span a two-year period will be prepared using multiple data sources such as morbidity, consumption and service data. The forecasts and procurement plans will be revised in accordance with National quantification guidelines every six months to allow for adjustment in the supply plan in line with prevailing consumption trends.

Quantification will provide the basis for commodity funding gap analysis and coordination of Government and partner funding to ensure uninterrupted supply of HIV/AIDS commodities.

10.1.4 PROCUREMENT

A uniform and harmonized procurement system is required to efficiently procure quality- assured and affordable HIV and AIDS commodities. Procurement should be based on supply plans derived from national quantification and routine pipeline updates. Transparent procedures should be adopted to achieve best-value for money procurement and a quality assurance system implemented to procure, store and distribute high-quality HIV and AIDS commodities.

ARVs shall be classified as Programme medicines and shall be by prescription only and not for sale in the open market.

Procurement systems should:

- Secure the most effective, heat-stable, fixed-dose quality-assured ARV drug formulations in the right quantities at the lowest possible cost in a timely manner.
- Request the partners supporting the national HIV programme to consolidate and harmonize ARV drugs and diagnostics procurement and supply management systems and pool demands for ARV drugs and diagnostics, exploring options for pooling under a common tender system.
- Follow the principles described in the United Nations interagency guidelines for donated drugs.

10.1.5 INVENTORY MANAGEMENT, STORAGE AND DISTRIBUTION

At the end of each month, physical inventory count shall be conducted, and the available stock shall be checked against the stock records.

HIV commodities and related supplies should be ordered in line with regional LMD schedule. Requisitions should be submitted to the Regional Medical Stores using the appropriate requisition tool (Manual or electronic).

The RMS will review orders, process and deliver the requested commodities directly to the health facility or agreed delivery point. Facilities should receive commodities in line with standard operating procedures for receiving commodities at health facilities. Stocks that have a short shelf life that cannot be used before their expiry dates shall be redistributed accordingly to facilities in need using a redistribution form.

Damaged and expired commodities should be immediately separated from usable stock and disposed of following appropriate procedures.

Facilities should have adequate storage space with conducive storage conditions manned by trained personnel with appropriate logistics tools to manage supplies effectively.

Commodities must be stored and issued according to the first-to-expire first-out (FEFO) procedure of stock management.

10.1.6 RECORD KEEPING

All information regarding ARVs and OI medicine dispensed should be recorded in a dedicated register book (dispensing registers/ or in the pharmacy database) and patient appointment card.

All information regarding usage of all Laboratory related HIV commodities such as Rapid Diagnostic Test (RDT) kits and reagents should be recorded in the Laboratory register.

At the store, all HIV commodity transactions should be recorded in the paper-based inventory control cards/bin cards, store ledgers and/or electronic LMIS.

Reports on HIV and AIDS commodities consumption and stocks should be kept and tracked by health facilities. Health facilities should use this information to forecast and quantify their needs.

10.1.7 GHANA INTEGRATED LOGISTICS MANAGEMENT INFORMATION SYSTEM (GHILMIS)

The current LMIS system uses manual processes and tools. Ghana is currently implementing an end-to-end electronic LMIS system. The implementation of the Ghana Integrated Logistics Management Information System (GhiLMIS) will automate and optimize all current processes including replenishment planning; warehousing; inventory management, forecasting and quantification, transportation and reporting.

10.1.8 SUPPLY CHAIN MONITORING

Monitoring and evaluation of supply chain functions will be conducted to ensure that targets are met, and corrective actions are implemented. This will ensure:

- Commodity availability at the service delivery points to impact on quality of care.
- Planned logistics activities are carried out according to schedule.
- Proper record keeping, improved data collection, analysis, reporting and timely decision-making and planning.
- Supply chain monitoring, supportive supervisions and on-the-Job training will be conducted regularly to address system inefficiencies.
- Procurement, storage, distribution, dispensing procedures and records, and stock on hand will be subject to internal and external audit (eg. Post Market Surveillance).

10.1.9 STAFFING FOR EFFECTIVE PSM

ARV managers /dispensers shall work closely with clinical staff to ensure appropriate prescribing especially on dosage and appropriate ARV combinations (ARV regimens).

Good collaboration will ensure correct estimates of the number of new patients to be initiated on treatment for proper ordering of their medicines.

Commodity managers within health facilities need to keep clinical staff informed of the current stock levels of ARVs, diagnostics and Laboratory consumables particularly of items nearing stock-out and those in excess and at risk of expiry.

In the event of nationwide supply shortage, commodity managers should communicate this information to clinical staff so that they can pursue the best course of action.

Pharmacists/dispensers are expected to keep abreast with new information and changes in ARVs and act as a resource to clinicians and other health care workers in advising on possible drug related side effects, changes in formulations or regimens and informing clinicians on available formulations and drug combinations (ARV regimens).

10.1.10 PHARMACOVIGILANCE

WHO defines Pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Monitoring and reporting of adverse drug events should be done according to the Ghana Food and Drugs Authority's (FDA) guidelines. Adverse drug reactions reporting forms (blue forms) will be distributed to facilities that have been certified to deliver ART. It is important that health facilities record the adverse drug reactions and report the information to FDA. Furthermore, facilities are encouraged to use the information to monitor patients and switch regimens where necessary.

HIV DATA MANAGEMENT

Data management forms an important component of the entire clinical care programme. Good data management practices ensure availability of information for patient care, policy development, planning, research, monitoring, evaluation, quantification and forecasting of commodities (ARVS and other consumables), advocacy and resource mobilization. The generation of strategic data require the use of adaptable registers, tools and indicators such as:

- Monthly facility record of number of people tested for HIV.
- Monthly log book for HIV Rapid test kit usage.
- Monthly LMIS report form.
- Monthly Assessment of stock status and order calculation work sheet (Adult and Paediatric).
- Monthly summary report form of ART patients.

- Monthly PMTCT and HTS summary report form.
- Monthly report form of EID tests performed.
- ART client booklet (Includes patient register, initial and follow-up assessment forms for adults and children and HIV exposed baby follow-up form).
- ART, PEP, ANC and HTS registers.
- Monthly report form of VL tests performed.
- Monthly report of number and percentage of virally suppressed clients.

To enhance the integration of services towards improvement of service coverage, HIV tools will be integrated in existing data collection tools to eliminate duplicate recording and reporting by service providers. For instance PMTCT indicators are part of ANC indicators and captured in a single register. Quality data is ensured through well harmonized and standardized country indicators and reporting tools.

11.1 HEALTH INFORMATION MANAGEMENT SYSTEM (HMIS)

This information is collected using client booklet for adults and paediatric; and captured electronically. Where applicable, information collated on monthly summary forms must be transmitted on a timely basis from each facility to the District/Regional Health Directorate for onward transmission to the national level for NACP attention. The following information should be obtained from each patient:

- Demographic data.
- Medical History (including a diagnosis of, Hepatitis and TB).
- Obstetrics and Gynaecological history including family planning.
- Sexual infection history including STI.

- HIV status of partner and children.
- Social History.
- Physical Examination.
- Psychosocial Evaluation.
- Laboratory Evaluation.
- Drug Treatment.
- Adherence to ARVS.
- Side Effects of ARVS.

The information received at the national level shall be processed for programming purposes and in support of the decision making process. Feedback will be provided by NACP to the facilities, health administrators and all relevant stakeholders.

11.2 DATA SYSTEMS

The Ministry of Health's Information Exchange (MoH/HIE) reflects the current concrete reality of "ground-up approach" of health service data flow; and systems delivering valid data for use. The two main existing functional components are the DHIMS II and the E-tracker. This reduces the burden of duplicating data gathering efforts and enhances the value of information otherwise not possible when viewed in isolation.

11.2.1 DHIMS II

DHIMS II is a comprehensive web-based Health Management Information System (HMIS) supporting data reporting and analytical needs of health facilities and district health administrations. It is used by health facilities and district health directorates to collect, collate, transmit and analyze routine health service data (i.e. aggregated or transactional).

11.2.2 HIV/AIDS E-TRACKER MODULE

The E-Tracker is an extension of the DHIMS II platform and supports data management and analysis of transactional or disaggregated data at the facility level. It enhances the management of case-based records of clients and track clients over time using a flexible set of identifiers to assure data confidentiality and integrity. The primary objective of e-tracker is to facilitate the generation of clients currently on ART at all times and to ensure an improvement in the tracking of clients lost-to-follow-up. The system has the added functionality of capturing information about anonymous events and cases.

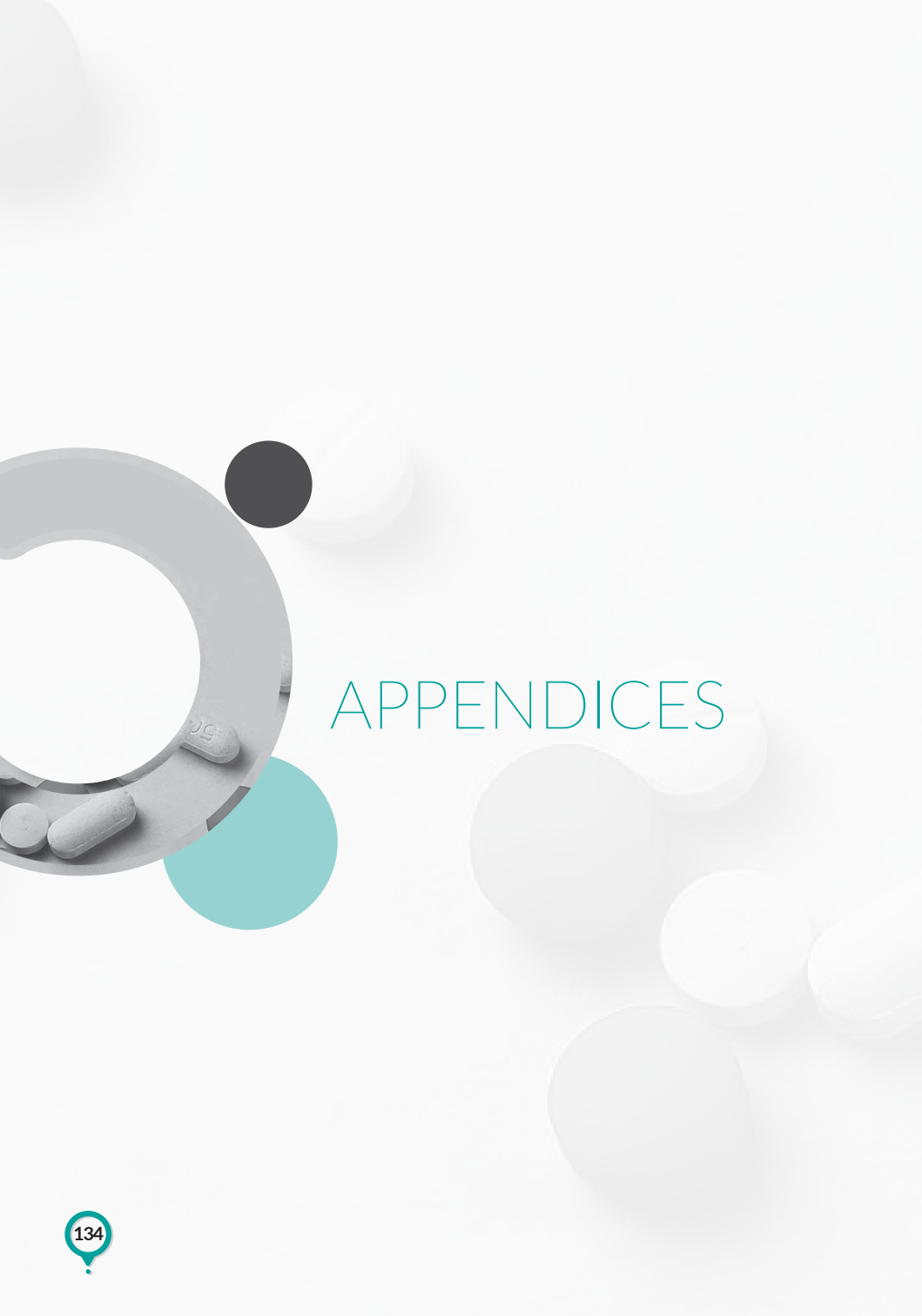
The HIV/AIDS E-tracker module includes a logistic management component (referred as the Logistics Management Information System [LMIS]) which ensures that all logistics related data are appropriately collected and managed from the facility level.

The deployment of e-tracker requires the use of both soft and hardware at facility, regional and national levels supported by a reliable internet connection. The hardware includes but not limited to tablets, computers, laptops and dedicated servers for hosting the anticipated huge client data.

To minimize the impact of an unstable internet system for relaying client data, both online and offline versions shall be deployed as part of e-tracker implementation.

Staffing for data management will include data officers, health information officers and service providers trained to facilitate the timely reporting of key HIV related indicators.

To ensure a full benefit of the e-tracker system for HIV data management, the system will be expanded to cover the full continuum of HIV care i.e. HIV testing, treatment and follow-up care in all Ghana health service facilities nationwide.



APPENDICES

APPENDIX 1: CLINICAL STAGING OF HIV/AIDS FOR ADULTS AND ADOLESCENTS (≥15YRS)

STAGES	
Clinical Stage 1	<ul style="list-style-type: none"> - Asymptomatic - Persistent generalized lymphadenopathy
Clinical Stage 2	<ul style="list-style-type: none"> - Moderate unexplained weight loss (<10% of presumed or measured body weight) - Recurrent respiratory tract infections (RTIs, Sinusitis, bronchitis, otitis media, pharyngitis) - Herpes zoster - Angular cheilitis - Recurrent oral ulcerations - Papular pruritic eruptions - Seborrhoeic dermatitis - Fungal nail infections of fingers.
Clinical Stage 3	<ul style="list-style-type: none"> - Unexplained severe weight loss (>10% of presumed or measured body weight) - Unexplained chronic diarrhoea for longer than one month - Unexplained persistent fever (intermittent or constant for longer than one month) - Persistent oral candidiasis - Oral hairy leukoplakia - Pulmonary tuberculosis - Severe bacterial infections (e.g. pneumonia, empyema, meningitis, pyomyositis, bone or joint infection, bacteraemia, severe pelvic inflammatory disease) - Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis - Unexplained anaemia (<8g/dl), neutropenia (<0.5x 10⁹/l) and/or chronic thrombocytopenia (<50 x 10⁹/l).

STAGES	
Clinical Stage 4	<ul style="list-style-type: none"> - HIV wasting syndrome - Pneumocystis (jiroveci) pneumonia - Recurrent severe bacterial pneumonia - Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral at any site) - Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) - Extrapulmonary tuberculosis - Kaposi sarcoma - Cytomegalovirus infection (retinitis or infection of other organs) - Central nervous system toxoplasmosis - HIV encephalopathy - Extrapulmonary Cryptococcosis, including meningitis - Disseminated non-tuberculous mycobacterial infection - Progressive multifocal leukoencephalopathy - Chronic cryptosporidiosis - Chronic Isosporiasis - Disseminated mycosis (Extrapulmonary histoplasmosis, coccidioidomycosis) - Lymphoma (cerebral or B-cell non-Hodgkin) - Symptomatic HIV-associated nephropathy or cardiomyopathy - Recurrent septicaemia (including non-typhoidal Salmonella) - Invasive cervical carcinoma - Atypical disseminated leishmaniasis

APPENDIX 2: WHO CLINICAL STAGING OF HIV AND AIDS FOR INFANTS AND CHILDREN

2A.1 PERSONS AGED UNDER 15 YEARS WITH CONFIRMED LABORATORY EVIDENCE OF HIV INFECTION

STAGES	
Clinical Stage 1	<ul style="list-style-type: none"> - Asymptomatic - Persistent Generalized Lymphadenopathy
Clinical Stage 2	<ul style="list-style-type: none"> - Unexplained persistent hepato-splenomegaly - Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis) - Herpes zoster - Lineal gingival erythema - Recurrent oral ulceration - Papular pruritic eruption - Fungal nail infections - Extensive wart virus infection - Extensive Molluscum contagiosum - Unexplained persistent parotid enlargement
Clinical Stage 3	<ul style="list-style-type: none"> - Unexplained moderate malnutrition ^a not adequately responding to standard therapy - Unexplained persistent diarrhoea (14 days or more) - Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than one 1 month) - Persistent oral candidiasis (after first 6 weeks of life) - Oral hairy leukoplakia - Lymph node tuberculosis - Pulmonary tuberculosis - Severe recurrent bacterial pneumonia - Acute necrotizing ulcerative gingivitis or periodontitis - Unexplained anaemia (<8g/dl), neutropenia (<0.5 x 10⁹/l) and/or chronic thrombocytopenia (<50 x 10⁹/l). - Symptomatic lymphoid interstitial pneumonitis - Chronic HIV-associated lung disease, including bronchiectasis

STAGES	
Clinical Stage 4	<ul style="list-style-type: none"> - Unexplained severe wasting, stunting or severe malnutrition^b not responding to standard therapy - Pneumocystis (jiroveci) pneumonia - Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) - Chronic herpes simplex infection (orolabial or cutaneous of more than 1 month's duration or visceral at any site) - Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) - Extrapulmonary tuberculosis - Kaposi sarcoma - Cytomegalovirus infection (retinitis or infection of other organs with onset at age more than 1 month) - Central nervous system toxoplasmosis (after the neonatal period) - HIV encephalopathy - Extrapulmonary Cryptococcosis, including meningitis - Disseminated non-tuberculous mycobacterial infection - Progressive multifocal leukoencephalopathy - Chronic cryptosporidiosis (with diarrhoea) - Chronic Isosporiasis - Disseminated endemic mycosis (Extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis) - Cerebral or B-cell non-Hodgkin lymphoma - HIV-associated nephropathy or cardiomyopathy

a. For children younger than 5 years, moderate malnutrition is defined as weight-for-height < -2 z-score or mid-upper arm circumference ≥ 115 mm to <125 mm.

b. For children younger than 5 years of age, severe wasting is defined as weight-for-height < -3 z-score; stunting is defined as length-for-age/height-for-age < -2 z-score; and severe acute malnutrition is either weight for height < -3 z-score or mid-upper arm circumference < 115 mm or the presence of oedema.

NB: Some additional specific conditions can be included in regional classifications, such as penicilliosis in Asia, HIV-associated rectovaginal fistula in southern Africa and reactivation of trypanosomiasis in Latin America.

2A.2 PRESUMPTIVE DIAGNOSIS OF CLINICAL STAGE 4 HIV IN CHILDREN AGED UNDER 18 MONTHS

The presumptive diagnosis is designed for use where access to confirmatory diagnostic testing for HIV infection by means of virological testing for infants and children aged less than 18 months is not readily available. It is not recommended for use by clinical care providers who are not trained in ART or experienced in HIV care. It should be accompanied by immediate efforts to confirm the HIV diagnosis with HIV DNA PCR. Presumptive diagnosis of clinical stage 4 disease suggests severe immunosuppression, and ART is indicated. A presumptive diagnosis of stage 4 clinical disease should be made if:

1. An infant is HIV-antibody positive (ELISA or rapid test), aged under 18 months and symptomatic with two or more of the following:
2. oral thrush
3. severe pneumonia
4. severe wasting/malnutrition
5. severe sepsis
6. Other factors that support the diagnosis of clinical stage 4 HIV infection in an HIV-Seropositive infant are:
7. recent HIV related maternal death
8. advanced HIV disease in the mother
9. CD4% < 20%
10. Confirmation of the diagnosis of HIV infection should be sought as soon as possible.

2A.3 IMMUNOLOGICAL CATEGORIES FOR PAEDIATRIC HIV INFECTION

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, therefore, age must be taken into account as a variable. The absolute CD4 count associated with a specific level of immunosuppression 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. Just as in adults, immunological staging assists clinical decision making in ART initiation for children more than 5 years of age.

CD4 LEVEL IN RELATION TO THE SEVERITY OF IMMUNOSUPPRESSION

STAGES				
Classification of HIV associated immune deficiency	Age-related CD4 values			
	<11 months (%)	12-35 months (%)	36-59 months (%)	≥5yrs (cells/mm ³)
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%

CD4% Formula:

$$\text{CD4\%} = \frac{\text{ABSOLUTE CD4 COUNT}}{\text{TOTAL LYMPHOCYTE COUNT}} \times 100$$

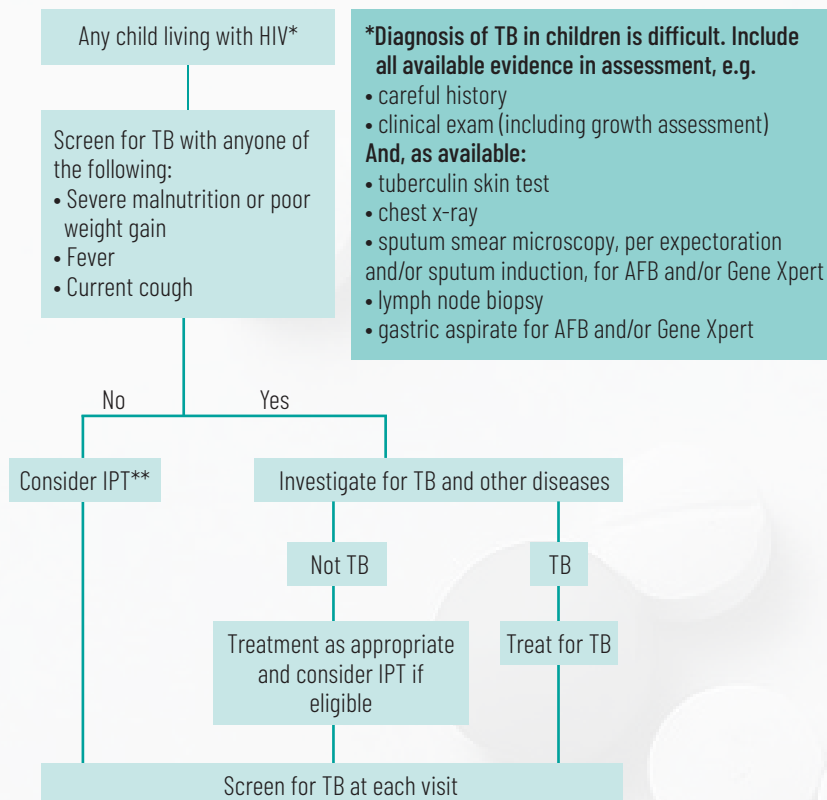
IMPLICATION FOR CLINICAL AND IMMUNOLOGICAL CRITERIA FOR INITIATING ART

The need for ART should be considered in all HIV infected children. All children with stages 3 or stage 4 diseases (advanced HIV defined clinically) should start ART following discussion with their families. For children less than 5 years with confirmed HIV infection, ART should be initiated.

CLINICAL AND IMMUNOLOGICAL CRITERIA FOR INITIATING ART IN INFANTS AND CHILDREN	
Clinical Stages	Treatment Recommendation
Stage 3 and 4	Treat
Presumptive Stage 4	Treat
Stage 1 and 2	Treat
Note: co-trimoxazole prophylaxis should be given to all HIV-exposed infants and children until HIV infection is excluded and to all HIV-infected infants and children.	

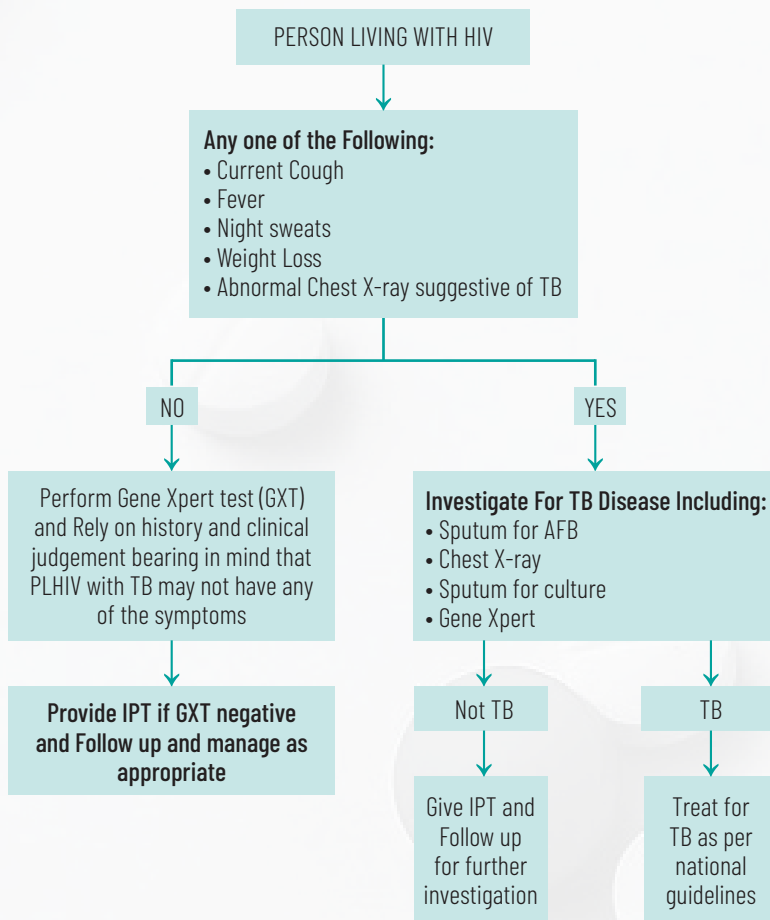
APPENDIX 3: WHO CLINICAL STAGING OF HIV AND AIDS FOR INFANTS AND CHILDREN

A3.1 CHILDREN LIVING WITH HIV

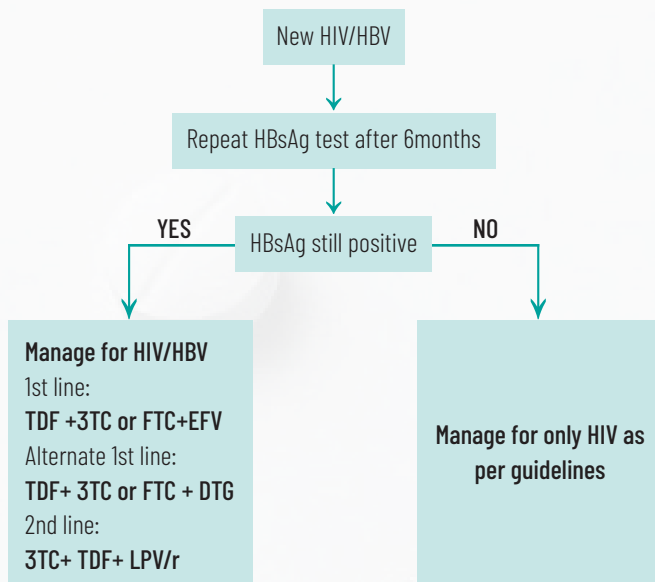


****NOTE:** Isoniazid Prophylaxis (IPT) to be given only to HIV-exposed infants born to mothers with TB disease who started treatment < 2 months before delivery or to infants and children with exposure to an adult with active TB disease.

A3.2 ADULT & ADOLESCENT LIVING WITH HIV



APPENDIX 4: ALGORITHM FOR THE MANAGEMENT OF HEPATITIS B-VIRUS CO-INFECTION WITH HIV



APPENDIX 5: DRUG INFORMATION

A5.1 DRUG-DRUG INTERACTIONS

DRUG	DRUG-DRUG INTERACTIONS
Abacavir	Methadone, Phenobarbital, Phenytoin, Rifampicin
Atazanavir	<p>As part of the ARV regimen:</p> <p>Efavirenz</p> <p>Nevirapine (may increase risk of NVP toxicity)</p> <p>Tipranavir</p> <p>Other Drugs</p> <p>Alfuzosin, alprazolam, astemizole, bepridil, cisapride, ergot derivatives, garlic supplements, irinotecan, lovastatin, midazolam, pimozone, pitavastatin, proton pump inhibitors, ranolazine, rifampin, rifapentine, high-dose sildenafil, simvastatin, St. John's wort, terfenadine, triazolam</p>
Dolutegravir	Antacids, laxatives, multivitamin supplements and anticonvulsant such as carbamazepine
Efavirenz	<p>Nevirapine, Antiarrhythmics (Lidocaine, amiodarone), Antiepileptics (Phenytoin, Carbamazepine, Primidone), Antihistamines (Astemizole, Terfenadine, Loratidine), Benzodiazepine, Ergometrine, Grapefruit juice, Indinavir, Lopinavir, Methadone, Nevirapine, Phenobarbital, Rifampicin, Ritonavir, Oral Contraceptives (oestrogen-based), Phenobarbital, Benzodiazepine, Saquinavir, St. John's Worts (Herbal)</p>
Emtricitabine	Lamivudine
Lamivudine	Emtricitabine,
Lopinavir/ Ritonavir	<p>Artemether+Lumefantrine, Alprazolam, Amiodarone, Astemizole, Carbamazepine, Chlorpheniramine, Clarithromycin, Dexamethasone, Diazepam, Efavirenz, Erythromycin, Itraconazole, Ketoconazole, Lidocaine, Loratidine, Metronidazole, Nelfinavir, Oral contraceptives, Phenobarbitalone, Phenytoin, Rifabutin, Rifampicin, Quinidine, Saquinavir, Simvastatin, St. John's worts, Tenofovir, Terfenadine, Tricyclic antidepressants,</p>

DRUG	DRUG-DRUG INTERACTIONS
Nevirapine	Carbamazepine, Cocaine, Efavirenz, Fluconazole, Indinavir, Levonorgestrol, Medroxyprogesterone, Methadone, Norethisterone, Oral contraceptives (oestrogens and progestogens), Phenytoin, Protease Inhibitors, Rifabutin, Rifampicin, Indinavir, Efavirenz, Saquinavir, St. John's worts, Warfarin, Carbamazepine, Phenytoin, Cocaine.
Tenofovir	Acyclovir, Aminoglycosides, Amphotericin B, Didanosine, Lopinavir, Pentamidine, Probenecid, Salicylates, Vancomycin
Zidovudine	Cytotoxics (Doxorubicin etc) Fluconazole, Ganciclovir, Ibuprofen, Interferon, Methadone, Phenytoin, Pyrimethamine, Ribavirin, Rifampicin, Stavudine, Valproic Acid

A5.2 ADULT & ADOLESCENT DRUG DOSAGE, FORMULATIONS AND ADVERSE EFFECTS

DRUG	ADULT DOSAGE	FORMU- LATIONS	ADVERSE EFFECTS MINOR, FREQUENT	ADVERSE EFFECTS SERIOUS, DOSE LIMITING	SPECIAL INSTRUCTIONS
Abacavir	300 mg bid	Tablet	Nausea, Poor Appetite, Vomiting Fatigue Sleep disturbance	Hypersensitivity reaction Lactic acidosis	Caution in liver or renal disease Discontinue use in symptoms of hypersensitivity
Dolutegravir	50mg daily	Tablet	Insomnia, weight gain/ clinical obesity	Neural tube defects, depression and suicide ideation	Caution in pregnancy first trimester
Efavirenz	600 mg & 400mg daily	Capsule/ Tablet	Elevated Liver enzyme Skin rash CNS disturbances	Suicidal ideations, Mania Teratogenicity	Caution in liver disease
Emtricitabine (FTC)	200mg daily	Capsule	Few side effects, rash, peripheral neuropathy reported	Lactic acidosis Hepatomegaly with steatosis	Caution in liver or renal disease Exacerbation of hepatitis in patients with chronic hepatitis B may occur on discontinuation of Emtricitabine
Lamivudine (3TC)	150 mg bid	Tablet	Few side effects, neutropenia, peripheral neuropathy reported	Lactic acidosis (Rare)	

DRUG	ADULT DOSAGE	FORMU-LATIONS	ADVERSE EFFECTS MINOR, FREQUENT	ADVERSE EFFECTS SERIOUS, DOSE LIMITING	SPECIAL INSTRUCTIONS
Lopinavir/ ritonavir	400 mg /100 mg bid	Tablet	Diarrhoea, nausea, dyslipidemia, lipodystrophy, headache	Hypersensitivity Pancreatitis Diabetes Mellitus	
Nevirapine	200 mg daily for 14 to 28 days then 200 mg bid	Tablet	Skin rash	Hypersensitivity Hepatotoxicity	Caution in liver disease
Tenofovir	300 mg daily	Tablet		Nephrotoxicity (Rare)	To be taken with a meal
Zidovudine (AZT)	300 mg bid	Tablet	Nausea Headache Fatigue Muscle pains	Anaemia, Neutropenia, gastrointestinal intolerance, Lactic acidosis	Caution in: pre-existing anaemia Liver and renal insufficiency

A5.3 PAEDIATRIC DRUG DOSAGE, FORMULATIONS AND ADVERSE EFFECTS

DRUG	PREPARATIONS	DOSAGE FOR CHILDREN	ADVERSE EFFECTS MINOR, FREQUENT	ADVERSE EFFECTS SERIOUS, DOSE LIMITING	SPECIAL INSTRUCTIONS
Abacavir	Oral solution: 20 mg/ml Tablet: 300mg	3 months to 16 years: 8 mg/ kg / dose bid (maximum, 600mg daily)	Nausea Poor Appetite Vomiting Fatigue Sleep disturbance	Hyper-sensitivity reaction Lactic acidosis	Caution in liver or renal disease Discontinue use if symptoms of hypersensitivity
Efavirenz	Capsules: 50mg, 100mg, 200mg, 600mg	Capsule/Tablet 40 kg and over, 600 mg once daily; over 3 years/10–14 kg, 200 mg once daily; 15–19 kg, 250 mg once daily; 20–24 kg, 300 mg once daily; 25–32 kg, 350 mg once daily; 33–39 kg, 400 mg once daily As oral solution 40 kg and over, 720 mg once daily; over 3 years/10–15 kg, 270 mg once daily; 15–20 kg, 300 mg once daily; 20–24 kg, 360 mg once daily; 25–32 kg, 450 mg once daily; 33–39 kg, 510 mg once daily	Elevated Liver enzyme Skin rash CNS disturbances		Only for children over 3 years Capsules may be opened and added to food but has a very peppery taste Avoid high fatty foods Best given at bed time to reduce CNS side effects

DRUG	PREPARATIONS	DOSAGE FOR CHILDREN	ADVERSE EFFECTS MINOR, FREQUENT	ADVERSE EFFECTS SERIOUS, DOSE LIMITING	SPECIAL INSTRUCTIONS
Emtricitabine (FTC)	Oral solution: 10mg/ml	Over 33 kg, 1 capsule (200 mg) or 24 ml (240 mg) oral solution once daily 4 months–18 years, under 33 kg, 6 mg/kg oral solution once daily	Few side effects, rash, peripheral neuropathy reported	Lactic acidosis Hepatomegaly with steatosis	Caution in liver or renal disease Exacerbation of hepatitis in patients with chronic hepatitis B may occur on discontinuation of Emtricitabine
Lamivudine (3TC)	Tablet: 150 mg Oral Solution: 10 mg/ml	Infants under 1 month: 2mg/kg 12 hourly Child over 1 month: 4mg/kg 12 hourly	Few side effects, neutropenia, peripheral neuropathy reported	Lactic acidosis	Store at room temperature can be administered with food. Decreased dosage with renal impairment
Lopinavir/Ritonavir (LPV/r)	Lopinavir/Ritonavir tablet: 200mg/50mg Oral solution: Lopinavir/Ritonavir: 80/20mg per ml	Surface area 6 months–13 years: Lopinavir, 225 mg/m ² + ritonavir, 56.25 mg/m ² twice daily Weight based 7–15 kg, Lopinavir, 12 mg/kg + ritonavir, 3 mg/kg twice daily; 15–40 kg, Lopinavir, 10 mg/kg + ritonavir, 2.5 mg/kg twice daily). > 40 kg: Lopinavir 400 mg/Ritonavir 100 mg twice daily	Diarrhoea, nausea, dyslipidemia, lipodystrophy, headache	Hypersensitivity Pancreatitis Diabetes Mellitus	Preferably oral solution and capsules should be refrigerated; must be reconstituted immediately prior to administration in water, milk, formula, pudding, etc- do not use acidic food or juices

DRUG	PREPARATIONS	DOSAGE FOR CHILDREN	ADVERSE EFFECTS MINOR, FREQUENT	ADVERSE EFFECTS SERIOUS, DOSE LIMITING	SPECIAL INSTRUCTIONS
					<p>increases bitter taste) ; solution stable for 6 hours</p> <p>Because of difficulties with use of powder, tablets preferred.</p> <p>Powder and tablets can be stored at room temperatures Take with food</p> <p>Drug interactions (less than ritonavir containing protease inhibitors</p>
Nevirapine (NVP)	<p>Oral suspension: 10mg/ml</p> <p>Tablet: 200 mg</p>	200 mg/m ² /dose once daily for 14 to 28 days; then 200 mg/m ² /dose twice daily	Skin rash	Hypersensitivity Hepatotoxicity	<p>If Rifampicin co-administration, avoid use</p> <p>Store suspension at room temperature; must shake well</p> <p>Can give with food can be crushed and combined with small amount of water or food and immediately administered</p> <p>warn parents about Rash.</p>
Zidovudine (AZT)	<p>Syrup: 10mg/ml</p> <p>Capsules: 100mg</p> <p>Tablets: 300mg</p>	<p>Neonatal dose: Oral: 4mg/kg body weight 12hrly.</p> <p>Paediatric dose: 240mg/m² every 12 hrs Max-300mg every 12hrs</p>	<p>Nausea</p> <p>Headache</p> <p>Fatigue</p> <p>Muscle pains</p>	Anaemia, Neutropenia, gastrointestinal intolerance, Lactic acidosis	<p>Caution in: pre-existing anaemia Liver and renal insufficiency.</p> <p>Can be administered with food</p> <p>Store at room temperature</p>

* Adolescent dose is same as adult dosage see adult section.

FIXED DOSE COMBINATIONS AVAILABLE IN GHANA

Abacavir + Lamivudine	600mg+300mg, 24 hourly	Side effects of fixed dose preparations are as for the individual components
Abacavir + Lamivudine	120mg+60mg	
Tenofovir + Emtricitabine	300mg+200mg, 24 hourly	
Tenofovir + Lamivudine	300mg+300mg, 24 hourly	
Tenofovir + Lamivudine + Dolutegravir	300mg+300mg+50mg, 24 hourly	
Tenofovir + Lamivudine + Efavirenz	300mg+300mg+400mg, 24 hourly	
Tenofovir + Lamivudine + Efavirenz	300mg+300mg+600mg, 24 hourly	
Zidovudine + Lamivudine	300mg+150mg, 12hourly	
Zidovudine + Lamivudine	60mg+30mg, 12hourly	

APPENDIX 6: PEP FOR RAPE SURVIVORS

APPENDIX A6.1 FORENSIC EVIDENCE COLLECTION

It is ideal to document injuries and collect samples, such as blood, hair, saliva and sperm within 72 hours of the incident. Whenever possible, this should be done during the medical examination following the order below:

Inspection of the Body

- Examine the survivor's clothing under good light before she undresses.
- Collect any foreign debris on clothes, body or in hair.
- Let survivor undress while standing on a sheet of paper to collect any debris that fall.
- Examine the upper part of body first followed by the lower half.
- Collect torn and stained items of clothing if possible.
- Document all injuries in as much detail as possible.
- Take samples on body or from the mouth for semen analysis in the event of ejaculation into survivor's mouth.
- Collect samples for DNA analysis from where there could be the assailants saliva or semen on the skin, using cotton tipped-swab moistened with sterile water.
- Take blood and urine for toxicology testing if survivor was drugged.

Inspection of the Perineum and Vulva

Inspect and collect samples for DNA analysis from around the anus, perineum and vulva using separate cotton-tipped swabs moistened with sterile water.

Examination of the Vagina and/or Rectum (depending on the site of penetration or attempted penetration)

- Lubricate speculum with normal saline or clean water.
- Using a cotton-tipped swab, collect fluid from the posterior fornix for examination of sperm.
- Use a wet mount to examine and take note of any motile sperm. In addition to the first slide a second slide could be made and both air-dried for future examinations.
- Take specimen from the posterior fornix and the endocervical canal for DNA analysis. Let them dry at room temperature.
- Collect separate samples from the cervix and the vagina for acid phosphatase analysis.
- Obtain samples from the rectum for similar examinations, if indicated.

Maintaining the Chain of Evidence

All evidence collected must be well processed, labelled, stored and transported properly; and documentation must include a signature of everyone who has possession of the evidence at any time, from the person who collects it to the one who takes it to the courtroom. Evidence should be kept in a safe, secured place, and should be released to the relevant authority at the request of the survivor, the police with the consent of the survivor or at the request of a court of competent jurisdiction.

A6.2 DRUG RECOMMENDATION FOR HIV PEP IN ADULTS AND ADOLESCENTS (>40KG) INCLUDING PREGNANT AND LACTATING WOMEN

DRUG RECOMMENDATION
TDF 300mg daily for 28 days + 3TC 150mg 12 hourly (or FTC 200mg daily) for 28 days DTG 50mg daily X 28 days OR DTG can be replaced by ATV/r (300mg/100mg daily) or LPV/r (400mg/100mg 12 hourly) or RAL (400mg 12 hourly) or DRV/r (800mg/100mg daily) depending on availability x 28 days

DRUG RECOMMENDATION FOR HIV PEP IN CHILDREN

Recommended drugs in children are the same as in the case of the adult but dosing must be according to age and body weight as outlined below:

WEIGHT OR AGE	REGIMEN
<2 years or 5 – 9kg	AZT syrup 10mg/ml 12 hourly plus 3TC syrup 10mg/ml 12 hourly (OR FTC 6mg/kg daily) plus LPV/r (80mg/20mg)/ml syrup 12 hourly
>3 years or 10–19kg	TDF 120mg daily OR (AZT 150mg 12 hourly) plus 3TC 75mg 12 hourly (OR FTC 6mg/kg daily) plus LPV/r (80mg/20mg)/ml syrup
20–39kg	TDF 200mg daily OR (AZT 200mg 12 hourly) plus 3TC 150mg tablet (OR FTC 6mg/kg up to a maximum of 200mg) daily plus LPV/r (80mg/20mg)/ml syrup OR 200mg/50mg 12 hourly

For all children aged 10 years and below, ABC + 3TC (or FTC) can be given as an alternative with DTG or ATV/r or LPV/r or RAL or DRV/r as alternates for the third option.

A6.3 PEP AND MANAGEMENT RECORD FORM FOR RAPE SURVIVORS

Facility: _____ Date: _____

Name of Survivor _____

Age: _____ Sex: _____

Date of Incident: / /
dd mm yy Time of Incident: _____

Location of Incident: _____

Brief Background and circumstances of the rape incident:

Survivor referred from another facility for the purpose of PEP only:

1. Details of Sexual Violence:

Raped by more than one person	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Sustained physical bodily injury	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Injuries in the genital area	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Assailant is not known to the Survivor	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Assailant is a regular sexual partner of Survivor	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Other (specify): _____

2. Action taken:

Attended to by a doctor	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other healthcare worker (specify): _____		
Client Reported incident to police	Yes <input type="checkbox"/>	No <input type="checkbox"/>

3. Assailant Information:

Assailant identified? Yes ☐ No ☐
Serological status: HIV +ve ☐ HIV -ve ☐ Unknown ☐

4. Survivor's Health Screen Information:

Pre-PEP HIV test done Yes ☐ No ☐
Pregnancy Test done Yes ☐ No ☐
Screening for STI done Yes ☐ No ☐

5. Outcome of Survivor's Health Screen:

HIV Positive – Referred to ART Clinic Yes ☐ No ☐
Survivor Pregnant – Referred Yes ☐ No ☐
STIs treatment given Yes ☐ No ☐
Hepatitis vaccination given Yes ☐ No ☐
For client who was not pregnant was emergency Contraception given? Yes ☐ No ☐
If Yes, specify type _____

6. PEP for HIV (even when Survivor refuses to undertake HIV test)

PEP Started Yes ☐ No ☐

If Yes Start date / / Start time
dd mm yy

Stop date / /
dd mm yy

Reasons for stopping: End of course ☐ Adverse reaction ☐

Other _____

7. Medications administered

Tenofovir ☐ Lamivudine/Emtricitabine ☐ Zidovudine ☐
Abacavir ☐ Lopinavir/r ☐ Atazanavir/r ☐
Raltegravir ☐ Darunavir/r ☐

Others: Specify: _____

8. Follow-up of a Survivor on PEP

HIV test at 6 weeks done

Yes ☐ No ☐

HIV test at 3 months done

Yes ☐ No ☐

HIV test at 6 months done

Yes ☐ No ☐

Outcome of follow-up _____

9. If PEP started but HIV test refused by Survivor she/he must sign below

By signing I acknowledge that I have refused HIV testing prior to taking PEP, contrary to medical advice.

Name: _____ Signature: _____

Date: _____

Name of Provider: _____ Signature: _____

Date: _____

A6.4 POST EXPOSURE PROPHYLAXIS OF HIV MONTHLY RETURNS FORM

Name of Facility: _____ Date: _____

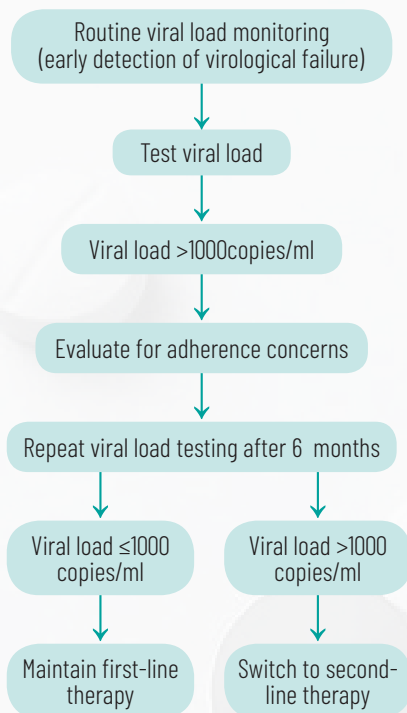
Month: _____

Name of Person Filing Report: _____ Sign: _____

INDICATOR	VERY LOW RISK	LOW RISK	HIGH RISK
Total Number of Healthcare Workers (HCW) Reporting after Occupational Exposure			
Number Counselling for HIV			
Number tested for HIV before PEP			
Number HIV positive			
Number starting PEP			
Number completing PEP			
Number of Rape Survivors Reporting			
Number Counselling and Tested for HIV before PEP			
Number HIV positive			
Number starting PEP			
Number completing PEP			
Follow-up Testing for HIV at 6 weeks, 3 months and 6 months			

	EXPOSED HCW		RAPE SURVIVORS	
	POSITIVE	NEGATIVE	POSITIVE	NEGATIVE
Number testing at 6 weeks				
Number testing at 3 months				
Number testing at 6 months				

APPENDIX 7: ALGORITHM FOR SWITCHING REGIMEN USING VL TESTING

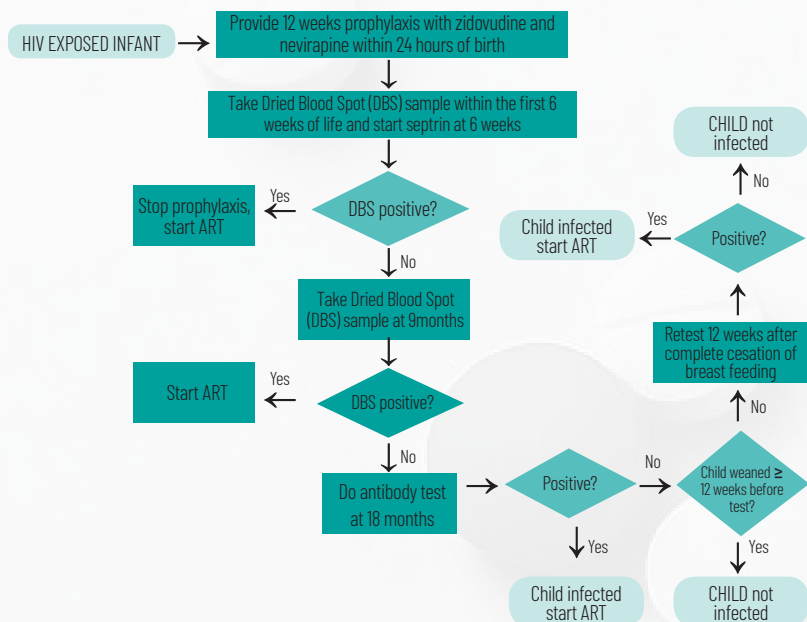


Note: Switching to second line must be done after consultation

APPENDIX 8: EARLY INFANT PROPHYLAXIS AND DIAGNOSIS



World Health Organization



Test
Boundaries (start&end)
◆ Decision
 ➔ Direction of Flow

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